UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 2024

OR

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

For the transition period from _____to _____

Commission File Number**: 001-34079**

Opus Genetics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**11-3516358**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
37000 Grand River Avenue, Suite 120 Farmington Hills, MI	**48335**
(Address of Principal Executive Offices)	(Zip Code)

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

Ocuphire Pharma, Inc.
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

Large accelerated filer	□	Non-accelerated filer	☒
Accelerated filer	□	Smaller reporting company	☒
		Emerging growth company	□

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

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

The number of outstanding shares of the registrant's common stock as of November 7, 2024 was 31,568,457.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	As of	
	September 30, 2024	December 31, 2023
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 36,632	$ 50,501
Accounts receivable	1,857	926
Contract assets and unbilled receivables	1,468	1,407
Prepaids and other assets	429	1,099
Short-term investments	3	15
Total current assets	40,389	53,948
Property and equipment, net	—	—
Total assets	$ 40,389	$ 53,948
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 844	$ 2,153
Accrued expenses	5,171	1,815
Derivative liability	74	74
Total current liabilities	6,089	4,042
Total liabilities	6,089	4,042
Commitments and contingencies (Note 3 and Note 8)		
Stockholders' equity:		
Preferred stock, par value $0.0001; 10,000,000 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023.	—	—
Common stock, par value $0.0001; 125,000,000 and 75,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively; 26,198,444 and 23,977,491 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.	3	2
Additional paid-in capital	138,160	131,370
Accumulated deficit	(103,863)	(81,466)
Total stockholders' equity	34,300	49,906
Total liabilities and stockholders' equity	$ 40,389	$ 53,948

See accompanying notes.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
License and collaborations revenue	$ 3,867	$ 11,935	$ 6,690	$ 17,358
Operating expenses:				
General and administrative	2,894	2,055	10,918	8,680
Research and development	8,982	3,494	19,817	13,812
Total operating expenses	11,876	5,549	30,735	22,492
(Loss) income from operations	(8,009)	6,386	(24,045)	(5,134)
Financing costs (Note 6)	—	(1,328)	—	(1,328)
Fair value change in derivative liability	—	61	—	61
Other income, net	483	456	1,648	1,224
(Loss) income before income taxes	(7,526)	5,575	(22,397)	(5,177)
Provision for income taxes	—	(14)	—	(14)
Net (loss) income	(7,526)	5,561	(22,397)	(5,191)
Other comprehensive (loss) income, net of tax	—	—	—	—
Comprehensive (loss) income	$ (7,526)	$ 5,561	$ (22,397)	$ (5,191)
Net (loss) income per share (Note 10):				
Basic	$ (0.29)	$ 0.26	$ (0.88)	$ (0.25)
Diluted	$ (0.29)	$ 0.25	$ (0.88)	$ (0.25)
Number of shares used in per share calculations:				
Basic	26,145,080	21,446,648	25,501,117	21,117,211
Diluted	26,145,080	22,405,995	25,501,117	21,117,211

See accompanying notes.

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

	Common Stock		Additional Paid–In Capital	Accumulated Deficit	Total Equity
	Shares	Amount			
Balance at December 31, 2022	20,861,315	$ 2	$ 117,717	$ (71,480)	$ 46,239
Issuance costs	—	—	(2)	—	(2)
Stock-based compensation	68,646	—	804	—	804
Exercise of warrants	17,869	—	—	—	—
Net and comprehensive loss	—	—	—	(5,791)	(5,791)
Balance at March 31, 2023	20,947,830	2	118,519	(77,271)	41,250
Issuance costs	—	—	(7)	—	(7)
Stock-based compensation	37,954	—	1,422	—	1,422
Net and comprehensive loss	—	—	—	(4,961)	(4,961)
Balance at June 30, 2023	20,985,784	2	119,934	(82,232)	37,704
Issuance of common stock in connection with the at-the-market program and purchase agreement	1,624,347	—	6,504	—	6,504
Issuance costs	—	—	(60)	—	(60)
Stock–based compensation	—	—	573	—	573
Net and comprehensive income	—	—	—	5,561	5,561
Balance at September 30, 2023	22,610,131	$ 2	$ 126,951	$ (76,671)	$ 50,282
Balance at December 31, 2023	23,977,491	$ 2	$ 131,370	$ (81,466)	$ 49,906
Issuance of common stock in connection with the at-the-market program and purchase agreement	1,000,550	1	2,478	—	2,479
Issuance costs	—	—	(165)	—	(165)
Stock–based compensation	120,516	—	985	—	985
Share repurchases for the payment of employee taxes	(12,965)	—	(42)	—	(42)
Net and comprehensive loss	—	—	—	(7,106)	(7,106)
Balance at March 31, 2024	25,085,592	3	134,626	(88,572)	46,057
Issuance of common stock in connection with the at-the-market program and purchase agreement	788,566	—	1,563	—	1,563
Issuance costs	—	—	(25)	—	(25)
Stock–based compensation	104,880	—	806	—	806
Net and comprehensive loss	—	—	—	(7,765)	(7,765)
Balance at June 30, 2024	25,979,038	3	136,970	(96,337)	40,636
Issuance of common stock in connection with the at-the-market program	219,406	—	456	—	455
Issuance costs	—	—	(42)	—	(41)
Stock–based compensation	—	—	776	—	776
Net and comprehensive loss	—	—		(7,526)	(7,526)
Balance at September 30, 2024	26,198,444	$ 3	$ 138,160	$ (103,863)	$ 34,300

See accompanying notes.

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

	For the Nine Months Ended September 30,	
	2024	**2023**
Operating activities		
Net loss	$ (22,397)	$ (5,191)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,567	2,799
Depreciation	—	3
Unrealized loss from short-term investments	12	38
Financing costs	—	1,328
Fair value change in derivative liability	—	(61)
Change in assets and liabilities:		
Accounts receivable	(931)	(8,834)
Contract assets and unbilled receivables	(61)	2,341
Prepaid and other assets	670	969
Accounts payable	(1,319)	709
Accrued and other liabilities	3,321	239
Net cash used in operating activities	(18,138)	(5,660)
Investing activities		
Net cash used in investing activities	—	—
Financing activities		
Proceeds from issuance of common stock in connection with the at-the-market program and purchase agreement	4,497	5,482
Issuance costs	(186)	(106)
Share repurchases for the payment of employee taxes	(42)	—
Net cash provided by financing activities	4,269	5,376
Net decrease in cash and cash equivalents	(13,869)	(284)
Cash and cash equivalents at beginning of period	50,501	42,634
Cash and cash equivalents at end of period	$ 36,632	$ 42,350
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ 318
Cash paid for interest	$ —	$ —
Supplemental non-cash financing transactions:		
Unpaid issuance costs	$ 46	$ 115
Non-cash issuance of common stock in connection with equity purchase agreement	$ —	$ 1,022
Value of derivative established in connection with the equity purchase agreement	$ —	$ 154

See accompanying notes.

Notes to Condensed Financial Statements

1. Company Description and Summary of Significant Accounting Policies

Nature of Business

On October 22, 2024, Opus Genetics, Inc., a Delaware corporation formerly known as Ocuphire Pharma, Inc. (the "Company" or "Opus"), acquired a private corporation then operating under the name of "Opus Genetics, Inc." ("Former Opus") pursuant to the terms of an Agreement and Plan of Merger, dated as of October 22, 2024 (such agreement, the "Merger Agreement" and the transaction consummated via the Merger Agreement, the "Opus Acquisition"), by and among the Company, Former Opus, and certain merger subsidiaries party thereto.

The accompanying unaudited condensed financial statements do not give effect to the Opus Acquisition. The historical financial statements have been labeled under the name "Ocuphire Pharma, Inc." solely for purposes of this filing, as this was the name of the Company for the entirety of the historical periods presented.

Following the Opus Acquisition, the Company is a clinical-stage ophthalmic biotechnology company developing gene therapies for the treatment of inherited retinal diseases (IRDs) and other ophthalmologic disorders. The pipeline includes adeno-associated virus (AAV)-based gene therapies that address mutations in genes that cause different forms of bestrophinopathy, Leber congenital amaurosis (LCA) and retinitis pigmentosa. The Company's most advanced gene therapy program is designed to address mutations in the LCA5 gene, which encodes the lebercilin protein and is currently being evaluated in a Phase 1/2 open-label, dose-escalation trial. The pipeline also includes Phentolamine Ophthalmic Solution 0.75%, a non-selective alpha-1 and alpha-2 adrenergic antagonist to reduce pupil size, and APX3330, a novel small-molecule inhibitor of Ref-1 to slow the progression of non-proliferative diabetic retinopathy. Phentolamine Ophthalmic Solution 0.75% is currently being evaluated in Phase 3 trials for presbyopia and dim (mesopic) light vision disturbances.

In November 2022, the Company entered into a license and collaboration agreement (the "Viatris License Agreement") with FamyGen Life Sciences, Inc. (acquired by and now known as Viatris, Inc. ("Viatris")), pursuant to which it granted Viatris an exclusive license to develop, manufacture, import, export and commercialize its refractive product candidate Phentolamine Ophthalmic Solution 0.75% (initially known as Nyxol) ("PS"). PS is a once-daily eye drop formulation of phentolamine mesylate designed to reduce pupil diameter and improve visual acuity. PS was approved by the FDA for the treatment for pharmacologically induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents, or a combination thereof under the brand name RYZUMVI™ in September 2023 and was launched commercially in April 2024. The Company reported positive top-line data from multiple late-stage clinical trials for PS in reversal of pharmacologically induced mydriasis, presbyopia and dim light disturbances. The VEGA-2 Phase 3 study in presbyopia achieved its primary endpoint. The VEGA-3 Phase 3 clinical trial evaluating PS for presbyopia (age-related blurry near vision) is underway. For decreased vision under mesopic (low) light conditions following keratorefractive surgery, we received FDA agreement under Special Protocol Assessment ("SPA") for LYNX-2, a Phase 3 Trial of PS. LYNX-2 continues enrollment. LYNX-3, an additional Phase 3 study for decreased vision under mesopic (low) light conditions following keratorefractive surgery, has commenced.

Basis of Presentation

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

The December 31, 2023 condensed balance sheet was derived from audited financial statements, and may not include all disclosures required by GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2023.

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

Notes to Condensed Financial Statements

Liquidity

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

As of September 30, 2024, the Company had $36.6 million in cash and cash equivalents. The Company believes its current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least twelve months from the date of issuance of these financial statements.

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

Use of Estimates

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

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer or such person functioning in such role. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development of products related to vision performance and health. Accordingly, the financial statements and accompanying notes contained herein include the measure of profit or loss, categories of expenses and other financial information that is evaluated by the Company's Chief Executive Officer.

Cash and Cash Equivalents

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. Management follows approved policies established by the Company's Board of Directors (the "Board") to reduce credit risk associated with the Company's cash deposit and investment accounts. Pursuant to these policies, the Company limits its exposure through the kind, quality and concentration of its investments. The Company's cash and cash equivalents are held or managed by two financial institutions in the United States. As of September 30, 2024, the Company had cash equivalents of $36.1 million that were not eligible for coverage by Federal Deposit Insurance Corporation. These balances are invested in funds whose assets consist almost entirely of securities issued by the U.S. Treasury or guaranteed by the U.S. government.

Short-term Investments

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and records them on a settlement date basis. The Company's short-term investments are comprised of equity securities, which in accordance with the fair value hierarchy described below are recorded at fair value using Level l inputs on the balance sheets. Subsequent changes in fair values are recorded in other income, net on the statements of comprehensive (loss) income. The Company classifies investments available to fund current operations as current assets on its balance sheets. The Company did not recognize any impairments on its investments to date through September 30, 2024.

Notes to Condensed Financial Statements

Revenue Recognition

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

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

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

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

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

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

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

Notes to Condensed Financial Statements

Contract Assets and Unbilled Receivables

The Company recognizes contract assets and unbilled receivables when goods or services are transferred to the customer before the customer pays or before reimbursement for payment is billed or due, excluding any amounts presented as an account receivable. The Company recorded contract assets and unbilled receivables in connection with a license and collaboration agreement (See Note 9 – License and Collaboration Agreements).

Accounts Receivable and Allowances for Credit Losses

The Company records a provision for credit losses, when appropriate, based on historical experience, current conditions and reasonable supportable forecasts. The Company estimates credit losses over the remaining expected life of an asset by, among other things, primarily using historical experience and current economic conditions that could affect the collectability of the balances in the future. Account balances are charged off against the allowance when the Company believes that it is probable that the receivable will not be recovered. Actual write-offs may be in excess of the Company's estimated allowance. The Company has not incurred any bad debt expense to date and no allowance for credit losses has been recorded during the periods presented.

General and Administrative Expenses

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

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities, including compensation, benefits and stock-based compensation costs for research and development employees and costs for consultants, costs associated with nonclinical studies and clinical trials, regulatory activities, manufacturing activities to support clinical activities, license fees, nonlegal patent costs, fees paid to external service providers that conduct certain research and development, and an allocation of overhead expenses. Research and development expenses include costs that are reimbursed under the Viatris License Agreement (See Note 9 – License and Collaboration Agreements).

Other Income, net

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

Stock-Based Compensation

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

Notes to Condensed Financial Statements

Derivative Liability

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

Fair Value Measurements

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

- Level 1 inputs: Unadjusted quoted prices for identical assets or liabilities in active markets;
- Level 2 inputs: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, whether directly or indirectly, for substantially the full term of the asset or liability; and
- Level 3 inputs: Unobservable inputs in which there is little or no market data available, which requires management to develop its own assumptions in pricing the asset or liability.

As of September 30, 2024 and December 31, 2023, the fair values of cash and cash equivalents, accounts receivable, contract assets and unbilled receivables, prepaid and other assets, accounts payable, and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The fair value of the short-term investments, while outstanding, were based on observable Level 1 inputs in the form of quoted market prices from a major stock exchange. The fair value of the derivative liability associated with the equity line financing facility (See Note 6 – Stockholders' Equity) was based on cash flow models discounted at current implied market rates representing expected returns by market participants for similar instruments and are based on Level 3 inputs as well the Company's underlying stock price and associated volatility, expected term of the financing and market interest rates. There were no transfers between fair value hierarchy levels during the three and nine months ended September 30, 2024 and 2023.

	As of September 30, 2024			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 3	$ 3	$ —	$ —
Total assets at fair value	$ 3	$ 3	$ —	$ —
Liabilities:				
Derivative liability	$ 74	$ —	$ —	$ 74
Total liabilities at fair value	$ 74	$ —	$ —	$ 74

	As of December 31, 2023			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 15	$ 15	$ —	$ —
Total assets at fair value	$ 15	$ 15	$ —	$ —
Liabilities:				
Derivative liability	$ 74	$ —	$ —	$ 74
Total liabilities at fair value	$ 74	$ —	$ —	$ 74

Notes to Condensed Financial Statements

The following table provides a roll-forward of short-term investments and derivative liabilities measured at fair value on a recurring basis using observable Level 1 and Level 3 inputs, as applicable, for the nine months ended September 30, 2024 and 2023 (in thousands):

	2024	2023
Short-term investments		
Balance as of beginning of period	$ 15	$ 49
Unrealized loss	(12)	(38)
Balance as of end of period	$ 3	$ 11

	2024	2023
Derivative liability		
Balance as of beginning of period	$ 74	$ —
Purchase agreement execution	—	154
Unrealized gain	—	(61)
Balance as of end of period	$ 74	$ 93

Rexahn Warrants

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

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

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07 - *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which enhances reportable segment disclosure requirements, primarily through disclosures of significant segment expenses. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The guidance must be applied retrospectively to all prior periods presented. The Company adopted the guidance on January 1, 2024. The adoption of this ASU did not have a material impact on the Company's financial statements.

In December 2023, the FASB issued ASU 2023-09 *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This guidance also includes certain other amendments to improve the effectiveness of income tax disclosures. This ASU is effective for fiscal years beginning after December 15, 2024, including interim periods within those fiscal years and should be applied on a prospective basis, with retrospective application permitted. The Company is currently evaluating the impact of adoption of this guidance on its financial statements.

2. Rexahn Merger

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

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

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

Notes to Condensed Financial Statements

- 90% of all payments received by Rexahn or its affiliates during such CVR Payment Period from or on behalf of BioSense Global LLC ("BioSense") pursuant to that certain License and Assignment Agreement, dated as of February 25, 2019, by and between BioSense and Rexahn, as amended by Amendment No. 1, dated August 24, 2019, and as further amended by Amendment No. 2, dated March 10, 2020, minus certain permitted deductions;

- 90% of all payments received by Rexahn or its affiliates during such CVR Payment Period from or on behalf of Zhejiang HaiChang Biotechnology Co., Ltd. ("HaiChang") pursuant to that certain Exclusive License Agreement, dated as of February 8, 2020, by and between HaiChang and Rexahn, minus certain permitted deductions; and

- 75% of the sum of (i) all cash consideration paid by a third party to Rexahn or its affiliates during the applicable CVR Payment Period in connection with the grant, sale or transfer of rights to Rexahn's pre-closing intellectual property (other than a grant, sale or transfer of rights involving a sale or disposition of the post-Merger combined company) that is entered into during the 10-year period after the closing ("Parent IP Deal"), plus (ii) with respect to any non-cash consideration received by Rexahn or its affiliates from a third party during the applicable CVR Payment Period in connection with any Parent IP Deal, all amounts received by Rexahn or its affiliates for such non-cash consideration at the time such non-cash consideration is monetized by Rexahn or its affiliates, minus (iii) certain permitted deductions.

The CVRs are not transferable, except in certain limited circumstances, will not be certificated or evidenced by any instrument, will not accrue interest and will not be registered with the SEC or listed for trading on any exchange. The CVR Agreement will continue in effect until the later of the end of the CVR Term and the payment of all amounts payable thereunder. As of September 30, 2024, no payments subject to the CVR Agreement had been received beyond those previously reported in the second and third quarters of calendar year 2021. In addition, no milestones had been accrued as there were no potential milestones yet considered probable beyond those previously reported.

Former Rexahn Warrants

As of September 30, 2024, none of the Rexahn warrants classified as equity remained outstanding. The remaining warrants in the amount of 58,597 with an exercise price of $38.40 per share expired unexercised in January 2024.

3. Commitments and Contingencies

Apexian Sublicense Agreement

On January 21, 2020, the Company entered into a sublicense agreement with Apexian Pharmaceuticals, Inc., pursuant to which it obtained exclusive worldwide patent and other intellectual property rights. In exchange for the patent and other intellectual rights, the Company agreed to certain milestone payments and royalty payments on future sales (See Note 8 — Apexian Sublicense Agreement). As of September 30, 2024, there was sufficient uncertainty with regard to any future cash milestone payments under the sublicense agreement that no liabilities were recorded related to the sublicense agreement.

Facility Leases

The Company has a short-term, non-cancellable facility lease (the "HQ Lease") for its headquarters. The HQ Lease qualified for the short-term lease exception under ASC 842, *Leases*. The monthly base rent for the HQ Lease is approximately $3,000. The rent expense associated with the HQ Lease amounted to $9,000 during each of the three-month periods ended September 30, 2024 and 2023, and $27,000 during each of the nine-month periods ended September 30, 2024 and 2023. The total remaining expected rental payments under the HQ Lease amount to $9,000 through its current expiration date of December 31, 2024.

Notes to Condensed Financial Statements

Other

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

4. Supplemental Balance Sheet Information

Prepaid and Other Assets

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

	September 30, 2024	December 31, 2023
Prepaids	$ 343	$ 997
Other	86	102
Total prepaids and other assets	$ 429	$ 1,099

Property and Equipment, net

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

	September 30, 2024	December 31, 2023
Equipment	20	$ 20
Furniture	5	5
Total property and equipment	25	25
Less accumulated depreciation	(25)	(25)
Property and equipment, net	$ —	$ —

Depreciation expense was $1,000 during the three months ended September 30, 2023 and $3,000 during the nine months ended September 30, 2023. There was no depreciation expense during the three and nine months ended September 30, 2024.

Notes to Condensed Financial Statements

Accrued Expenses

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

	September 30, 2024	December 31, 2023
Payroll	$ 410	$ 753
Professional services	973	591
Research and development services and supplies	3,725	400
Other	63	71
Total	$ 5,171	$ 1,815

5. Related Party Transactions

Rodgers Letter Agreement

On April 19, 2023, the Company appointed Richard Rodgers, a director of the Company, as interim President and Chief Executive Officer. In connection with his appointment, the Company and Mr. Rodgers entered into a letter agreement, dated as of April 20, 2023, concerning Mr. Rodgers's services (the "Letter Agreement"). The Letter Agreement provided that Mr. Rodgers (i) was to receive a $40,000 monthly salary, and (ii) was eligible for a potential prorated bonus at the discretion of the Board, at the end of his term as interim President and Chief Executive Officer. Pursuant to the bonus clause, a $100,000 bonus was expensed in December 2023 and paid on March 4, 2024. Mr. Rodgers also received 50,000 restricted stock units under the Company's 2020 Equity Incentive Plan which vested 12 months following the grant date. Mr. Rogers's services as interim President and Chief Executive Officer concluded on October 31, 2023 with the appointment of George Magrath to the role, the Letter Agreement has expired, and the Company does not expect to incur further expenses related thereto. The Company incurred related consulting expenses of $120,000 and $215,000 during the three and nine months ended September 30, 2023, respectively. As of December 31, 2023, $100,000 of the related expenses were unpaid related to a prorated bonus and were paid in full on March 4, 2024.

Dr. Pepose Consulting Agreement

On April 8, 2022, the Company entered into a consulting agreement (as amended, the "2022 Consulting Agreement") with Jay Pepose, M.D., a director of the Company. The consulting agreement originally provided for $10,000 a month in cash payments and a stock option grant for 50,000 options, of which 25% vested on March 31, 2023, with the remainder vesting in equal monthly installments over 36 months. The consulting agreement was amended on September 19, 2022 to provide for vesting acceleration for stock-based awards in the event of a change in control. The consulting agreement was also amended effective December 1, 2022 to increase the cash payment to $25,000 per month and amended effective January 1, 2024 to extend the expiration to March 31, 2024 and to increase the retainer for March 2024 to $49,000.

On April 11, 2024, the Company entered into another consulting agreement (the "2024 Consulting Agreement") with Dr. Pepose following the expiration of the 2022 Consulting Agreement. Pursuant to the 2024 Consulting Agreement, Dr. Pepose is paid a monthly consulting fee of $39,583. Additionally, Dr. Pepose received an award of 32,000 RSUs, as well as stock options to purchase 48,000 shares of the Company's common stock. The RSUs will vest on April 11, 2025, subject to Dr. Pepose's continued service over that period. The options vest in 12 equal monthly installments that began on May 11, 2024, subject to Dr. Pepose's continued service over such period. The 2024 Consulting Agreement is scheduled to terminate on April 11, 2025.

For the agreements with Dr. Pepose above, the Company incurred related consulting expenses of $119,000 and $337,000 during the three and nine months ended September 30, 2024, respectively; the Company incurred related consulting expenses of $75,000 and $225,000 during the three and nine months ended September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023, $40,000 and $25,000 of the related consulting expenses were unpaid, respectively.

Notes to Condensed Financial Statements

6. Stockholders' Equity

Amendment to Articles of Incorporation

At the Company's 2024 annual meeting of stockholders held on June 11, 2024, the Company's stockholders voted to approve an amendment to the Company's Amended and Restated Certificate of Incorporation that resulted in an increase in the number of authorized shares of the Company's common stock from 75 million to 125 million shares. The increase in authorized shares became effective on June 12, 2024.

Lincoln Park Purchase Agreement

On August 10, 2023, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") for an equity line financing (the "Purchase Agreement"). The Purchase Agreement provides that, subject to the terms and conditions set forth therein, the Company has the sole right, but not the obligation, to direct Lincoln Park to purchase up to $50 million of shares of the Company's common stock from time to time over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park (the "Registration Rights Agreement"), pursuant to which the Company agreed to register the resale of the shares of the Company's common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to a registration statement. Lincoln Park has agreed not to cause or engage in any manner whatsoever in any direct or indirect short selling or hedging of the Company's common stock.

A total of 400,000 shares were issued under the Purchase Agreement during the nine months ended September 30, 2024 for net proceeds of $0.7 million. The Company incurred de minimis issuance costs during the nine months ended September 30, 2024. There was no activity under the Purchase agreement during the three months ended September 30, 2024.

A total of 800,000 shares of the Company's common stock were sold under the Purchase Agreement for net proceeds in the amount of $3.1 million during the three and nine months ended September 30, 2023. The Company incurred issuance costs of $0.2 million, consisting of investor expense reimbursement and legal costs, during the three- and nine-months periods ended September 30, 2023 which were recorded as a component of financing costs in the accompanying statements of comprehensive (loss) income during the three and nine month periods ended September 30, 2023.

In addition to the initial commitment shares issued upon the execution of the Purchase Agreement of 246,792, a total of 1,700,000 shares of common stock were sold under the Purchase Agreement for gross proceeds through September 30, 2024 in the amount of $5.2 million and with issuance costs in the aggregate of $1.4 million.

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

In addition, the Company may also direct Lincoln Park, on any business day on which the Company has submitted a Regular Purchase notice for the maximum amount allowed for such Regular Purchase, to purchase an additional amount of the Company's common stock (an "Accelerated Purchase") based on certain market and trading conditions.

The pricing and settlement provisions in the Purchase Agreement result in the recognition of a derivative liability accounted for on a fair value basis under the provisions of ASC 815 - *Derivatives and Hedging*. A Monte Carlo simulation model was used to estimate future stock pricing and purchase activity to determine the fair value of the derivative liability. As of September 30, 2024, the change in the derivative liability from December 31, 2023 was *de minimis*. The fair value change in the derivative liability is recorded in the fair value change in derivative liabilities line item in the accompanying condensed statements of comprehensive (loss) income during periods with valuation changes.

Notes to Condensed Financial Statements

At-The-Market Program

On February 4, 2021, the Company filed a Form S-3 shelf registration under the Securities Act of 1933 which was declared effective by the SEC on February 12, 2021 (the "2021 Shelf") under which the Company may offer and sell, from time to time in its sole discretion, securities having an aggregate offering price of up to $125 million. In connection with the 2021 Shelf, on March 11, 2021, the Company entered into a sales agreement with JonesTrading Institutional Services LLC ("JonesTrading") under which the Company may offer and sell, from time to time at its sole discretion, to or through JonesTrading, acting as agent and/or principal, shares of its common stock having an aggregate offering price of up to $40 million (the "2021 ATM").

During the three and nine months ended September 30, 2024, 219,406 and 1,608,522 shares of common stock were sold under the ATM, respectively, for aggregate gross proceeds in the amount of $0.5 million and $3.8 million, respectively, before deducting issuance expenses, including the placement agent's fees, legal and accounting expenses, in the amount of $42,000 and $232,000, respectively.

During the three and nine months ended September 30, 2023, 577,555 shares of common stock were sold under the 2021 ATM for aggregate gross proceeds in the amount of $2.4 million before deducting issuance expenses, including the placement agent's fees, legal and accounting expenses, in the amount of $69,000.

As of September 30, 2024. 7,653,838 shares of common stock were sold under the ATM since its inception for gross proceeds in the amount of $26.4 million and with issuance costs in the aggregate of $0.9 million.

Registered Direct Offering

On June 4, 2021, the Company entered into a placement agency agreement for a registered direct offering ("RDO") with A.G.P./Alliance Global Partners ("AGP"). Pursuant to the terms of the placement agency agreement, AGP on June 8, 2021 sold an aggregate of 3,076,923 shares of the Company's common stock and warrants to purchase 1,538,461 shares of the Company's common stock (the "RDO Warrants") at an offering price of $4.875 per one share and per one-half of each RDO Warrant. The RDO was made pursuant to the Company's 2021 shelf registration.

The RDO Warrants have an exercise price of $6.09 per share, are exercisable from the initial issuance date of June 8, 2021, and will expire five years following the initial issuance date. As of September 30, 2024, 1,538,461 RDO Warrants were outstanding and none have been exercised since issuance.

Subject to limited exceptions, a holder of a RDO Warrant will not have the right to exercise any portion of its RDO Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of a holder prior to the date of issuance, 9.99%) of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise; provided that upon prior notice to the Company, the holder may increase or decrease the beneficial ownership limitation, provided further that in no event shall the beneficial ownership limitation exceed 9.99%.

Pre-Merger Financing

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

Notes to Condensed Financial Statements

Series A Warrants

The Series A Warrants were issued on November 19, 2020 at an initial exercise price of $4.4795 per share, were immediately exercisable upon issuance and have a term of five years from the date of issuance. The Series A Warrants are exercisable for 5,665,838 shares of common stock in the aggregate (without giving effect to any limitation on exercise contained therein) and were outstanding as of September 30, 2024. The Series A Warrants were accounted for and classified as equity on the accompanying balance sheets.

Series B Warrants

The Series B Warrants had an exercise price of $0.0001, were exercisable upon issuance and would have expired on the day following the later to occur of (i) the Reservation Date (as defined therein) or (ii) the date on which the investor's Series B Warrants would have been exercised in full (without giving effect to any limitation on exercise contained therein). None of the Series B Warrants were outstanding as of September 30, 2024 or December 31, 2023.

7. Stock-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative	$ 549	$ 335	$ 1,850	$ 1,969
Research and development	227	238	717	830
Total stock-based compensation	$ 776	$ 573	$ 2,567	$ 2,799

Notes to Condensed Financial Statements

Stock Options

Inducement Plan

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

2020 Equity Incentive Plan

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

2020 Plan Evergreen Provision

Under the 2020 Plan, the shares reserved automatically increase on January 1 of each year, for a period of not more than ten years from the date the 2020 Plan is approved by the stockholders of the Company, commencing on January 1, 2021 and ending on (and including) January 1, 2030, by an amount equal to 5% of the shares of common stock outstanding as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1 increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence. On January 1, 2024, 1,198,875 shares were added to the 2020 Plan as a result of its evergreen provision.

Notes to Condensed Financial Statements

2018 Equity Incentive Plan

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

Stock Options

During the three and nine months ended September 30, 2024, zero and 1,021,166 stock options were granted to directors, officers, employees and consultants, respectively, generally vesting over a one- to four-year period with monthly, quarterly and annual vesting tranches. During the three and nine months ended September 30, 2023, 30,000 and 793,578 stock options were granted to directors, officers, employees and consultants, respectively, generally vesting over a five (5) to forty-eight (48) month period.

The Company recognized $474,000 and $400,000 in stock-based compensation expense related to stock options during the three months ended September 30, 2024 and 2023, respectively, and $1,431,000 and $2,087,000 during the nine months ended September 30, 2024 and 2023, respectively. Stock-based compensation expense during the nine-month period ended September 30, 2023 included a one-time charge of $0.4 million attributed to the modification of the Company's former Chief Executive Officer's stock options with respect to their exercisability provisions.

During the three and nine months ended September 30, 2024 and 2023, there were no exercises of stock options during these periods.

As of September 30, 2024 and December 31, 2023, 4,848,064 and 4,410,258 stock options were outstanding, respectively.

The weighted average fair value per share of options granted during the nine months ended September 30, 2024 was $1.95. The weighted average fair value per share of options granted during the three and nine months ended September 30, 2023 was $3.30 and $2.85, respectively. The Company measures the fair value of stock options with service-based vesting criteria to employees, directors, consultants and directors on the date of grant using the Black-Scholes option pricing model. The Company does not have sufficient share trading history to support an internal calculation of volatility and expected term. As such, the Company has used a weighted average volatility considering the volatilities of several guideline companies.

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

Notes to Condensed Financial Statements

The weighted average assumptions used in the Black-Scholes option pricing model are as follows during the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected stock price volatility	—%	96.4%	97.7%	95.3%
Expected life of options (years)	—	6.1	5.9	6.1
Expected dividend yield	—%	0%	0%	0%
Risk free interest rate	—%	4.2%	4.2%	3.7%

During the three and nine months ended September 30, 2024, 79,725 and 386,097 stock options vested, respectively. During the three and nine months ended September 30, 2023, 94,347 and 715,171 stock options vested, respectively, inclusive of the vesting acceleration of stock options attributed to the departure of the Company's former Chief Executive Officer in the amount of 145,418 during the second quarter of 2023.

During the three and nine months ended September 30, 2024, 114,425 and 583,360 options were forfeited, respectively. During the three and nine months ended September 30, 2023, 5,267 and 260,233 options were forfeited, respectively, inclusive of the stock option forfeited in connection with the departure of the Company's former Chief Executive Officer in the amount of 249,633 during the second quarter of 2023.

Restricted Stock Units

During the three and nine months ended September 30, 2024, the Company granted zero and 592,222 restricted stock units ("RSUs"), respectively, to certain officers and employees under the 2020 Plan. The weighted average grant date per unit fair value of the RSUs granted during the nine months ended September 30, 2024 was $2.24. The vesting period of the RSUs ranges from a one-year period to a four-year period during which 25 percent of the RSUs vest annually on each anniversary of the grant date, subject to the recipient's continued service on such dates.

During the three and nine months ended September 30, 2023, the Company granted an aggregate of zero and 416,464 RSUs, respectively, to the Board, officers, employees and consultants under the 2020 Plan. The weighted average grant date per unit fair value of the RSUs granted during the nine months ended September 30, 2023 was $3.98. The vesting period of the RSUs ranges from a one year period to a four year period where 25% of the RSUs vest annually on each anniversary of the grant date, subject to the recipient's continued service on such dates.

During the three and nine months ended September 30, 2024, zero and 144,162 RSUs vested, respectively, and 36,660 and 119,330 RSUs were forfeited during the three and nine months ended September 30, 2024, respectively. The total expense for the three and nine months ended September 30, 2024 related to these RSUs was $302,000 and $891,000, respectively.

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

Common Stock Issued for Services

The Company granted stock for services in the amount of zero and 81,234 common shares during the three and nine months ended September 30, 2024, respectively, to board members who elected to receive their board retainers in the form of stock for services with a weighted grant date fair value of $3.01 per share. The Company granted stock for services in the amount of zero and 72,986 common shares during the three and nine months ended September 30, 2023, respectively, to board members who elected to receive their board retainers in the form of stock for services with a weighted grant date fair value of $3.77 per share.

The stock-based compensation related to these services amounted to zero and during the three months ended September 30, 2024 and 2023, and $245,000 and $275,000 during the nine months ended September 30, 2024 and 2023, respectively.

Notes to Condensed Financial Statements

General

As of September 30, 2024, 1,747,911 shares were available for future issuance under the 2020 Plan and Inducement Plan, in the aggregate. No shares were available for future issuance under the 2018 Plan. Unrecognized stock-based compensation cost was $6.1 million as of September 30, 2024. The unrecognized stock-based expense is expected to be recognized over a weighted average period of 1.6 years.

8. Apexian Sublicense Agreement

On January 21, 2020, the Company entered into a sublicense agreement (as amended on June 4, 2020, the "Apexian Sublicense Agreement") with Apexian, pursuant to which it obtained exclusive worldwide patent and other intellectual property rights that constitute a Ref-1 Inhibitor program relating to therapeutic applications to treat disorders related to ophthalmic and diabetes mellitus conditions. In connection with the Apexian Sublicense Agreement, the Company issued a total of 891,422 shares of its common stock to Apexian and to certain affiliates of Apexian in calendar year 2020. As a result of the shares of common stock issued pursuant to the Apexian Sublicense Agreement, Apexian is considered by the Company to be a related party.

The Company also agreed to make one-time milestone payments under the Apexian Sublicense Agreement for each of the first ophthalmic indication and the first diabetes mellitus indication for the development and regulatory milestones, and once for each of several sales milestones. These milestone payments include (i) payments for specified developmental and regulatory milestones totaling up to $11 million in the aggregate and (ii) payments for specified sales milestones of up to $20 million in the aggregate, which net sales milestone payments are payable once, upon the first achievement of such milestone. Lastly, the Company also agreed to make a royalty payment equal to a single-digit percentage of its net sales of products associated with the covered patents under the Apexian Sublicense Agreement.

None of the milestone or royalty payments were triggered or deemed probable as of September 30, 2024.

9. License and Collaboration Agreements

Viatris License Agreement

On November 6, 2022, the Company entered into the Viatris License Agreement, pursuant to which it granted Viatris (as successor to Famy) an exclusive, perpetual, sub-licensable license to develop, manufacture, import, export and commercialize (i) PS, for treating (a) reversal of mydriasis, (b) night vision disturbances or dim light vision, and (c) presbyopia, and (ii) PS and low dose pilocarpine for treating presbyopia (together, the "PS Products") worldwide except for certain countries and jurisdictions in Asia (the "Viatris Territory"). The Company retains the exclusive right to develop, manufacture, have manufactured, import, export and commercialize the PS Products outside of the Viatris Territory.

Under the terms of the Viatris License Agreement, the Company in partnership with Viatris, will develop the PS Products in the United States. Viatris will reimburse the Company for agreed-to budgeted costs related to the development of the PS Products through FDA approval, and then share costs above the agreed upon threshold amount. Viatris will be responsible for developing the PS Products in countries and jurisdictions in the Viatris Territory outside of the United States.

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

Notes to Condensed Financial Statements

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

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

Recognition of Revenue

Revenue recognized under the Viatris License Agreement during the three and nine months ended September 30, 2024 was $3.9 million and $6.7 million, respectively, related to the output of research and development services and to a much lesser extent royalty payments.

Revenue recognized under the Viatris License Agreement during the three and nine months ended September 30, 2023 was $11.9 million and $17.4 million, respectively, related to the output of research and development services and to milestone payments. On September 25, 2023, the Company met the $10 million milestone payment requirements attributed to the FDA's approval of PS for reversal of mydriasis under the name "RYZUMVI", and the $10 million milestone payment was included in the revenue recognized during the three and nine months ended September 30, 2023.

Regulatory Milestones under the Viatris License Agreement

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

Sales Milestone and Royalty Payments

Sales milestones and royalties relate predominantly to a license of intellectual property granted to Viatris and are determined by sales or usage-based thresholds. The sales milestones and royalties are accounted for under the royalty recognition constraint and are accounted for as constrained variable consideration. The Company applies the royalty recognition constraint for each commercial milestone and only recognize revenues for each once a sale of a licensed product (achievement of each) occurs. Royalty payments in the amount of $14,000 and $36,000 were recognized related to the sale of RYZUMVI by Viatris during the three and nine months ended September 30, 2024, respectively.

Each of the remaining regulatory and sales milestone performance obligations (aside from the $10 million milestone payment related to the FDA's approval of PS in the third quarter of 2023) were constrained as of September 30, 2024 and no revenue was recognized related to these milestones.

A reconciliation of the closing balance of the contract assets and unbilled receivables associated with the Viatris License Agreement is as follows as of September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Contract Assets and Unbilled Receivables		
Balance as of beginning of nine-month period	$ 1,407	$ 3,552
Revenue recognized	6,690	17,358
Reclassification to accounts receivable related to costs billed under the Viatris License Agreement	(6,629)	(19,699)
Balance as of end of nine-month period	$ 1,468	$ 1,211

The remaining amounts in contract assets and unbilled receivables as of September 30, 2024 attributed to the research and development services are expected to be settled during the fourth quarter of 2024.

BioSense License and Assignment:

On March 10, 2020, prior to the Rexahn Merger, Rexahn entered into an amendment to its collaboration and license agreement, (as amended, the "BioSense License and Assignment Agreement") with BioSense to advance the development and commercialization of the Rexahn RX-3117 drug compound ("RX-3117") for all human uses in the Republic of Singapore, China, Hong Kong, Macau, and Taiwan (the "BioSense Territory").

Under the BioSense License and Assignment Agreement, the Company is eligible to receive additional milestone payments in an aggregate of up to $84,500,000 upon the achievement of development, regulatory and commercial goals and will also be eligible to receive tiered royalties at low double-digit rates on annual net sales in the BioSense Territory. The Company determined that none of the milestone payments under the BioSense License and Assignment Agreement were probable of payment as of September 30, 2024, and as a result, no revenue related to the milestones was recognized, as the achievement of events entitling the Company to any milestone payments were highly susceptible to factors outside of the Company's control. Future sales-based royalties related to the exclusive license to develop RX-3117 will be recognized in the period the underlying sales transaction occurs.

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

Processa License Agreement

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

Processa will make future payments to the Company upon the achievement of certain development, regulatory and commercial milestones. In addition, Processa will pay the Company mid-single-digit percentage royalties based on annual sales. The Company determined that none of the milestone payments under the Processa License Agreement were probable of payment as of September 30, 2024, and as a result, no revenue related to the milestones was recognized, as the achievement of events entitling the Company to any milestone payments were highly susceptible to factors outside of the Company's control.

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

10. Net (Loss) Income per Share

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

Notes to Condensed Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Basic	26,145,080	21,446,648	25,501,117	21,117,211
Dilutive stock options	—	914,583	—	—
Dilutive RSUs	—	44,764	—	—
Dilutive warrants	—	—	—	—
Diluted common shares outstanding	26,145,080	22,405,995	25,501,117	21,117,211

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Series A and RDO warrants	7,204,299	7,204,299	7,204,299	7,204,299
Stock options	4,848,064	2,554,806	4,848,064	3,469,389
RSUs	1,130,430	237,244	1,130,430	282,008
Former Rexahn warrants	—	58,597	—	58,597

11. Income Taxes

The effective tax rate for the nine months ended September 30, 2024 and 2023 was 0% and nominal, respectively. As of September 30, 2024, a full valuation allowance has been established to reduce the Company's net deferred income tax assets. As such, no tax benefit related to the Company's pre-tax loss was recognized for any of the periods presented.

The Company's corporate returns are subject to examination for tax years beginning in 2020 for federal income tax purposes and subject to examination in various state jurisdictions. The Company does not have any reserves for income taxes that represent the Company's potential liability for uncertain tax positions.

12. Deferred Compensation Plan

Effective October 1st, 2021, the Company began offering a 401(k) plan ("401K Plan") to its employees. All employees are eligible to participate in the 401K Plan. The Company makes matching contributions equal to 100% on the first 3% of compensation that is deferred as an elective deferral and an additional 50% on the next 2% of compensation. The Company's matching contributions are made on a payroll-by-payroll basis. During the three months ended September 30, 2024 and 2023, the Company contributed $40,000 and $21,000 to the 401K Plan, respectively. During the nine months ended September 30, 2024 and 2023, the Company contributed $141,000 and $77,000 to the 401K Plan, respectively.

13. Subsequent Events

Acquisition of Opus Genetics

Summary of Transaction

As described in Note 1, "Nature of Business," on October 22, 2024, the Company completed the stock purchase of Former Opus. Under the terms of the Merger Agreement, at the closing of the Opus Acquisition, the Company issued to the security holders of Former Opus 5,237,063 shares of the Company's common stock, par value $0.0001 per share and 14,145.374 shares of the Company's preferred stock, par value $0.0001 per share, designated as Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"), each share of which is convertible into 1,000 shares of common stock, subject to stockholder approval. Following the closing of the Opus Acquisition, the Company had 31,435,507 shares of common stock and 14,145.374 shares of preferred stock outstanding.

Notes to Condensed Financial Statements

Ancillary Documents

In connection with the execution of the Merger Agreement, the Company and Former Opus entered into stockholder support agreements (the "Support Agreements") with certain of the Company's directors and officers. The Support Agreements provide that, among other things, each of the stockholders has agreed to vote or cause to be voted all of the shares of common stock owned by such stockholder at the next annual meeting of stockholders (the "Stockholders' Meeting") in favor of (i) the approval of the conversion of the Series A Preferred Stock into shares of common stock (the "Conversion Proposal") and (ii) the approval of one or more adjournments of the Stockholders' Meeting to solicit additional proxies if there are not sufficient votes cast in favor of the Conversion Proposal.

Concurrently and in connection with the execution of the Merger Agreement, certain of Former Opus security holders and all of the directors and officers of the Company entered into lock-up agreements, pursuant to which each such stockholder will be subject to a 180-day lock-up on the sale or transfer of shares of common stock held by such stockholder at Closing, including those shares received by Opus's security holders in the Opus Acquisition.

In connection with the Merger Agreement, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with certain Former Opus security holders (the "Selling Security Holders"). Pursuant to the Registration Rights Agreement, the Company will prepare and file a resale registration statement covering the shares of common stock and shares of common stock underlying the Series A Preferred Stock issued to Former Opus security holders upon the closing of the Opus Acquisition (the "Registrable Securities") with the SEC within 120 calendar days following the date of the Merger Agreement or such later date agreed to by the holders of no less than a majority of the then outstanding Registrable Securities (the "Filing Deadline"). The Company will use its reasonable best efforts to cause such registration statement to be declared effective by the SEC within 30 calendar days of the Filing Deadline (or within 60 calendar days if the SEC reviews and has written comments to the registration statement).

The Company has also agreed to, among other things, indemnify the Selling Security Holders as well as their officers, directors, agents, partners, members, managers, stockholders, any person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a person, as such terms are used in and construed under Rule 405 of the Securities Act of 1933 (as amended, the "Securities Act" and each such person, an "Affiliate"), investment advisers and employees of each of them, each person who controls any such Selling Security Holders (within the meaning of Section 15 of the Securities Act or Section 20 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) and the officers, directors, partners, members, managers, stockholders, agents, Affiliates, investment advisers and employees of each such controlling person under the registration statement from certain liabilities and pay all fees and expenses incident to the Company's obligations under the Registration Rights Agreement.

Certificate of Designation

On October 22, 2024, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock with the Secretary of State of the State of Delaware (the "Certificate of Designation") in connection with the Opus Acquisition. The Certificate of Designation provides for the issuance of shares of Series A Preferred Stock.

Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock (on an as-if-converted-to-Common-Stock basis) equal to and in the same form, and in the same manner, as dividends (other than dividends on shares of our common stock payable in the form of common stock) actually paid on shares of our common stock when, as and if such dividends (other than dividends payable in the form of common stock) are paid on shares of our common stock. In addition to any dividends payable as described above, commencing on October 15, 2025, holders of Series A Preferred Stock will be entitled to receive when, as and if declared by the Board or a duly authorized committee of the Board, and the Company will pay, out of funds legally available therefor, cumulative quarterly cash dividends of $26.00 per share of Series A Preferred Stock; provided that for the Series A Dividend Payment Date occurring on October 15, 2025, the amount of such quarterly cash dividend shall be $15.26. Any such dividends will be payable quarterly in arrears on January 15, April 15, July 15 and October 15 of each year, commencing with the first payment on October 15, 2025 (each such date, a "Series A Dividend Payment Date").

Notes to Condensed Financial Statements

Except as otherwise required by law, the Series A Preferred Stock will have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock: (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, the Certificate of Incorporation or the Bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock, regardless of whether any of the foregoing actions will be by means of amendment to the Certificate of Incorporation or by merger, consolidation or otherwise, (ii) issue further shares of Series A Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock, (iii) amend, in any manner that would be reasonably likely to prevent, impede or materially delay the stockholder approval of the Conversion Proposal or the Automatic Conversion (as defined in the Certificate of Designation), or terminate any Support Agreements, or agree to any transfer, sale or disposition of such shares subject to the Support Agreements (except for such transfers, sales or dispositions with respect to which the approval of the Company is not required pursuant to the applicable Support Agreement), (iv) amend Sections 4.02, 4.03 or 4.07 of the Merger Agreement in any manner that would be reasonably likely to prevent, impede or materially delay the stockholder approval of the Conversion Proposal or (v) enter into any agreement with respect to any of the foregoing.

Following stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock will be convertible into shares of common stock at any time at the option of the holder thereof, into 1,000 shares of common stock, subject to certain limitations.

Consulting Agreement with Dr. Bennett

In connection with Dr. Jean Bennett's appointment as a member of the Board, effective October 22, 2024, she and the Company entered into a consulting agreement (the "Bennett Consulting Agreement"), pursuant to which Dr. Bennett will provide consulting services to the Company for a one-year period. Pursuant to the Bennett Consulting Agreement, Dr. Bennett was granted a restricted stock unit award with respect to 100,000 shares of common stock, which award is scheduled to vest on October 22, 2025, subject to her continued service with the Company through and including such date; provided, that the award will vest in full if the Bennett Consulting Agreement is terminated by (i) Dr. Bennett due to a breach of the Bennett Consulting Agreement by the Company, or (ii) the Company other than due to Dr. Bennett's embezzlement, non-performance, fraud or deceit, or her violation of law or breach of the Bennett Consulting Agreement.

Appointment of President and Employment Agreement

Dr. Yerxa, age 58, has also been appointed to serve as the Company's President, effective October 22, 2024. Dr. Yerxa has been the Chief Executive Officer and President of Former Opus since July 2022. In connection with his appointment, on and effective October 22, 2024, Dr. Yerxa and the Company entered into an employment agreement (the "Yerxa Employment Agreement"). The Yerxa Employment Agreement provides for a one-year employment term expiring on October 21, 2025, following which Dr. Yerxa will continue to provide consulting services to the Company for a period of three years (the "Yerxa Consulting Term"). Pursuant to the Yerxa Employment Agreement, Dr. Yerxa will receive an annual base salary of $425,000 and will be eligible for a target annual bonus equal to 35% of his base salary, prorated based on the number of days that Dr. Yerxa is employed by the Company during the applicable fiscal year and based on the achievement of performance metrics approved by the Compensation Committee of the Board (the "Compensation Committee").

As provided in the Yerxa Employment Agreement, as an inducement for Dr. Yerxa to enter into the Yerxa Employment Agreement and subject to the terms of the Inducement Plan, Dr. Yerxa will be granted a time-based restricted stock unit award with respect to 332,800 shares of common stock, which award is scheduled to vest in four equal annual installments on each of the first four anniversaries of the grant date, subject to Dr. Yerxa's continued service with the Company through each vesting date. During the Yerxa Consulting Term, Dr. Yerxa will receive an annual payment in the amount of $400,000, which amount may be paid in cash or, in the Company's sole discretion with respect to up to 50% of the amount, in shares of common stock (or such greater amount as may be mutually agreed upon by the parties). The amounts to be paid to Dr. Yerxa during the Yerxa Consulting Term will be accelerated in the event that the Consulting Term is terminated by (i) Dr. Yerxa due to a breach of the consulting agreement by the Company, or (ii) the Company other than a for cause termination.

Notes to Condensed Financial Statements

In the event of a termination of his employment by the Company without "Cause" or by Dr. Yerxa for "Good Reason" (each as defined in the Yerxa Employment Agreement and each, a "Qualifying Termination"), in each case, within twelve months following the closing date of the Opus Acquisition, then subject to Dr. Yerxa's execution of a release of claims in favor of the Company (a "Release") and continued compliance with certain restrictive covenants, Dr. Yerxa will be entitled to receive (i) a lump sum payment equal to the sum of 0.5 times (a) his base salary and (b) an amount equal to a prorated portion of his target annual bonus, (ii) continued health coverage for Dr. Yerxa and his covered dependents at the Company's expense for up to twelve months, and (iii) all outstanding and unvested equity awards held by Dr. Yerxa will become fully vested and exercisable. In addition, in the event of a Qualifying Termination that occurs within three months prior to a "Change in Control" (as defined in the Yerxa Employment Agreement), then, in lieu of the amounts described in clause (i) above, and subject to Dr. Yerxa's execution of a Release and continued compliance with certain restrictive covenants, Dr. Yerxa will be entitled to receive a lump sum payment equal to the sum of 0.5 times (x) his base salary and (y) his target annual bonus.

Dr. Yerxa will be subject to certain non-competition and non-solicitation covenants for twelve months following the termination of his employment with the Company.

Accounting Treatment

Given the timing of the closing of the Opus Acquisition, the purchase accounting is incomplete at this time. As such, it is not practicable for the Company to disclose the allocation of purchase price to assets acquired and liabilities assumed and pro forma revenues and earnings of the combined entity.

Inducement Plan Amendment

Effective as of October 20, 2024, the Company amended the 2021 Inducement Plan reserve to 2,625,258 shares of its common stock.

Opus Genetics, Inc.
Form 10-Q

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

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited financial statements and notes included in Part I "Financial Information", Item 1 "Financial Statements" of this Quarterly Report on Form 10-Q (the "Report") and the audited financial statements and related footnotes included in our Annual Report on Form 10-K for the year ended December 31, 2023.

Forward-Looking Statements

Certain statements contained in this Report are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements give current expectations or forecasts of future events or our future financial or operating performance. Such statements include, but are not limited to, statements concerning our strategic business plans, the applications of our product candidates, ongoing discussions with the U.S. Federal Drug Administration (the "FDA") regarding various of our drug products, and continued drug development and commercialization under our agreement with Viatris, Inc. ("Viatris"). In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "could," "continue," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements.

These forward-looking statements reflect our management's beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this Report and are subject to risks and uncertainties, many of which are beyond our control, that could cause our actual results to differ materially from those in these forward-looking statements, including, without limitation:

- The success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts;
- Regulatory requirements or developments;
- Changes to or unanticipated events in connection with clinical trial designs and regulatory pathways;
- Delays or difficulties in the enrollment of patients in clinical trials;
- Substantial competition and rapid technological change;
- Our development of sales and marketing infrastructure;
- Future revenue losses and profitability;
- Our relatively short operating history;
- Changes in capital resource requirements;
- Risks related to the inability of the Company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs;
- Domestic and worldwide legislative, regulatory, political and economic developments;
- Employee misconduct;
- Changes in market opportunities and acceptance;
- Reliance on third-parties;
- Future, potential product liability and securities litigation;
- System failures, unplanned events, or cyber incidents;
- The substantial number of shares subject to potential issuance associated with our Equity Line of Credit arrangement with Lincoln Park Capital Fund, LLC;
- Risks that our partnership with Viatris, or our other licensing arrangements, may not facilitate the commercialization or market acceptance of the Company's product candidates;
- Future fluctuations in the market price of our common stock;
- The success and timing of commercialization of any of the Company's product candidates; and
- Obtaining and maintaining the Company's intellectual property rights.

We discuss many of these risks in greater detail under Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent reports filed with or furnished to the Securities and Exchange Commission (the "SEC"). Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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

Overview

On October 22, 2024, Opus Genetics, Inc., a Delaware corporation formerly known as Ocuphire Pharma, Inc. (the "Company" or "Opus"), acquired a private corporation then operating under the name of "Opus Genetics, Inc." ("Former Opus") pursuant to the terms of an Agreement and Plan of Merger, dated as of October 22, 2024 (such agreement, the "Merger Agreement" and the transaction consummated via the Merger Agreement, the "Opus Acquisition"), by and among the Company, Former Opus, and certain merger subsidiaries party thereto. As consideration for the Opus Acquisition, the Company issued 5,237,063 shares of its common stock and 14,145.374 shares of Series A Preferred Stock, each of which is convertible into 1,000 shares of common stock. As of November 7, 2024 there were 31,568,457 shares of the Company's common stock outstanding. If the shares of Series A Preferred Stock were converted as of that date, there would be a total of 45,713,831 shares of common stock outstanding. Further information about the Opus Acquisition can be found in Note 13 – Subsequent Events, included in "Part I, Item 1 – Financial Statements and Supplementary Data" of this Report.

Following the Opus Acquisition, the Company is a clinical-stage ophthalmic biotechnology company developing gene therapies for the treatment of inherited retinal diseases (IRDs) and other ophthalmologic disorders. The expanded pipeline includes multiple assets from its adeno-associated virus (AAV) based gene therapy portfolio that address mutations in genes that cause different forms of bestrophinopathy, Leber congenital amaurosis (LCA) and retinitis pigmentosa. The company's most advanced gene therapy program is designed to address mutations in the LCA5 gene, which encodes the lebercilin protein. The pipeline also includes Phentolamine Ophthalmic Solution 0.75%, a non-selective alpha-1 and alpha-2 adrenergic antagonist to reduce pupil size, and APX3330, a novel small-molecule inhibitor of Ref-1 to slow the progression of non-proliferative diabetic retinopathy. Phentolamine Ophthalmic Solution 0.75% is currently being evaluated in Phase 3 trials for presbyopia and dim (mesopic) light vision disturbances.

Due to the capital requirements and developmental timelines of APX3330, an oral small-molecule inhibitor of Ref-1 for the treatment of non-proliferative diabetic retinopathy, the company will seek a strategic partner to advance the clinical development of the late-stage diabetic retinopathy program and will redirect its existing resources towards the acquired gene therapy programs.

The most advanced gene therapy candidate, OPGx-LCA5, is being developed to treat LCA5, an early-onset retinal degeneration, and an open-label, dose-escalation Phase 1/2 clinical trial with encouraging early data is ongoing. The trial has shown early clinical proof-of-concept, with new six-month data demonstrating visual improvement in three out of three adult patients participating in the trial, each of whom has late-stage disease.

Enrollment of the first pediatric patients in the LCA5 Phase 1/2 trial is expected in the first quarter of 2025, with the first data anticipated in the third quarter of 2025. As the program has received Rare Pediatric Disease Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA), OPGx-LCA5 will be eligible to receive a priority review voucher upon biologics license application (BLA) approval.

OPGx-BEST1 is a gene therapy candidate acquired from Iveric Bio in late 2022. This asset is being developed for the treatment of IRDs associated with mutations in the BEST1 gene ("Best disease"), which can lead to legal blindness. Preclinical studies conducted in a naturally occurring canine model of Best disease treated with OPGx-BEST1 exhibited both safety and efficacy in support of a first in man clinical trial, which is planned for 2025.

RYZUMVI and Phentolamine Ophthalmic Solution 0.75% (PS)

In November 2022, we entered into a license and collaboration agreement (the "Viatris License Agreement") with FamyGen Life Sciences, Inc. (acquired by and now known as Viatris, Inc. ("Viatris")), pursuant to which we granted Viatris an exclusive license to develop, manufacture, import, export and commercialize (i) our refractive product candidate Phentolamine Ophthalmic Solution 0.75%, formerly known as Nyxol ("PS"), for treating (a) reversal of pharmacologically-induced mydriasis, (b) decreased vision under mesopic (low) light conditions after keratorefractive surgery, and (c) presbyopia; and (ii) PS and low dose pilocarpine for treating presbyopia (together, the "PS Products") worldwide except for certain countries and jurisdictions in Asia (the "Viatris Territory"). PS was approved by the FDA for the treatment for pharmacologically-induced mydriasis under the brand name RYZUMVI in September 2023, which triggered a $10 million milestone payment under the Viatris License Agreement. RYZUMVI was commercialized by Viatris in April 2024. For more information on the Viatris License Agreement, please refer to Note 9 – License and Collaboration Agreements included in "Part I, Item 1– Financial Statements and Supplementary Data" of this Report.

PS is a once-daily eye drop formulation of phentolamine mesylate designed to reduce pupil diameter and improve visual acuity. PS can potentially be used across multiple indications such as treatment of pharmacologically-induced mydriasis ("RM") (dilation of the pupil), presbyopia (age-related blurry near vision) and decreased vision under mesopic (low) light conditions after keratorefractive surgery. PS has been studied in a total of 13 clinical trials (three of which were Phase 1 trials, five of which were Phase 2 trials, and five of which were Phase 3 trials) in a total of over 1,400 study participants (with over 800 participants being treated with PS) and has demonstrated promising clinical data across the three targeted refractive indications.

We reported positive top-line data from multiple late-stage clinical trials for PS in reversal of pharmacologically induced mydriasis, presbyopia and dim light disturbances. The VEGA-2 Phase 3 study in presbyopia achieved its primary endpoint. The VEGA-3 Phase 3 clinical trial evaluating PS for presbyopia (age-related blurry near vision) is underway and topline data is expected in the first half of 2025. For decreased vision under mesopic (low) light conditions following keratorefractive surgery, we received FDA agreement under Special Protocol Assessment ("SPA") for LYNX-2, a Phase 3 Trial of PS. LYNX-2 continues enrollment and topline data is expected in the first quarter of 2025. LYNX-3, an additional Phase 3 study for decreased vision under mesopic (low) light conditions following keratorefractive surgery, has commenced and is expected to enroll the first patient in the fourth quarter of 2024.

APX3330

APX3330 is a small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein). Ref-1 is a regulator of transcription factors such as HIF-1α and NF-kB. Inhibiting Ref-1 has been shown to reduce levels of vascular endothelial growth factor ("VEGF") and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. APX3330 is an oral tablet intended to be administered twice per day in development for the treatment of diabetic retinopathy ("DR").

DR affects approximately 10 million diabetics and is projected to impact over 14 million Americans by 2050. DR is classified as either Non-Proliferative Diabetic Retinopathy ("NPDR"), the early stage of the disease in which symptoms may be mild or non-existent, or Proliferative Diabetic Retinopathy ("PDR"), which is the more advanced stage of diabetic eye disease that can be highly symptomatic with loss of vision. Approximately 8 million DR patients have NPDR that may progress to PDR if left untreated. APX3330, as an oral tablet, has the potential to be an early, non-invasive treatment for the 8 million NPDR patients in the US.

In January 2023, we reported top-line efficacy and safety results from the ZETA-1 Phase 2 trial conducted in 103 subjects in DR, including moderately severe and severe NPDR and mild PDR, as well as patients with diabetic macular edema without loss of central vision. Although administration of APX3330 daily did not meet the study's primary endpoint of percentage of patients with a ≥ 2-step improvement in Early Treatment of Diabetic Retinopathy Study ("ETDRS") diabetic retinopathy severity scale ("DRSS") in the study eye at week 24 compared to placebo, efficacy was seen on the ≥3-step worsening on a binocular DRSS Person Scale. Prevention or slowing of progression of DR to vision-threatening complication such as PDR is a clinically meaningful endpoint. APX3330 also demonstrated favorable safety and tolerability in diabetic patients. An End-of-Phase 2 ("EOP2") meeting with the U.S. Food and Drug Administration (the "FDA") was held in October 2023 . APX3330 demonstrated favorable safety and tolerability in the ZETA-1 trial. The Company submitted a SPA to the FDA in February 2024 to seek agreement on the clinical trial protocol and statistical analysis plan. The company continues dialog with the FDA and will update the market upon conclusion of these discussions.

Strategic Outlook

We intend to advance our current active pipeline, and may explore opportunities to in-license or out-license other drug candidates. To date, our primary activities have been conducting research and development activities, performing business and financial planning, recruiting personnel and raising capital. We have only one product, RYZUMVI, approved for sale that is generating royalties based on sales by Viatris, and we do not expect to consistently generate significant revenues, other than license and collaborations revenue, unless and until the FDA or other regulatory authorities approve, and we successfully commercialize, LCA5, BEST1, other internally-developed assets or PS for other indications. Until such time, if ever, as we can consistently generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings as well as through collaborations, strategic alliances and licensing arrangements.

Through September 30, 2024, we have funded our operations primarily through equity financings that totaled $67.8 million in gross proceeds, of which $21.15 million was received in connection with the merger ("Rexahn Merger") with Rexahn Pharmaceuticals, Inc. ("Rexahn") and through the issuance of convertible notes in private placements that totaled $8.5 million in gross proceeds net cash. In addition, we have received license fee and milestone payments of $45.0 million in the aggregate and reimbursement for costs related to development, all in connection with the Viatris License Agreement.

Our net loss was $7.5 million and $22.4 million for the three and nine months ended September 30, 2024, respectively, as compared to net income of $5.6 million and a net loss of $5.2 million for the three and nine months September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $103.9 million. We anticipate ongoing and new expenses as we look to:

- continue certain clinical and nonclinical work for LCA5, BEST1, other internally-developed assets, PS and for any other product candidate in our future pipeline;
- develop additional product candidates that we identify, in-license or acquire;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- contract to manufacture our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, operational and financial personnel, to execute our business plan;
- add operational, financial and management information systems and personnel to support our product development and potential future commercialization efforts;
- continue to operate as a public company; and
- establish on our own or with partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval.

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

Financial Operations Overview

License and Collaborations Revenue

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

To date, outside of the license and collaborations revenue referenced above, we do not expect to generate significant revenue unless or until RYZUMVI sales become material, or regulatory approval is obtained, and commercialization begins for LCA5, BEST1, other internally-developed assets or PS for indications other than RM. If we fail to complete the development of LCA5, BEST1, PS, or any other product candidate we may pursue in the future in a timely manner or fail to obtain regulatory approval, our ability to generate significant revenue would be compromised.

Operating Expenses

The Company's operating expenses are classified into two categories: general and administrative and research and development.

General and Administrative Expenses

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

Research and Development Expenses

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

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

We expect that LCA5, BEST1, PS and other internally-developed assets will have higher development costs during the later stages of clinical development, as compared to costs incurred during their earlier stages of development, primarily due to the increased size and duration of the later-stage clinical trials and associated nonclinical studies. We expect our research and development expenses to increase over the next several years. However, it is difficult for us to determine with certainty the duration, costs and timing to complete our current or future nonclinical programs and clinical trials of LCA5, BEST1, PS and other internally-developed assets.

Financing costs

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

Fair value change in derivative liabilities

The fair value change in derivative liabilities consists of the fair value change of the derivative liability associated with our equity line financing during the periods the equity line financing is outstanding. In addition, the fair value change of the warrant liabilities associated with the Rexahn warrants, while outstanding, was also included in this line item.

Other Income, net

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

Provision for Income Taxes

Provision for income taxes consists of federal and state income taxes in the United States, as well as deferred income taxes and changes in related valuation allowance reflecting the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Currently, a full valuation allowance has been provided on the net deferred tax assets as of September 30, 2024 and December 31, 2023 given the uncertainty of future taxable income and other related factors impacting the realizability or our remaining net deferred tax assets.

Results of Operations

The following discussion of the Company's results of operations refers to the Company's results of operations prior to the Opus Acquisition, and are not indicative of the Company's future results of operations.

Comparison of Three Months Ended September 30, 2024 and 2023

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

	For the Three Months Ended September 30,		
	2024	2023	Change
License and collaborations revenue	$ 3,867	$ 11,935	$ (8,068)
Operating expenses:			
General and administrative	2,894	2,055	839
Research and development	8,982	3,494	5,488
Total operating expenses	11,876	5,549	6,327
Loss from operations	(8,009)	6,386	(14,395)
Financing costs	—	(1,328)	1,328
Fair value change in derivative liability	—	61	(61)
Other income, net	483	456	27
(Loss) income before income taxes	(7,526)	5,575	(13,101)
Provision for income taxes	—	(14)	14
Net (loss) income	$ (7,526)	$ 5,561	$ (13,087)

License and Collaborations Revenue

License and collaborations revenue was $3.9 million and $11.9 million for the three months ended September 30, 2024 and 2023, respectively. Revenue during both quarterly periods was derived from the Viatris License Agreement. Revenue for the three months ended September 30, 2024 was comprised largely of the reimbursement of research and development services. In addition, revenue during the current period quarter included an earned royalty payment in the amount of $14,000 from the sales of RYZUMVI, indicated for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents by our commercial partner. The decrease in license and collaborations revenue during the current three month period ended September 30, 2024 compared to the corresponding prior year period was largely due to the one-time achievement of a $10.0 million milestone attributed to the FDA's approval of PS, for reversal of mydriasis in the prior year period.

General and Administrative

General and administrative expenses for the three months ended September 30, 2024 were $2.9 million compared to $2.1 million for the three months ended September 30, 2023. The increase period over period of $0.8 million was primarily attributable to personnel related costs of $0.2 million, stock-based compensation of $0.2 million, legal support costs of $0.1 million and business development costs of $0.4 million, offset in part by a reduction in non-legal professional service costs of $0.1 million. General and administrative expenses included $0.5 million and $0.3 million in stock-based compensation expense, a non-cash expense, during both three months ended September 30, 2024 and 2023, respectively.

Research and Development

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

	For the Three Months Ended September 30,		
	2024	2023	Change
External costs:			
Phentolamine Ophthalmic Solution 0.75% ("PS")	$ 3,561	$ 1,561	$ 2,000
APX3330	4,272	1,294	2,978
Unallocated	90	158	(68)
Total external cost	7,923	3,013	4,910
Internal costs:			
Employee related expenses	993	469	524
Facilities, supplies and other	66	12	54
Total internal costs	1,059	481	578
Total research and development expenses	$ 8,982	$ 3,494	$ 5,488

Research and development expenses for the three months ended September 30, 2024 were $9.0 million compared to $3.5 million for the three months ended September 30, 2023. The $5.5 million increase in the current period was primarily attributable to increased clinical costs of $2.7 million for the Lynx-2 and Vega-3 trials and other research and development activities period over period, drug manufacturing costs of $0.8 million and toxicology service costs of $1.2 million, related to APX3330, and increased payroll related costs of $0.5 million and regulatory and operating related expenses of $0.3 million on a net basis. Pursuant to the Nyxol License Agreement, our budgeted research and development expenses related to the development of PS are fully reimbursed by Viatris. Research and development expenses also included $0.2 million in stock-based compensation expense, a non-cash expense, during each of the three month periods ended September 30, 2024 and 2023.

Financing costs

Financing costs for the three months ended September 30, 2023 of $1.3 million was comprised of issuance costs attributed to the equity line financing with Lincoln Park described further below. There were no financing costs during the three month period ended September 30. 2024.

Fair value change in derivative liability

The fair value change in derivative liability attributed to the equity line financing with Lincoln Park, described further below, was a gain of $0.1 million for the three months ended September 30, 2023 attributed to the fluctuations in our common stock fair value and the number of potential shares of common stock issuable at the various discount tiers under the equity line financing. The fair value change in derivative liability attributed to the equity line financing with Lincoln Park was de minimis during the three months ended September 30, 2024.

Other Income, net

During the three months ended September 30, 2024, the Company had other income, net of $0.5 million related primarily to interest income of $0.5 million in connection with our cash and cash equivalents on-hand.

Comparison of Nine Months Ended September 30, 2024 and 2023

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

	For the Nine Months Ended September 30,		
	2024	**2023**	**Change**
License and collaborations revenue	$ 6,690	$ 17,358	$ (10,668)
Operating expenses:			
General and administrative	10,918	8,680	2,238
Research and development	19,817	13,812	6,005
Total operating expenses	30,735	22,492	8,243
Loss from operations	(24,045)	(5,134)	(18,911)
Financing costs	—	(1,328)	1,328
Fair value change in derivative liability	—	61	(61)
Other income, net	1,648	1,224	424
Loss before income taxes	(22,397)	(5,177)	(17,220)
Provision for income taxes	—	(14)	14
Net loss	$ (22,397)	$ (5,191)	$ 17,206)

License and Collaborations Revenue

License and collaborations revenue was $6.7 and $17.4 million for the nine months ended September 30, 2024 and 2023, respectively. Revenue during the nine month period ended September 30, 2024 was derived primarily from the reimbursement of research and development services under the Viatris License Agreement, and to much less extent, an earned royalty payment of $36,000 from the sales of RYZUMVI indicated for the treatment of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents by our commercial partner. Revenue during the nine month period ended September 30, 2023 was derived from both the reimbursement of research and development services under the Viatris License Agreement and a one-time achievement of a $10.0 million milestone attributed to the FDA's approval of PS, for reversal of mydriasis which resulted in the decrease in revenue period over period.

General and Administrative

General and administrative expenses for the nine months ended September 30, 2024 were $10.9 million compared to $8.7 million for the nine months ended September 30, 2023. The increase period over period of $2.2 million was primarily attributable to legal support of $1.4 million, business development activities of $0.7 million, non-legal profession service support costs of $0.1 million and other costs of $0.2 million on a net basis, offset in part by stock-based compensation of $0.1 million and payroll related costs of $0.1 million. General and administrative expenses totaled $1.9 million and $2.0 million in stock-based compensation expense, a non-cash expense, during the nine months ended September 30, 2024 and 2023, respectively.

Research and Development

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

	For the Nine Months Ended September 30,		
	2024	**2023**	**Change**
External costs:			
Phentolamine Ophthalmic Solution 0.75% ("PS")	$ 5,678	8,732	(3,054)
APX 3330	10,959	2,947	8,012
Unallocated	238	536	(298)
Total external cost	16,875	12,215	4,600
Internal costs:			
Employee related expenses	2,776	1,578	1,198
Facilities, supplies and other	166	19	147
Total internal costs	2,942	1,597	1,345
Total research and development expenses	$ 19,817	13,812	6,005

Research and development expenses for the nine months ended September 30, 2024 were $19.8 million compared to $13.8 million for the nine months ended September 30, 2023. The $6.0 million increase was primarily attributable to increased manufacturing costs of $2.5 million and toxicology activity costs of approximately $2.5 million for APX3330, offset by decreased clinical costs of $0.4 million for the APX3330 ZETA-1 trial and other research and development activities period over period. Additionally, higher payroll costs, including stock-based compensation, and consulting costs of $1.1 million in the aggregate, and regulatory and other operating expenses of $0.3 million, on net basis, contributed to the expense increase during the current nine-month period. Pursuant to the Nyxol License Agreement, our budgeted research and development expenses related to the development of PS are fully reimbursed by Viatris. Research and development expenses also included $0.7 million and $0.8 million in stock-based compensation expense, a non-cash expense, during the nine months ended September 30, 2024 and 2023, respectively.

Financing costs

Financing costs for the nine months ended September 30, 2023 of $1.3 million was comprised of issuance costs attributed to the equity line financing with Lincoln Park described further below. There were no financing costs for the nine months ended September 30, 2024.

Fair value change in derivative liability

The fair value change in derivative liability attributed to the equity line financing, described further below, was a gain of $0.1 million for the nine months ended September 30, 2023 attributed to the fluctuations in our common stock fair value and the number of potential shares of common stock issuable at the various discount tiers under the equity line financing. The fair value change in derivative liability attributed to the equity line financing with Lincoln Park was de minimis during the nine months ended September 30, 2024.

Other Income, net

During the nine months ended September 30, 2024, the Company had other income, net of $1.6 million related primarily to interest income in connection with our cash and cash equivalents on-hand.

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

Liquidity and Capital Resources

Capital Resources

As of September 30, 2024, our principal sources of liquidity consisted of cash and cash equivalents of $36.6 million. We believe that our cash on hand as of September 30, 2024 will be sufficient to fund our operations for at least twelve months beyond the date of this filing. As of September 30, 2024, our cash and cash equivalents were invested primarily in cash deposits and cash equivalent investments at two large financial institutions.

Historical Capital Resources

Our primary source of cash to fund our operations has been various equity offerings in the amount of approximately $67.8 million and the issuance of convertible notes in the amount of $8.5 million, inclusive of the promissory notes exchanged for the Company's convertible notes (the "Company Convertible Notes"). In addition, we received a one-time non-refundable cash payment of $35.0 million during the fourth quarter of 2022, a $10.0 million milestone payment during the fourth quarter of 2023, and have received reimbursement for costs related to development since the fourth quarter of 2022, all in connection with the Viatris License Agreement.

Lincoln Park Purchase Agreement

On August 10, 2023, we entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") for an equity line financing (the "Purchase Agreement"). The Purchase Agreement provides that, subject to the terms and conditions set forth therein, we have the sole right, but not the obligation, to direct Lincoln Park to purchase up to $50 million of shares of the Company's common stock from time to time over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a Registration Rights Agreement, pursuant to which we agreed to register the resale of the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement pursuant to a registration statement. Upon the execution of the Purchase Agreement, we issued 246,792 shares of the Company's common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement. Lincoln Park has agreed not to cause or engage in any manner whatsoever in any direct or indirect short selling or hedging of our common stock. In addition to the commitment shares referenced above, a total of 1,700,000 shares of common stock were sold under the Purchase Agreement for gross proceeds through September 30, 2024 in the amount of $5.2 million.

At-The-Market Program

On January 10, 2024, we filed a Form S-3 shelf registration under the Securities Act which was declared effective by the SEC on January 23, 2024 under which the Company may offer and sell, from time to time in our sole discretion, securities having an aggregate offering price up to $175 million. On March 11, 2021, we entered into a sales agreement with JonesTrading Institutional Services LLC ("JonesTrading") under which we may offer and sell, from time to time at our sole discretion, to or through JonesTrading, acting as agent and/or principal, shares of our common stock having an aggregate offering price of up to $40 million (the "ATM"). A total of 7,653,838 shares of common stock were sold under the ATM since its inception for gross proceeds through September 30, 2024 in the amount of $26.4 million.

Registered Direct Offering

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

The RDO Warrants have an exercise price of $6.09 per share, are exercisable upon the initial issuance date of June 8, 2021, and will expire five years following the initial exercise date. Subject to limited exceptions, a holder of a RDO Warrant will not have the right to exercise any portion of its RDO Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of a holder prior to the date of issuance, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise; provided, however, that upon prior notice to us, the holder may increase or decrease the beneficial ownership limitation, provided further that in no event shall the beneficial ownership limitation exceed 9.99%. As of September 30, 2024, 1,538,461 RDO Warrants were still outstanding. The offering of the securities was made pursuant to our effective shelf registration statement on Form S-3.

Pre-Rexahn Merger Financing

Securities Purchase Agreement

On June 17, 2020, the Company, Rexahn and certain investors entered into a Securities Purchase Agreement, which was amended and restated in its entirety on June 29, 2020 (as amended and restated, the "Securities Purchase Agreement"). Pursuant to the Securities Purchase Agreement, the investors invested a total of $21.15 million in cash, including $300,000 invested by directors of the Company, and one director of Rexahn, upon closing of the Rexahn Merger. For more information, please refer to Note 6 - Stockholders' Equity - Pre-Merger Financing included in "Part I, Item 1– Financial Statements and Supplementary Data" of this Report.

Waiver Agreements

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

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

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

Series A Warrants

The Series A Warrants were issued on November 19, 2020 at an initial exercise price of $4.4795 per share, were immediately exercisable upon issuance and have a term of five years from the date of issuance. The Series A Warrants are exercisable for 5,665,838 shares of common stock in the aggregate (without giving effect to any limitation on exercise contained therein). As of September 30, 2024, 5,665,838 Series A Warrants were still outstanding.

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

Series B Warrants

The Series B Warrants had an exercise price of $0.0001 and ultimately became exercisable for 1,708,335 shares of common stock upon execution of the Waiver Agreements. As of September 30, 2024, none of the Series B Warrants remained outstanding.

Company Convertible Notes

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

Cash Flows

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

	For the Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (18,138)	$ (5,660)
Net cash provided by (used in) investing activities	—	—
Net cash provided by financing activities	4,269	5,376
Net decrease in cash and cash equivalents	$ (13,869)	$ (284)

Cash Flow from Operating Activities

For the nine months ended September 30, 2024, cash used in operating activities of $18.1 million was attributable to a net loss of $22.4 million, partially offset by $2.6 million in non-cash operating expenses and a net change cash source of $1.7 million in the Company's net operating assets and liabilities. The non-cash expenses consisted principally of stock-based compensation of $2.6 million. The change in operating assets and liabilities was primarily attributable to increases in our accrued expenses and to decreases in our prepaid expenses, all associated with the Company's operating expenses under the normal course of business. Our net sources of cash during the period were partially offset by a net increase in the Company's accounts receivable attributed to the timing of payments from Viatris and to a net decrease in our accounts payable due to the timing of payments under the normal course of business.

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

Cash Flow from Investing Activities

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

Cash Flow from Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2024 was $4.3 million, consisting of net proceeds received from both the 2021 ATM and the equity line financing in the aggregate of $4.3 million.

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

Liquidity and Capital Resource Requirements

As of September 30, 2024, we had cash and cash equivalents of $36.6 million. License and collaborations revenue inception to date was derived from a one-time non-refundable payment of $35 million, a milestone payment of $10 million, reimbursement and expected reimbursement of expenses and royalties earned under the Viatris License Agreement and, to a much lesser degree, from license agreements with BioSense Global LLC ("BioSense") and Processa Pharmaceuticals, Inc. ("Processa") in connection with the Rexahn RX-3117 drug compound. We anticipate that we will recognize revenue as we earn reimbursement for research and development services in connection with the Viatris License Agreement and we may earn additional revenues from future potential milestone and royalty payments from the agreements with Viatris, BioSense or Processa, or from other license agreements entered into in the future; however, the attainment of milestones or level of sales required to earn royalty payments is highly uncertain for the reasons explained below.

To date, outside of the license and collaborations revenue referenced above, we do not expect to generate significant revenue unless or until RYZUMVI sales become material, or regulatory approval is obtained and commercialization begins for LCA5, BEST1, other internally-developed assets or PS for indications other than RM. If we fail to complete the development of LCA5, BEST1, other internally-developed assets, PS or any other product candidate we may pursue in the future in a timely manner or fail to obtain regulatory approval for any of such product candidates, our ability to generate significant revenue would be compromised.

Through the ATM, we may offer and sell, from time to time at our sole discretion, to or through JonesTrading, acting as agent and/or principal, shares of our common stock having an aggregate offering price of up to $40 million. A total of 7,653,838 shares of common stock were sold under the ATM since its inception for gross proceeds through September 30, 2024 in the amount of $26.4 million.

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

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

Future Capital Requirements

Pursuant to the Viatris License Agreement, our budgeted research and development expenses related to the development of PS are fully reimbursed by Viatris. The development of LCA5, BEST1 and other internally-developed assets is subject to numerous uncertainties, and we have based these estimates on assumptions that may prove to be substantially different than what we currently anticipate and could result in cash resources being used sooner than what we currently expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical trials is costly, and the timing of progress in these clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support our cost structure. We cannot give any assurance that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Commitments

Facility Lease

We lease a facility under a non-cancellable operating lease that expires on December 31, 2024, as amended, for a base rent in the amount of $3,000 per month.

Apexian Sublicense Agreement

On January 21, 2020, we entered into the Apexian Sublicense Agreement, pursuant to which we obtained exclusive worldwide patent and other intellectual property rights that constitute a Ref-1 Inhibitor program relating to therapeutic applications to treat disorders related to ophthalmic and diabetes mellitus conditions. The mechanism of action of Ref-1 inhibitors (e.g., APX3330, APX2009 and APX2014) of reducing angiogenesis and inflammation could potentially be beneficial in treating other retinal diseases such as diabetic macular edema, wet age-related macular degeneration and geographic atrophy as well as non-ophthalmic indications.

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

We agreed to make one-time milestone payments under the Apexian Sublicense Agreement for each of the first ophthalmic indication and the first diabetes mellitus indication. These milestone payments include (i) payments for specified developmental and regulatory milestones totaling up to $11 million in the aggregate and (ii) payments for specified sales milestones of up to $20 million in the aggregate, each of which net sales milestone payments is payable once, upon the first achievement of such milestone.

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

Other Commitments

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

Other Funding Requirements

As noted above, certain of our cash requirements relate to the funding of our ongoing research and development of APX3330, inclusive of any potential milestone and royalty obligations under our intellectual property licenses. See "Part I, Item 1— Business— Potential Clinical Plans for APX3330—PS Potential Clinical Plans—Future In-Licensing and Acquisition Opportunities—Manufacturing—Apexian Sublicense Agreement— Review and Approval of Drugs in the United States" in our Annual Report on Form 10-K for the year ended December 31, 2023 for a discussion of design, development, pre-clinical and clinical activities that we may conduct in the future, including expected cash expenditures required for some of those activities, to the extent we are able to estimate such costs.

Our other cash requirements within the next twelve months include accounts payable, accrued expenses, purchase commitments and other current liabilities. Our other cash requirements greater than twelve months from various contractual obligations and commitments may include operating leases and contractual agreements with third-party service providers for clinical research, product development, manufacturing, commercialization, supplies, payroll, equipment maintenance, and audits for periods into calendar year 2025. Refer to Note 3 – Commitments and Contingencies included in Part 1, Item 1 – "Financial Statements" of this Report for further detail of our lease obligation and license agreements with regard to the timing of expected future payments.

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

Critical Accounting Policies and Estimates

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

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

License and Collaborations Revenue

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

Stock-based Compensation

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

Income Tax Assets and Liabilities

A full valuation allowance has been provided on our net deferred tax assets given the uncertainty of future taxable income and other related factors impacting the realizability of our remaining net deferred tax assets. For additional information, see Note 11 — Income Taxes included in "Part II, Item 8 – Financial Statements and Supplementary Data" in our Annual Report filed on Form 10-K for the year ended December 31, 2023, and see Note 11 — Income Taxes included in "Part 1, Item 1 – Financial Statements" of this Report.

Contingencies

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

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15(d)- 15(e) promulgated under the Exchange Act as of September 30, 2024. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2024.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in our most recent Annual Report on Form 10-K for the year ended December 31, 2023, this Quarterly Report and our other filings with the Securities and Exchange Commission. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.

Opus Genetics, Inc.
Form 10-Q

Due to the recent expansion of our business following the Merger, we are restating our risk factors in their entirety in this Quarterly Report on Form 10-Q.

Risks Related to the Opus Acquisition

The integration with Former Opus presents challenges, and the failure to successfully integrate the businesses could have a material adverse effect on our business, financial condition and results of operations.

The Opus Acquisition combined two independent companies with different operations and focuses on drug development. We are devoting significant management attention and resources to integrating our business practices and portfolio of assets and reorienting our operations so that we may focus on developing gene therapy treatments. We may fail to realize some or all of the anticipated benefits of the Opus Acquisition if the integration process takes longer than expected or is more costly than expected. Potential difficulties we may encounter in the integration process include the following:

- the inability to successfully combine our assets in a manner that permits us to expand our product pipeline or achieve the anticipated benefits from the Opus Acquisition, which would result in the anticipated benefits of the Opus Acquisition not being realized partly or wholly in the time frame currently anticipated or at all;
- the creation of uniform standards, controls, procedures, policies and information systems;
- the addition of new personnel, including new management, which may be difficult to smoothly integrate; and
- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the Opus Acquisition.

It is likely that the integration process could result in the diversion of our management's attention, the disruption or interruption of, or the loss of momentum in our ongoing businesses or potential partnerships which could adversely affect our ability to maintain our current business relationships or the ability to achieve the anticipated benefits of the Opus Acquisition, or could otherwise adversely affect our business and financial results.

After the Opus Acquisition, we significantly expanded our product pipeline and the business operations and strategies of the Company fundamentally changed, and these changes may not result in an improvement in the value of our common stock.

Following the Opus Acquisition, we are now a biotech company focused on developing gene therapies to treat inherited retinal diseases ("IRDs"). We expanded our product pipeline by including gene therapy programs. We cannot guarantee that implementing the Opus Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Opus Acquisition poses significant integration challenges between our businesses and management teams which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Opus Acquisition to our stockholders.

Our stockholders may not realize a benefit from the Opus Acquisition commensurate with the ownership dilution they experienced in connection with the Opus Acquisition.

In the event we are unable to realize the strategic benefits currently anticipated from the Opus Acquisition, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. We have devoted and will continue to devote significant management attention and resources to integrate the two companies and we may not manage these processes successfully. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price. Even if we are able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits anticipated. It is also possible that undisclosed, contingent or other liabilities or problems in connection with the acquired company may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and prospects.

If our stockholders do not approve the conversion of our Series A Preferred Stock at the 2025 Annual Meeting of Stockholders, we may be required to divert funds from our business to pay dividends on outstanding shares of Series A Preferred Stock.

In connection with the Opus acquisition, we issued 14.1 thousand shares of convertible Series A Preferred Stock to existing stockholders of Former Opus. The shares of Series A Preferred Stock will be convertible into shares of common stock, subject to stockholder approval at the 2025 Annual Meeting of Stockholders, to be held in April 2025. If the conversion is not approved by stockholders, the holders of Series A Preferred Stock will be entitled to quarterly cash dividends commencing on October 15, 2025. The payment of such dividends could divert capital away from the development of our business to the detriment of our stockholders.

Risks Related to the Development of Our Gene Therapy Products and other Product Candidates

Our gene therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

We have focused our business on the development of gene therapy programs for the treatment of IRDs and plan to continue to expand our gene therapy portfolio. Our future success depends on our successful development of viable gene therapy products. There can be no assurance that we will not experience problems or delays in developing new products and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. We may be unable to reduce development timelines and costs for our other gene therapy development programs. We also may experience unanticipated problems or delays in expanding our manufacturing capacity, which may prevent us from completing our clinical trials, meeting the obligations of our collaborations or successfully.

In addition, the clinical trial requirements of FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as our products, including OPGx-BEST, can be more expensive and take longer than for other, better known or more extensively studied product candidates. Even if we are successful in developing additional product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for these product candidates, or how long it will take to commercialize any other products for which we receive marketing approval.

Regulatory bodies and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be materially and adversely affected.

Our gene therapy approach utilizes vectors derived from viruses, which may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our product and product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Gene therapy remains a novel technology with few approved to date in the United States and EU. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product and product candidates, if approved, prescribing treatments that involve the use of our product and product candidates, if approved, in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia and death seen in other trials using other vectors. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any products for which we obtain marketing approval.

Gene therapies are novel, complex and difficult to manufacture. We could experience production problems in our network of external facilities that result in delays in our development or commercialization programs or otherwise adversely affect our business.

Our gene therapy product and product candidates require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the product or product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EU or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, FDA, EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, FDA, EMA or other foreign regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. We have experienced lot failures in the past and there is no assurance we will not experience such failures in the future. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. We also may encounter problems hiring and retaining the experienced specialist scientific, quality control and manufacturing personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Because we are developing product candidates for the treatment of IRD in which there is less clinical experience for gene therapy products as compared to other diseases and, in some programs, using new endpoints or techniques, there is increased risk that certain regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There are no pharmacologic therapies approved to treat IRDs caused by LCA5 gene mutations in the United States or EU. In addition, there has been limited clinical trial experience for the development of pharmaceuticals to treat IRDs. Certain aspects of IRDs render efficacy endpoints historically used for vision clinical trials less applicable as clinical endpoints. As a result, the design and conduct of clinical trials for these disorders is subject to increased risk. In addition, the treatment of certain IRDs, such as BEST1 mutations, may require assessment of clinical endpoints that reflect a stabilization, as opposed to an improvement, of functional vision. Assessing these endpoints may require longer periods of observation and may delay the completion of any trials we may undertake.

Our gene therapy product candidates and the process for administering our gene therapy product candidates may cause undesirable and unforeseen side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia and death seen in other trials using other vectors. While new recombinant vectors have been developed to reduce these side effects, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

Possible adverse side effects that could occur with treatment with gene therapy products include an immunologic reaction early after administration which, while not necessarily adverse to the patient’s health, could substantially limit the effectiveness of the treatment. In previous clinical trials involving AAV vectors for gene therapy, some subjects experienced the development of a T-cell response, whereby after the vector is within the target cell, the cellular immune response system triggers the removal of transduced cells by activated T-cells. If our vectors demonstrate a similar effect, which we are unable to mitigate with immuno-suppressive regimens, we may decide or be required to halt or delay further clinical development of our product candidates and our commercial efforts could be materially and adversely affected.

In addition to any potential side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our marketing authorization or clinical trials could be suspended or terminated.

In addition, FDA could impose a Risk Evaluation and Mitigation Strategy ("REMS"), and other non-US regulatory authorities could impose other specific obligations as a condition of approval to ensure that the benefits of our product candidates outweigh their risks, which could delay approval or commercial acceptance of our product candidates. A REMS may include, among other things, a communication plan to health care practitioners or patients, and elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Similar risk management programs could be imposed by equivalent authorities in foreign jurisdictions, including by the European Commission. Furthermore, if we or others later identify undesirable side effects caused by our product candidate, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings or limitations of use in product labeling;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused by our products to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any products for which we receive marketing approval and could significantly harm our business, financial condition, results of operations and prospects.

Orphan Drug Designation and Rare Pediatric Disease Designation, among other designations by the FDA, may not lead to a faster development, regulatory review or approval process and it does not increase the likelihood that any of our gene therapy product candidates will receive marketing approval in the United States. The potential award of a Priority Review Voucher may not result in a financial benefit to us.

We received Orphan Drug Designation in September 2024 and Rare Pediatric Disease Designation in August 2024 for OPGx-LCA5 to treat LCA5, an early-onset retinal degeneration that causes vision loss. We may, in the future, apply for such designations for our other gene therapy product candidates in the United States.

Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug status provides incentives that include specialized guidance to help expedite development, exemption from user fees and potential for seven years of market exclusivity following approval. Qualification to maintain orphan drug status is generally monitored by the regulatory authorities during the orphan drug exclusivity period, currently seven years from the date of approval in the United States. It is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to the orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan products.

Under the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 the FDA is authorized to award a priority review voucher ("PRV") to a drug sponsor upon approval of that sponsor's drug to treat a rare pediatric disease. A drug sponsor can later redeem the voucher when submitting another new drug application to treat any disease or condition in adults or children, or it may sell or transfer the voucher to another sponsor. A voucher entitles a sponsor to a 6-month priority review by FDA rather than the 10-month standard review. In some instances, recipients of PRVs have transferred them to other drug developers in exchange for substantial financial consideration. Even if OPGx-LCA5 is approved, it is not certain that we will be awarded a PRV as it may no longer meet the conditions for such an award at that time. In addition, even if we receive a PRV, there can be no assurance that we will be able to apply it to review of one of our other drug candidates or to transfer it for significant consideration, if at all. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. The FDA may determine that an NDA or BLA for one or more of our product candidates does not meet the eligibility criteria for a priority review voucher upon approval. Moreover, due to the current statutory authority for the RPD and voucher program, the FDA may not award the voucher to sponsors of marketing applications unless either (i) the drug has received rare pediatric disease designation as of December 20, 2024, and is then approved by the FDA no later than September 30, 2026; or (ii) Congress reauthorizes the program. If Congress does not enact legislation reauthorizing the program, additional indications will not be eligible for an RPD designation or priority review voucher. Even if legislation is enacted that extends the date by which approval of the rare pediatric disease-designated drug must obtain approval to receive a priority review voucher, we may not obtain approval by that date, and even if we do, we may not obtain a priority review voucher.

If we request orphan drug designation or rare pediatric disease designation for our other current or future product candidates, there can be no assurances that the FDA will grant any of our product candidates such designation. Accordingly, even if we believe one of our product candidates meets the criteria for designations, the FDA may disagree. In any event, the receipt of a designation, or the redemption of a PRV for a product candidate, may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA, nor does it limit the ability of the FDA to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving exclusive marketing approval. Further, there may be changes to the regulatory scheme surrounding these designations, which render them obsolete.

We may encounter substantial delays in our planned clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive, time-consuming and uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely commencement and completion of preclinical and clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board or independent Ethics Committee approval at each clinical trial site;
- delays in recruiting and enrolling suitable subjects to participate in our clinical trials, due to factors such as the size of the trial or subject population, process for identifying subjects, design or expansion of protocols, eligibility and exclusive criteria, perceived risks and benefits of the relevant product candidate or gene therapy generally, availability of competing therapies and trials, severity of the disease under investigation, need and length of time required to discontinue other potential therapies, availability of genetic testing, availability and proximity of trial sites for prospective subjects, ability to obtain subject consent and referral practices of physicians;
- imposition of a clinical hold by regulatory authorities, including as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites;
- failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with GCP, or applicable regulatory guidelines in the European Union and other countries;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or subjects dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete research studies and preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates, if approved, and may harm our business, financial condition, results of operations and prospects.

We may be negatively impacted if the results of our planned clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates.

If the results of our planned clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;

- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing or other requirements;
- have regulatory authorities withdraw, vary or suspend their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA.

The results from the prior nonclinical studies and clinical trials for our product candidates may not necessarily be predictive of the results of future nonclinical studies or clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, the results from our prior clinical trials of our product candidates may not be replicated in these future trials. Many companies in the pharmaceutical and biotechnology industries (including those with greater resources and experience than us) have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless have failed to obtain FDA approval. If we fail to produce adequate results reflecting adequate efficacy and safety in our clinical trials of any of our product candidates, the development timelines, regulatory approvals, and commercialization prospects for our product candidates, as well as the Company's business and financial prospects, would be adversely affected. Further, our product candidates may not be approved even if they achieve their respective primary endpoints in additional Phase 3 registration trials. The FDA may disagree with our trial designs or our interpretation of data from nonclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical registration trial that has the potential to result in approval by the FDA or another regulatory authority. For instance, although we have reached an SPA agreement with FDA for a Phase 3 study for PS for decreased vision under dim (mesopic or low) light conditions after keratorefractive surgery, the FDA may ultimately require additional studies for approval.

The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances like if public health concerns emerge that were unrecognized at the time of the SPA agreement.

In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. However, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval.

Furthermore, regulatory authorities may also approve our product candidates for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. Before obtaining regulatory approvals for the commercial sale of any product candidate for any target indication, we must demonstrate with substantial evidence gathered in nonclinical studies and adequate and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication. We cannot assure you that the FDA or non-U.S. regulatory authorities would consider our planned clinical trials to be sufficient to serve as the basis for approval of our product candidates for any indication. The FDA and non-U.S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that our product candidates are safe and effective. If we are required to conduct clinical trials of our product candidates in addition to those we have planned prior to approval, we may need substantial additional funds, and cannot assure you that the results of any such outcomes trial or other clinical trials will be sufficient for approval. Furthermore, if our current and planned nonclinical and clinical trials do not satisfy the requirements of the FDA or non-U.S. regulatory authorities, our business may be materially harmed.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our ability to conduct and complete those clinical trials, and our ability to seek and receive necessary regulatory approvals, could be delayed or prevented.

We or our future collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States. Patient enrollment can be affected by many factors, including:

- perceived risks and benefits of gene therapy-based approaches or our product candidate under study;
- availability of genetic testing for potential subjects;
- availability and efficacy of medications already approved for the disease under investigation;
- eligibility criteria and visit schedule for the trial in question;
- competition for eligible patients with other companies conducting clinical trials for product candidates seeking to treat the same indication or patient population;
- our payments for conducting clinical trials;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials or retain sufficient enrollment through the completion of our trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and cause our stock price to decline.

Changes in regulatory requirements or FDA guidance, or unanticipated events during our clinical trials, may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us or delays in development timelines.

Changes in regulatory requirements or FDA guidance, or unanticipated events during our clinical trials, may require us to amend clinical trial protocols or the FDA may impose additional clinical trial requirements. Amendments to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, and may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any trials, or if we are required to conduct additional clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues may be delayed.

We may expend a substantial amount of our resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are currently focusing on gene therapy development programs. As a result, we may forego or delay pursuit of opportunities for other indications from our non-gene therapy portfolio or with other potential product candidates that later prove to have greater commercial potential. Due to changes or failure to accurately predict the size of the addressable market, among other reasons, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications or future product candidates may not yield any commercially viable product. If we do not accurately evaluate the commercial potential or target market for our product candidates, we may not gain approval or achieve market acceptance of that candidate, and our business and financial results will be harmed.

Risks related to the commercialization of RYZUMVI and product candidates which obtain marketing approval

We depend heavily on the success of our product pipeline. If we fail to find strategic partners or we (including our strategic partner) fail to adequately commercialize our pipeline products, our business will be materially harmed.

Our business depends largely on the successful clinical development, regulatory approval and commercialization of gene therapies and Phentolamine Ophthalmic Solution 0.75% Eye Drops "PS". Viatris is our strategic partner for the commercialization of FDA-approved RYZUMVI and for the further development and commercialization, if FDA-approved, of PS. APX300 is still in clinical development and we are seeking strategic partners to continue its development. We (or any future our strategic partners) plan to invest a significant portion of our efforts and financial resources in the development of our products. Further, we have already spent significant efforts in developing our pipeline of products. Our ability to generate product revenues depends heavily on obtaining marketing approval for and commercializing our gene therapy products and PS for additional indications.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of a drug product are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, where regulations may differ. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA or in any foreign countries until we receive the requisite approval from such countries. Before obtaining regulatory approval for the commercial sale of our product candidates for a particular indication, we must demonstrate through nonclinical testing and clinical trials that the applicable product candidate is safe and effective for use in that target indication. This process can take many years and may be followed by post-marketing studies and surveillance together which will require the expenditure of substantial resources beyond the proceeds raised in our equity and debt financings to date. Of the large number of drugs in development in the United States, only a small percentage of drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to complete development and FDA approval of our product candidates, we cannot assure you that our product candidates will be approved or commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. The success of our product candidates could be impacted by several factors, including the following:

- delays in, termination, or numerous unforeseen events during, or as a result of, manufacturing or clinical trials;
- obtaining unfavorable results from nonclinical and clinical studies for our product candidates;
- the cost of clinical trials being greater than anticipated;
- the willingness of patients or medical investigators to follow our clinical trial protocols and the number of patients willing to participate;
- delays in applying for and receiving marketing and NDA approvals from applicable regulatory authorities for our product candidates;
- other government or regulatory delays and changes in regulatory requirements, policy and guidelines may require us to perform additional clinical trials or use substantial additional resources to obtain regulatory approval;
- issues with making arrangements with third-party manufacturers for commercial quantities of RYZUMVI and our product candidates and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of RYZUMVI and our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of RYZUMVI and our product candidates by patients, the medical community, and third-party payors;
- effectively competing with other therapies, including the existing standard-of-care;
- maintaining a continued acceptable safety profile of RYZUMVI and our product candidates following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio related to RYZUMVI and our product candidates; and
- our ability to fulfill requests for additional data regarding our product candidates.

In addition, under the Apexian License Agreement, the Company has rights to certain compounds for use in ophthalmic and diabetic diseases. The Company does not control the development of these compounds in other non-ophthalmic indications.

Viatris has exclusive global rights to commercialize RYZUMVI and PS in key global markets. Viatris' failure to timely develop or commercialize these products would have a material adverse effect on our business and operating results.

We granted Viatris an exclusive right to commercialize RYZUMVI and PS in key global markets. Additionally, we granted Viatris the exclusive right and license to develop RYZUMVI and PS outside of the United States. The collaboration with Viatris may not be successful due to several factors, including the following:

- Viatris may not be able to manufacture our products in a timely or cost-effective manner;
- Viatris may not timely perform its obligations under the Viatris License Agreement;
- Viatris may fail to effectively commercialize our products;
- Viatris may not be able to sublicense RYZUMVI or PS to one or more suitable parties outside the United States; or
- contractual disputes or other disagreements between us and Viatris, including those regarding the development, manufacture, sub licensure and commercialization of our products, interpretation of the License Agreement, and ownership of proprietary rights. Viatris may select a new development partner for RYZUMVI and PS in the U.S. upon 90 days' notice to the Company.

Any of the foregoing could adversely impact the likelihood and timing of any payments we are eligible to receive under the Viatris License Agreement. The Company will be reliant on Viatris to drive the commercialization and sales of our products. If Viatris does not perform its obligations under the Viatris License Agreement, this could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline

If we fail to receive regulatory approval for gene therapy treatment of IRDs or any of our planned indications for our non-gene therapy product candidates or fail to develop additional product candidates, our commercial opportunity will be limited.

We are focused on the development of our gene therapy candidates for IRDs and our other product candidates for our target indications, DR, the reversal of pharmacologically-induced mydriasis, treatment of presbyopia, and decreased vision under dim (mesopic or low) lighting conditions after keratorefractive surgery. RYZUMVI has been approved for the treatment of pharmacologically-induced mydriasis. However, we cannot assure you that we will be able to obtain regulatory approval of our product candidates for any other indication, or successfully commercialize our product candidates, following approval. If we do not receive regulatory approval for, or successfully commercialize, our product candidates for one or more of our targeted or other indications, our commercial opportunity will be limited.

Even if we do receive regulatory approval for, or successfully commercialize, our product candidates, they will be subject to ongoing regulatory review and critique. This ongoing review and critique may cause the loss of regulatory approval.

We may pursue clinical development of additional acquired or in-licensing product candidates. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of our completed equity and debt financings, and are prone to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any additional product candidates through the development process.

We or others could discover that our product candidates lack sufficient efficacy, or sufficient efficacy compared to competitor products or that they cause undesirable side effects that were not previously identified, which could delay or prevent regulatory approval or commercialization.

Because our products have been tested in relatively small patient populations, at a limited range of daily doses, and for limited durations to date, it is possible that our clinical trials have or will indicate an apparent positive effect that is greater than the actual positive effect, if any, or that additional and unforeseen side effects may be observed as its development progresses. The discovery that product candidates lack sufficient efficacy, or that they cause undesirable side effects (including side effects not previously identified in our completed clinical trials), could cause us or regulatory authorities to interrupt, delay, or discontinue clinical trials, and could result in the denial of regulatory approval by the FDA or other non-U.S. regulatory authorities for any or all targeted indications.

The discovery that our product candidates lack sufficient efficacy or that they cause undesirable side effects that were not previously identified could prevent us from commercializing such product candidates and generating revenues from sales. In addition, if we receive marketing approval for our product candidates:

- we may discover that they are less effective, or identify undesirable side effects caused by our product candidates:
- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way this product is administered, conduct additional clinical trials, or change the labeling or distribution of the product (including REMS);
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product;
- we may be subject to fines, injunctions, or the imposition of civil or criminal penalties;
- we could be sued and held liable for harm caused to patients;
- the product may be rendered less competitive and sales may decrease; or
- our reputation may suffer generally among both clinicians and patients.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant, or any, revenues from the sale of the product candidate.

We face substantial competition and rapid technological change, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

The development and commercialization of new drug products, including in the gene therapy field, is highly competitive. We expect to face competition with respect to our product candidates, if approved, and will face competition with respect to any future product candidates that we may seek to develop or commercialize from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions, and government agencies worldwide. The ophthalmic therapies market is highly competitive and dynamic. Our success will depend, in part, on our ability to obtain a share of the market for our planned indications. [While there are currently no direct competitors for our OPGx-LCA5 gene therapy program, there are various companies developing gene therapies for the treatment of IRDs, which may ultimately directly compete with us in the future.] Further, other pharmaceutical companies may develop therapies for the same indications that would compete with or our product candidates, if approved, and that would not infringe the claims of our in-licensed patents, pending patent applications, or other proprietary rights, which could adversely affect our business and results of operations.

Our competitors may develop products that are more effective, safer, more convenient, or less costly than any that we are developing, or that would render our product candidates obsolete or non-competitive. Our competitors may also render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products more rapidly than we obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater name recognition, financial resources, and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting, hiring, and retaining qualified scientific and management personnel, engaging contract service providers, manufacturers and consultants, establishing clinical trial sites, recruiting patients for clinical trials, and entering into strategic transactions, as well as in acquiring technologies complementary to, or necessary for, our programs.

We do not currently have any sales or marketing infrastructure in place and may face difficulties in establishing sales and marketing capabilities or engaging third parties to sell, market and distribute our products.

We do not have any sales or marketing infrastructure and have no capabilities in place at the present time for the sale, marketing, or distribution of our products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource part or all of these functions to other third parties.

There are risks involved with us both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming, which could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred the costs of the commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- the inability to recruit and retain adequate numbers of effective sales and marketing personnel or enter into distribution agreements with third parties;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- the inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

If we enter into arrangements with third parties to perform sales, marketing, and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell a product that we developed ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market any product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market a drug effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors, and others in the medical community.

Our product candidates, even if they do receive marketing approval, may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, or others in the medical community, particularly in the gene therapy space, which is a growing industry. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and may not become profitable. The degree of market acceptance for RYZUMVI and our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- any restrictions on the use of our product together with other medications;
- interactions of our product with other medicines patients are taking;
- inability of certain types of patients to take our product;
- demonstrated ability to treat patients and, if required by any applicable regulatory authority in connection with the approval for target indications as compared with other available therapies;
- the relative convenience and ease of administration as compared with other treatments available for approved indications;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the labeling approved by the FDA;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness through marketing efforts;
- guidelines and recommendations of organizations involved in research, treatment and prevention of various diseases that may advocate for alternative therapies;
- our ability to obtain sufficient third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- physicians or patients may be reluctant to switch from existing therapies even if potentially more effective, safe or convenient.

Aside from RYZUMVI, which we launched through the Viatris partnership, we have not yet sold any of our products. Further, our gene therapy products, if approved, may have limited commercial opportunity due to the relatively uncommon genetic conditions targeted by such products. We cannot assure investors that there is a sufficient market demand for our products. Achieving market acceptance for our products will require substantial marketing efforts and expenditure of funds to create awareness and demand by participants in the industry. We have not conducted any independent market research to determine the extent of any demand that exists for the products to be provided by us and there is no guarantee that a sufficient interest in the market will exist for the products and services being produced by, or for, us. Any lack of sufficient demand for the products contemplated to be provided by us will have a material adverse effect on us.

If the FDA or a comparable foreign regulatory authority approves generic versions of our product candidates that receive marketing approval, or if such authorities do not grant our product candidates appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications ("ANDAs") in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use or labeling as the reference listed drug ("RLD") and that the generic version is bioequivalent to the RLD, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the RLD, and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or RLD may be lost to the generic product.

The FDC Act provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years after approval of the RLD. It is unclear whether the FDA will treat the active ingredients in its product candidates as NCEs and, therefore, afford them five years of NCE exclusivity if they are approved. If any product we develop does not receive five years of NCE exclusivity, we may nonetheless be eligible for three years of exclusivity. Competition that our product candidates would face from generic versions could materially and adversely impact our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in any such product candidate.

Our profitability will likely depend in significant part on third-party reimbursement practices, which, if unfavorable, would harm our business.

Our (or our partners') ability to commercialize our product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, whether the level of reimbursement will be adequate. Assuming we obtain coverage for our product candidates, if approved, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or some of the costs associated with their prescription drugs. Patients are unlikely to use a product candidate, if approved, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of its products. Therefore, coverage and adequate reimbursement are critical to new product acceptance. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Furthermore, drug pricing and access policies in the United States and internationally may change and negatively impact our product candidates' commercial viability. Proposed policy changes, including the potential for Medicare to negotiate with drug manufacturers, may limit our ability to competitively price our product candidates, if approved. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which a product candidate is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for a new product, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, there is no uniform policy requirement for coverage and reimbursement for drug products among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly, and it will require us to provide scientific and clinical support for the use of our products to each payor separately. There is no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Any inability to promptly obtain coverage and profitable payment rates from government-funded or private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Product liability lawsuits against us, or our suppliers and manufacturers, could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims might be brought against us by patients, healthcare providers, or others selling or otherwise coming into contact with our product candidates during product testing, manufacturing, marketing, or sale. For example, we may be sued under allegations that a product candidate caused injury or that the product was otherwise unsuitable. Any such product liability claims may include allegations of manufacturing or design defects, failure to warn of dangers inherent in the product, such as interactions with alcohol or other drugs, negligence, or breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidate caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we are developing;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- increased FDA warnings on product labels;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- distraction of management's attention from our primary business;
- loss of revenue;
- the inability to commercialize any product candidate that we may develop;
- the initiation of investigations by regulators; and
- the inability to take advantage of limitations on product liability lawsuits that apply to generic drug products, which could increase our exposure to liability for products deemed to be dangerous or defective.

Our product liability and/or clinical trial insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand clinical trials and if we successfully commercialize our product candidates. Insurance coverage is increasingly expensive, and we may not be able to obtain product liability insurance on commercially reasonable terms or for a sufficient amount to satisfy liabilities that may arise.

Similarly, we may be a party to, or may be otherwise responsible for, pending or threatened lawsuits or other claims related to products purchased from our manufacturers and suppliers. Although we intend to require our providers to have product liability insurance, the ability to obtain such coverage and the sufficiency thereof is uncertain. Such litigation could result in additional expense and exposure in excess of our anticipated reserves, especially if such matters are not covered by insurance. Upon resolution of any pending legal matters or other claims, we may incur charges in excess of established reserves. Product liability lawsuits and claims, safety alerts or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on the business and reputation and on our ability to attract and retain customers and strategic partners. The business, profitability and growth prospects could suffer if we face such negative publicity.

If we or our third-party manufacturers fail to comply with environmental or health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by ourselves and our third-party manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, or federal, state, city, or local authorities may curtail our use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or fined, and such liability or fines could exceed our resources. We do not have insurance for liabilities arising from medical or hazardous materials. Although we maintain workers' compensation insurance for costs and expenses that we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Compliance with applicable environmental and health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, or results of operations.

We have limited drug research and discovery capabilities and may need to acquire or license product candidates from third parties, raise additional capital, or shift capital resources to expand our product candidate pipeline.

We currently have limited drug research and discovery capabilities. Accordingly, if we are to expand our pipeline beyond our product pipeline candidates, we may need to acquire or license product candidates from third parties, or either raise additional capital or shift capital resources to fund such expansion. We would face significant competition in seeking to acquire or license promising product candidates, may not be able to raise additional capital, or may divert capital resources from other areas of the Company that may then face material consequences from less funding. Many of our competitors for such promising product candidates may have significantly greater financial resources and more extensive experience in nonclinical testing and clinical trials, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products, and thus, may be a more attractive option to a potential licensor than us. If we are unable to acquire or license additional promising product candidates, raise additional capital, or shift capital resources, we may not be able to expand our product candidate pipeline.

If we are able to acquire or license other product candidates, such license agreements will likely impose various obligations upon us, and our licensors may have the right to terminate the license thereunder in the event of a material breach or, in some cases, at will. A termination of a future license could result in our loss of the right to use the licensed intellectual property, which could adversely affect our ability to develop and commercialize a future product candidate, if approved, as well as harm our competitive business position and our business prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We have not generated significant revenue from sales of any products, expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Our only product approved for commercial sale is RYZUMVI, which launched in the first half of 2024 by Viatris, our commercialization partner. We do not anticipate generating any additional product revenue, unless and until our product candidates receive the regulatory approvals necessary for commercialization in one or more jurisdictions. Our ability to generate revenue depends on a number of factors, including our ability to:

- the successful launch and widespread commercialization of our gene therapy candidates and other product candidates;
- obtain favorable results from and complete the nonclinical and clinical development of our product candidates for their planned indications, including successful completion of additional clinical trials for these indications;
- submit applications to regulatory authorities for both product candidates and receive timely marketing approvals in the United States and foreign countries;
- establish and maintain commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates that we develop, if approved;
- establish sales and marketing capabilities to effectively market and sell our product candidates in the United States or other markets, either alone or with a pharmaceutical partner;
- address any competing products and technological and market developments;
- obtain coverage and adequate reimbursement for customers and patients from government and third-party payors for our product candidates that we develop; and
- achieve market acceptance of our product candidates.

Furthermore, as of September 30, 2024, we had an accumulated deficit of $104 million. We have funded our operations primarily through issuance of promissory notes and convertible notes in private placements, and then common stock and warrants after becoming a publicly-traded company, and more recently, through fees and a milestone payment received under the Viatris License Agreement. We have devoted substantially all of our financial resources and efforts to the clinical development of our product candidates. Even assuming we obtain additional regulatory approval for one or more of our product candidates, we expect it to be several years before products currently in our pipeline are potentially ready for commercialization, and our product candidates may not gain market acceptance or achieve commercial success. We may not achieve profitability soon after generating product revenue, if ever, and may be unable to continue operations without continued funding.

To become and remain profitable from our product candidates, we must develop and eventually commercialize a product with market potential. This will require us to be successful in a range of challenging activities, including completing nonclinical testing and clinical trials, obtaining regulatory approval for a product candidate, manufacturing, marketing, and selling any drug for which it may obtain regulatory approval and satisfying any post-marketing requirements. We anticipate incurring significant costs associated with these activities. We are in the early stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability.

If we do achieve profitability from our product candidates, we may not be able to sustain or increase profitability on an annual basis. Our failure to become or remain profitable from our product candidates may decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

Our relatively short operating history as a combined company may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company, and our operations to date have been limited. We have not yet demonstrated our ability to manufacture a product at commercial scale or conduct sales and marketing activities necessary for successful product commercialization.

Additionally, there is no operating history on which investors may evaluate our business and our prospects. Investment in a clinical stage company such as ours is inherently subject to many risks. These risks and difficulties include challenges in accurate financial planning as a result of: (a) accumulated losses; (b) uncertainties resulting from a relatively limited time period in which to develop and evaluate business strategies as compared to companies with longer operating histories; (c) compliance with regulations required to commence sales on future products; (d) reliance on third parties for clinical, manufacturing, analytical laboratory work, nonclinical, regulatory, commercialization or other activities; (e) financing the business; and (f) meeting the challenges of the other risk factors described herein. We have no operating history upon which investors may base an evaluation of our performance; therefore, we are subject to all risks incident to the creation and development of a new business. There can be no assurance that we can realize our plans on our projected timetable in order to reach sustainable or profitable operations.

Adverse developments affecting the financial services industry could negatively affect our current and projected business operations and our financial condition and results of operations.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may material adverse impacts on our business.

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We will need to raise additional capital to continue to fund the further development of our product candidates and operations. Our future capital requirements may be substantial and will depend on many factors including:

- the scope, size, rate of progress, results, and costs of researching and developing our product candidates, and initiating and completing our nonclinical studies and clinical trials;
- the cost, timing and outcome of our efforts to obtain further marketing approval for our product candidates in the United States and other countries, including to fund the preparation and filing of NDAs with the FDA for our product candidates and to satisfy related FDA requirements and regulatory requirements in other countries;
- the number and characteristics of any additional product candidates we develop or acquire, if any;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the amount of revenue, if any, from commercial sales, should our product candidates receive marketing approval;
- the costs associated with commercializing our product candidates, if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell our product candidates;
- the ability to secure grant funding from government and nongovernment foundations;
- the cost of manufacturing our product candidates or products we successfully commercialize; and
- the costs associated with general corporate activities, such as the cost of filing, prosecuting and enforcing patent claims and making regulatory filings.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval and commercialization of our product candidates. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are unavailable to us on a timely basis, or at all, we may not be able to continue the development of our product candidates, or commercialize our product candidates, if approved, unless we find a strategic partner.

Worldwide economic and social instability or adverse global economic conditions could adversely affect our revenue, financial condition, or results of operations.

The health of the global economy, and the equity and credit markets in particular, as well as the stability of the social fabric of our society, affects our business and operating results. For example, the equity and credit markets may be adversely affected by current conflicts in Europe and the Middle East, negative trends in the real estate and other sectors in China, and measures taken in response thereto. If the equity and credit markets are not favorable, we may be unable to raise additional financing when needed or on favorable terms. Our vendors and development partners may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. Any weak or declining economy or political disruption, including international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have affected, and may continue to adversely affect our suppliers' ability to provide our manufacturers with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

Furthermore, a general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U.S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross margin and expenses, and may make it more difficult to raise or refinance debt.

Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and debt financings as well as potential strategic collaborations and licensing arrangements. We do not have any committed external source of funds. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Thus, raising additional capital may not be able to be achieved, even if desired, and if possible to raise additional capital, it may not be done so on terms that are desirable. If we raise funds through strategic collaborations or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. This may reduce the value of our common stock.

Risks Related to Government Regulation

Even if we receive marketing approval for our product candidates in the United States, we may never receive regulatory approval to market such product candidates outside of the United States.

In addition to the United States, we intend to seek regulatory approval to market our product candidates in Europe, Japan, Canada, and Australia, and potentially other markets. If we pursue additional product candidates in the future, we may seek regulatory approval of such product candidates outside the United States. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of these other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have an adverse impact on our business, results of operations and prospects.

Even if we obtain further marketing approval for our product candidates, such product candidates could be subject to post-marketing, obligations, restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or experience unanticipated problems with a product following approval.

Any product candidate for which we, or our future collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising, and promotional activities for such drug, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could include requirements for a restricted distribution system.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product candidate. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborator, does not market a product candidate for which it receives marketing approval for only its approved indications, we, or the collaborator, may be subject to warnings or enforcement action for off-label promotion. Violation of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs, may lead to investigations or allegations of violations of federal or state healthcare fraud and abuse laws and state consumer protection laws

In addition, later discovery of previously unknown AEs or other problems with our product candidates or our manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- litigation involving patients taking our drugs;
- restrictions on such drugs, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product recall or public notification or medical product safety alerts to healthcare professionals;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of drugs;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Legislative reform or changes in the regulatory environment affecting our business may increase the difficulty and cost for obtaining marketing approval of our product candidates, or otherwise affect the pricing and commercial viability of or product candidates.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of a product candidate, restrict or regulate post-approval activities and affect our ability, or the ability of our future collaborators, to profitably sell any drug for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and cause downward pressure on the price that we, or our future collaborators, may charge for any approved drug.

For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act ("ACA"), and the Health Care and Education Reconciliation Act, or the Healthcare Reform Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices. General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on results of operations. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

There have been judicial and congressional challenges and amendments to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, as well as efforts to repeal and replace it. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws have resulted in additional reductions in Medicare and other healthcare funding and otherwise may affect the prices we may obtain for any product candidate for which marketing approval is obtained. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures, such as capping the costs for prescription drugs covered by Medicare Part D and by setting the annual out-of-pocket limit at $2,000 beginning in 2024, as part of other health reform initiatives. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of a product candidate, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval or subject us or our future collaborators to more stringent drug labeling and post-marketing testing and other requirements. More recently, President Biden signed the Inflation Reduction Act of 2022 into law in August of 2022, which, among other things, requires manufacturers to pay rebates to Medicare if prices increase faster than inflation for products used by Medicare beneficiaries.

Our relationships with healthcare providers and third-party payors will be subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings, among other penalties and consequences.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain marketing approval. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute product candidates for which we obtain marketing approval. Restrictions and obligations under applicable federal and state healthcare laws and regulations include the following. For additional detail on potentially applicable laws, see the section titled "Part I, Item 1 - Business - Healthcare Fraud and Abuse and Compliance Laws and Regulations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023. Certain state and foreign laws also govern the privacy and security of health information in ways that differ from each other and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, and administrative sanctions, including exclusions from government funded healthcare programs. Defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our employees or representatives may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to:

- comply with the regulations of the FDA and applicable non-U.S. regulators;
- provide accurate information to the FDA and applicable non-U.S. regulators;
- comply with healthcare fraud and abuse laws and regulations in the United States and abroad;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity, including employee compliance training, may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for a certain indication, physicians may nevertheless prescribe such products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would adversely affect our business and financial condition.

Changes to U.S. tax laws and state tax laws, such as those impacting our ability to use our net operating loss carryforwards and certain other tax attributes, may adversely affect our financial condition or results of operations and create the risk that we may need to adjust our accounting for these changes.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the federal tax laws.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.

The accounting treatment of additional changes in U.S. or state tax law changes is complex, and changes may affect both current and future periods. Consistent with guidance from the SEC, our consolidated financial statements reflect our estimates of the tax effects of the current tax laws and regulation.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our nonclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be harmed.

We rely on third-party CROs and other third parties to assist in managing, monitoring, and otherwise carrying out our nonclinical studies and clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our nonclinical studies and clinical trials in the future. We compete with many other companies for the resources of these third parties.

As a result, we will have limited control over the conduct, timing, and completion of these nonclinical studies and clinical trials and the management of data developed through the nonclinical studies and clinical trials. We have experienced in the past, and may experience in the future, schedule disruptions due to events affecting the performance of third parties on which we rely. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Additionally, other unexpected natural events and disruptions in the supply chain and operations may affect the ability of third parties to fulfill their obligations to us. Outside parties may have staffing difficulties;

- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in ownership or management;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control.

While our reliance on these third parties for research and development activities will reduce our control over these activities, it will not relieve us of our responsibilities and requirements. For example, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCP"), for conducting recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected.

Problems with the timeliness or quality of the work of any CRO may lead us to seek to terminate our relationship with any such CRO and use an alternative service provider. Making this change may be costly or delay our clinical trials, and contractual restrictions may make such a change difficult or impossible. If we must replace any CRO that is conducting our clinical trials, our clinical trials may have to be suspended until we find another CRO that offers comparable services. The time that it would take us to find alternative organizations may cause a delay in the commercialization of our product candidates, or it may cause us to incur significant expenses to replicate any lost data. Although we do not believe that any CRO on which we would rely would offer services that are not available elsewhere, we may be difficult to find a replacement organization that can conduct our clinical trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval for our product candidates and preclude our ability to commercialize our product candidates, thereby limiting or preventing our ability to generate sales revenue.

Further, requirements related to clinical trials continue to evolve, which may require additional oversight, greater costs, and/or delay. In 2023, FDA published guidance documents related to informed consent and GCPs that may present additional requirements to CROs.

In August 2023, FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. Further, in December 2023, FDA published a final rule, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. These guidance documents present evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial, which may increase costs and delay clinical programs.

Additionally, in June 2023, FDA published a draft guidance, E6(R3) Good Clinical Practice (GCP), which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.

We rely completely on third parties to supply and manufacture bulk drug substances and to formulate and package nonclinical and clinical drug supplies of our product candidates as well as to conduct analytical testing of drug substances and products in the manufacturing processes and we intend to rely on third parties to produce and test commercial supplies of our current and any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our clinical drug supply of product candidates for use in the conduct of our nonclinical studies and clinical trials. We lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The process of manufacturing drug products is complex, highly regulated, and subject to several risks. For example, the facilities used by our contract manufacturers to manufacture and conduct analytical testing of the active pharmaceutical ingredient (or drug substance) and final drug product for product candidates must be inspected by the FDA and other comparable foreign regulatory agencies in connection with our submission of an NDA or relevant foreign regulatory submission to the applicable regulatory agency. In addition, the manufacturing of drug substance or product is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error. Moreover, the manufacturing facilities in which product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures, or other factors. Manufacturing timelines may be negatively affected by material shortages, construction delays and supply chain challenges due to, among other factors, global supply chain shortages.

Further, requirements related to the manufacturing of ophthalmic products may evolve, which may require modifications to our current manufacturing processes. In December 2023, FDA published a revised draft guidance, Quality Considerations for Topical Ophthalmic Drug Products, which focuses on quality considerations for ophthalmic drug products intended for topical delivery in and around the eye. Updated quality considerations may cause delay to adapt to new requirements and may also increase costs associated with manufacturing.

We do not control the manufacturing and testing processes of our contract manufacturers and analytical labs, and are completely dependent on them to comply with current good manufacturing practices (“cGMP”) for manufacture and good lab practices (“GLP”) of both active drug substances and finished drug products. If our contract manufacturers and analytical labs cannot successfully manufacture and test materials that conform to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, we will not be able to secure and/or maintain regulatory approval for our products. In addition, we have no control over our contract manufacturers’ and analytical labs’ ability to maintain adequate quality control, quality assurance, and qualified personnel. Failure to satisfy the regulatory requirements for the production and testing of those materials and products may affect the regulatory clearance of our contract manufacturers’ and analytical labs’ facilities generally. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture and testing of product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing and testing facilities, which would adversely impact our ability to develop, obtain regulatory approval for, or market product candidates. Furthermore, all of our contract manufacturers and analytical labs are engaged with other companies to supply and/or manufacture and/or test materials or products for such companies, which exposes our manufacturers to regulatory and sourcing risks for the production of such materials and products. To the extent practicable, we have attempted to identify more than one supplier. However, some raw materials are available only from a single source or only one supplier has been identified, even in instances where multiple sources exist.

We have relied and will rely upon third-party manufacturers and testing labs in the United States and overseas for the manufacture and testing of our product candidates for nonclinical and clinical testing purposes and intend to continue to do so in the future, including for commercial purposes. If our third-party manufacturers and analytical labs are unable to supply or test drug substance and/or drug product on a commercial basis, we may not be able to successfully produce and market product candidates, if approved, or we could be delayed in doing so. For instance, we presently rely on one supplier in Italy for the drug substance for PS, one supplier in India for raw materials for the drug substance for APPX330, and one manufacturer in the United States for APX3330 drug substance. If there is any delay or problem with the manufacture of these drug substances or if there is a delay in producing finished drug product from these drug substances, the development and PS, the possible approval of our product candidates and potential commercial launch may be delayed or otherwise adversely affected. We will rely on comparison of product specifications (identity, strength, quality, and purity) to demonstrate equivalence of the current drug substance and/or drug product to the drug substance and/or drug product used in previously completed nonclinical and clinical testing. If we are unable to demonstrate such equivalence, we may be required to conduct additional nonclinical and/or clinical testing of our product candidates. Due to other potential problems related to transfers, we have established additional sources of supply, with U.S. manufacturers, for the active pharmaceutical ingredients of APX3330 and are working towards the same for PS. Establishing these additional sources, including qualifying their manufacturing processes and demonstrating the equivalence of their products, may be costly, time-consuming, and difficult to effectuate, and may delay our research and development activities. Any future transfers of manufacturing to a different third party will likely be expensive and time consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before using or selling any products manufactured at that facility. If we must replace any manufacturer, our research and development activities may have to be suspended until we find another manufacturer that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the development and commercialization of product candidates.

We have entered and may enter into licensing arrangements for the development or sale of product candidates (such as the Viatris License Agreement) and may form or seek additional strategic alliances or enter into licensing arrangements in the future. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed.

We have entered into and may form or seek additional strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates (such as the Viatris License Agreement). Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, or issue securities that dilute our existing stockholders, which may disrupt our management and business. Our likely collaborators include large, mid-size, regional, or national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Collaborations involving product candidates pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more attractive than ours;
- a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing or distribution of any such product candidate;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between us and collaborators that result in the delay or termination of research, development, or commercialization of our product candidates, or in litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborations may be terminated and such terminations may create a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- the results of collaborators' nonclinical or clinical studies could harm or impair other development programs;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- the number and nature of our collaborations could adversely affect our attractiveness to potential future collaborators or acquirers;
- collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If a present or future collaborator of us were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated; and
- collaborators may be unable to obtain the necessary marketing approvals.

If future collaboration partners fail to develop or effectively commercialize product candidates for any of these reasons, such product candidates may not be approved for sale and our sales of such product candidates, if approved, may be limited, which would have an adverse effect on our operating results and financial condition.

If we are not able to establish new collaborations for APX3330 on commercially reasonable terms, we may have to alter our development, manufacturing, and commercialization plans.

We face significant competition in attracting collaborators for development, manufacturing or commercialization plans. We already have a collaboration with Viatris for the development and commercialization of RYZUMVI and PS. Following the Opus Acquisition, we have discontinued our internal development of APX3330 and are now going to pursue a potential partnership to further advance this exciting program to allow us to focus on our gene therapy programs while extending our cash runway. Whether we reach a definitive agreement for collaboration for APX3330 will depend, among other things, upon our assessment of the proposed collaborator's resources, expertise, and evaluation of a number of factors related to the associated product candidate, as well as the terms and conditions of the proposed collaboration. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which may exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaborations and whether such a collaboration could be more attractive than one with us. We may not be able to enter into these agreements on commercially reasonable terms, or at all.

If we engage in additional acquisitions, in-licensing or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may continue to engage in various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our strategy of focusing on the cash-pay utilization for future sales of RYZUMVI may limit our ability to increase sales or achieve profitability with this product.

With regard to the commercialization of RYZUMVI, our strategy is to focus on cash-pay utilization. This focus may limit the potential profitability of this product. We believe pursuing a non-insurance reimbursed product strategy in connection with RYZUMVI allows for meaningful strategic advantages in the United States, including pricing and marketing flexibility. However, companies offering products competitive to RYZUMVI may nonetheless try to compete on price, both directly through rebates, promotional programs, and coupons, as well as indirectly through product bundling and customer loyalty programs. In addition, we cannot predict how the market, including customers, doctors, patients, and governmental agencies, will react to this strategy. If RYZUMVI does not achieve sufficient success and market acceptance, if we face retaliation from third parties as a result of this arrangement and program (for example, in the form of non-coverage determinations, limitations on coverage, or unfavorable reimbursement with respect to our other products) or if any part of this arrangement is found to be non-compliant with applicable law or regulations, this could have a material adverse effect on our business, financial condition, cash flows, and results of operations and could cause the market value of our common shares to decline. Our business, financial results, and future prospects will be materially harmed if we cannot generate sufficient consumer demand for RYZUMVI with this strategy.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our product candidates, our competitors could develop and commercialize products or technology similar or identical to those of us, which would adversely affect our ability to successfully commercialize any product candidates we may develop, our business, results of operations, financial condition and prospects.

We and our licensors have sought to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and product candidates.

Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional pre-clinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all.

The patent prosecution process is expensive and time-consuming, and we and our future licensors, licensees, or collaboration partners may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or any future licensors, licensees, or collaboration partners may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. We and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications, and then only to the extent the issued claims cover the technology.

We cannot assure you that any of our patents have matured, or that any of our pending patent applications will mature, into issued patents that will include, claims with a scope sufficient to protect our product candidates. Others have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, for example by claiming the same compounds, methods or formulations or by claiming subject matter that could dominate the patents that we owns or in-licenses. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity, and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, *ex parte* reexamination, or *inter partes* review proceedings, supplemental examination and challenges in district court. Patents may be subjected to opposition, post-grant review, or comparable proceedings in various national and regional patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, opposition, post-grant review, *inter partes* review, supplemental examination, or revocation proceedings may be costly or time-consuming. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates.

Furthermore, the issuance of a patent, while presumed valid, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs, or methods. We may not be able to prevent the unauthorized disclosure or use of any technical knowledge or trade secrets by consultants, vendors, former employees, or current employees. The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If, in any proceeding, a court invalidated or found unenforceable our patents covering our product candidates, our financial position and results of operations would be adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered our product candidates, our financial position and results of operations would also be adversely impacted.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates;
- any of our pending patent applications will result in issued patents;
- we will be able to successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

Patents have a limited lifespan. The natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the extensive period of time between patent filing and regulatory approval for a product candidate, the time during which we can market a product candidate under patent protection is listed, and our patent may expire before we obtain such approval. Without patent protection for our product candidates, we may be vulnerable to competition from generic versions of our product candidates, which may affect the profitability of our product candidates.

Furthermore, obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment or other provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Maintaining patents in the U.S. is an expensive process and it is even more expensive to maintain patents and patent applications in foreign countries. As a result, it is possible that we and our licensors will fail to maintain such patents thereby reducing the rights of our portfolio. The patent position of pharmaceutical, biotechnology, and medical device companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, or which effectively prevent others from commercializing competitive technologies and products.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidate, our business may be materially harmed.

Depending upon the timing, duration of regulatory review, and date of FDA marketing approval of our or other product candidates, if any, one of such U.S. patents may be eligible for patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act provides for a patent restoration term, or patent term extension, of up to five years as compensation for the time the product is under FDA regulatory review. The duration of patent term extension is calculated based on the time spent in the regulatory review process. In the future, we may plan to seek patent term extension for one or more of our patents related to our RYZUMVI or other product candidates. However, we may not be granted an extension because of, for example, failing to apply within the applicable deadline, expiration of relevant patents prior to obtaining approval, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be shorter or less than what we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our revenue could be reduced, possibly materially.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

In 2011, the United States enacted wide-ranging patent reform legislation with the America Invents Act ("AIA"). An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before we could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Additionally, the U.S. Supreme Court's holdings in several patent cases in recent years, such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I), Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank International, have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty about our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect or practice our intellectual property rights throughout the world.

In jurisdictions where we have not obtained patent protection, competitors may use our intellectual property to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our product candidates in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to pharmaceuticals. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we, or any future licensor, encounters difficulties in protecting, or is otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, or any licensor, is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe on our patents, the patents of our licensing partners, or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded.

Litigation proceedings may fail and, even if successful, may be costly and a distraction to our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, we could have a substantial adverse effect on the price of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our medicines and technology, including interference or derivation proceedings, post-grant reviews, *inter partes* reviews, or other procedures before the USPTO or other similar procedures in foreign jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our medicines and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, we could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. We could be forced, including by court order, to cease developing and commercializing the infringing technology or medicine. In addition, we could be held liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if found to have willfully infringed. A finding of infringement could prevent us from commercializing a product candidate or force us to cease some of our business operations, which could harm our business. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. The cost to us of any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial and may result in substantial costs and distraction to our management and other employees. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may be subject to damages resulting from claims that our employees or we have wrongfully misappropriated their intellectual property of their former employers.

Our employees and consultants have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information or intellectual property of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could detract from our ability to develop or commercialize our product candidates.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of any product we may pursue could be significantly diminished.

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own.

Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. We may rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or has had access to trade secrets. If a party breaches an agreement and discloses our proprietary information, including our trade secrets, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third party, our competitive position would be harmed.

Obtaining and maintaining our trademark protection depends on approval from the USPTO and other foreign government agencies, and third parties may challenge, infringe, or otherwise weaken our trademark rights.

We have obtained registration of the "RYZUMVI" trademark in the United States. We have not yet registered trademarks for any other product candidates in any jurisdiction (other than "Nyxol", which we are no longer using). If we do not secure and maintain registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could affect our business. When we file trademark applications for a product candidate, those applications may not be allowed for registration, and registered trademarks may not be obtained, maintained, or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but may not be able to overcome such rejections. In addition, the SPTO and comparable agencies in many foreign jurisdictions allow third parties opportunities to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings. In addition, any proprietary name we propose to use with a future product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed drug names, including an evaluation of potential for confusion with other drug names. If the FDA objects to any proposed proprietary drug name for any product candidate, we may be required to expend significant additional resources in an effort to identify a suitable substitute proprietary drug name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. If we register any of our trademarks, our trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to infringe on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

We may enter into certain license or other collaboration agreements in the future. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with such obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property; and
- the priority of invention of patented technology.

In addition, the agreements under which intellectual property or technology is licensed from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, we cannot be certain that the preparation, filing, prosecution and maintenance activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

We depend on intellectual property sublicensed from third parties (such as Apexian Pharmaceuticals, Inc. for product candidates ("Apexian") for our APX3330 product candidate under development) and our additional pipeline candidates, and the termination of, or reduction or loss of rights under, this sublicense would harm our business.

We entered into a sublicense agreement with Apexian (as amended, the "Apexian Sublicense Agreement") to in-license patents and other intellectual property relating to the APX3330 product candidate and second-generation product candidates owned by Apexian, and intellectual property that Apexian in-licensed from Eisai Co., Ltd. ("Eisai") including certain study reports, manufacturing and analytical records, data, know-how, technical and other proprietary information relating to APX3330. We may, in the future, enter into additional sublicense agreements of the same or a similar nature for APX3330 or other product candidates. The rights granted under sublicense agreements, such as the Apexian Sublicense Agreement, are and may be subject to various milestone payment, royalty, insurance or other obligations on us, and may be revocable under certain circumstances including if we cease to do business, fail to make the payments due thereunder, commit a material breach of the agreement that is not cured within a certain time period after receiving written notice or fail to meet certain specified development and commercial timelines. Termination of sublicense agreements, such as the Apexian Sublicense Agreement, may result in us having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop or commercialize APX3330 and second-generation assets. We do not have total control over the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license under sublicense agreements, including the Apexian Sublicense Agreement.

Under the Sublicense Agreement, Indiana University Research and Technology Corp. ("IURTC"), the owner of the patents licensed to Apexian and sublicensed to us, maintains the right to control all prosecution and maintenance of such patents. Therefore, we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business. Although we have a right to have our comments considered in connection with, and have agreed to bear the costs of, the prosecution and maintenance of the licensed patents, if IURTC fails to prosecute and maintain such patents, or loses rights to those patents or patent applications as a result of its control of the prosecution activities, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. Similar reductions of rights or terminations may occur with regards to future sublicense agreements. Further, if Apexian breaches its license agreement with IURTC and fails to cure such breach within a 60-day cure period, IURTC may terminate such license agreement with Apexian, in which case, our license shall also terminate and we will lose all rights under the license agreement with Apexian.

While the Apexian Sublicense Agreement provides that Apexian must cooperate with us to remedy and cure Apexian's breach of the license agreement with IURTC in order to prevent the termination of such license agreement, we cannot guarantee that such efforts will be successful in preventing the termination of the license agreement between Apexian and IURTC. Similarly, if Apexian breaches its license agreement with Eisai and fails to cure such breach within a 60-day cure period, Eisai may terminate such license agreement with Apexian, in which case, our sublicense rights under such license shall also terminate. While we do not have any material obligations under the license agreement between Eisai and Apexian, Apexian has certain confidentiality and payment obligations that, if not met, could result in breach of the Eisai license agreements.

Under Apexian's license agreement with IURTC, any act or omission by us that would be a breach of the license agreement with IURTC if imputed to Apexian is deemed to be a breach by Apexian of such license agreement and cause for termination, including, in particular, any breach by us of our payment, reporting, audit, and indemnification obligations.

Expansion through obtaining rights to product candidates and approved products through acquisitions may not be successful.

We may acquire the rights to other products, product candidates, or technologies in the future. The future growth of our business may depend in part on our ability to acquire the rights to approved products, additional product candidates, or technologies. However, we may be unable to acquire the rights to any such products, product candidates, or technologies from third parties. The acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates, or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire the rights to the relevant product, product candidate, or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates, or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired.

Risks Related to Our Employee Matters and Managing Growth

We are dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on our management, scientific, and medical personnel, including George Magrath, MD, MBA, MS, Chief Executive Officer and Board Director. We have entered into employment agreements with our executive officers, but any employee may terminate his or her employment with us. The loss of the services of any of our executive officers, other key employees or consultants, or other scientific and medical advisors in the foreseeable future might impede the achievement of our research, development, and commercialization objectives. If we fail to retain key personnel and are unable to hire highly qualified replacements, we may not be able to meet key objectives, such as meeting financial goals, and maintaining or expanding our business. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and business and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical trials may also make it more challenging to recruit and retain qualified scientific personnel.

We expect that we will need to develop and expand a number of corporate functions in our company (including sales, marketing, and distribution teams), and, as a result, we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We expect to increase our number of employees and the scope of our operations as we further the clinical development of our product candidates. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees, or reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage our future development and expansion.

A variety of risks associated with operating internationally for us and our collaborators could adversely affect our business.

In addition to our U.S. operations, we may pursue international operations in the future and would face risks associated with such global operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax, and labor conditions, which could harm our business. We plan to conduct clinical trials outside of the United States. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for our product candidates;
- different medical practices and customs affecting acceptance of our product candidates, if approved, or any other approved product in the marketplace;
- language barriers;
- the interpretation of contractual provisions governed by foreign law in the event of a contract dispute;
- difficulties in staffing and managing foreign operations, and an inability to control commercial or other activities where it is relying on third parties;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practice Act of 1977 or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capability abroad;
- foreign government taxes, regulations, and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, natural disasters, war, events of terrorism, or political instability in particular foreign countries;

- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues;
- compliance with tax, employment, immigration, and labor laws, regulations, and restrictions for employees living or traveling abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

If we experience any of these risks, our sales in non-U.S. jurisdictions may be harmed, our results of operations would suffer, and our reputation and business prospects would be negatively impacted.

Our business and operations would suffer in the event of system failures or unplanned events, including cyber incidents, network security breaches, service interruptions, or data corruption.

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunications and electrical failures. In March 2021, we were the victim of a business email compromise. This fraud did not cause any losses to us. If another such event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual or potential vulnerabilities. Furthermore, failure to protect our information technology infrastructure against cyber incidents, network security breaches, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business, operating results, or the effectiveness of our internal controls over financial reporting. Furthermore, any unplanned event, such as flood, fire, explosion, tornadoes, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunications failure, cybersecurity incidents, network security breaches, service interruptions, or data corruption other natural or manmade accidents or incidents, or pandemics, that result in us being unable to fully utilize the facilities, may have an adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on its financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates, or interruption of our business operations.

Risks Related to Ownership of Our Common Stock

The market price of our common stock is expected to be volatile.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the announcement of new products or product enhancements by us or our competitors;
- changes in our relationships with our licensors or other strategic partners;
- developments concerning intellectual property rights and regulatory approvals;
- variations in ours and our competitors' results of operations;
- substantial sales of shares of our common stock due to the release of lock-up agreements;
- the announcement of clinical trial results;
- the announcement of potentially dilutive financings;
- changes in earnings estimates or recommendations by securities analysts;
- changes in the structure of healthcare payment systems;
- developments and market conditions in the pharmaceutical and biotechnology industries; and
- the results of clinical trials of our gene therapy products, PS, or any other product candidate that we may develop.

Further, the stock market, in general, and the market for biotechnology companies, in particular, have experienced extreme price and volume fluctuations. As a result of this volatility, investors may not be able to sell their securities at a profit. Continued market fluctuations could result in extreme volatility in the price of our common stock, which may be unrelated or disproportionate to our operating performance and which could cause a decline in the value of our common stock and result in substantial losses for purchasers of our common stock.

We currently have a substantial number of shares of common stock subject to potential issuance associated with our Equity Line of Credit arrangement. The issuance or sale of shares under our ELOC arrangement would substantially increase the number of shares outstanding and result in dilution to our security holders. This might substantially decrease the market price of our common stock.

We have a substantial number of shares of our common stock that may be issued in the future. In connection with our equity line of credit, or ELOC, arrangement, we issued Lincoln Park Capital Fund, LLC 246,792 shares of our common stock. Under our ELOC arrangement, we can sell up to $50,000,000 worth of our common stock over the thirty-six month term of the ELOC arrangement, to Lincoln Park Capital, LLC, beginning only after certain conditions set forth in the Purchase Agreement have been satisfied. To the extent that shares of common stock are issued or sold under our ELOC arrangement, dilution to our security holders may occur. The issuance of these additional securities may have an adverse effect on the market price of our securities.

We do not anticipate paying any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain, if any, for the foreseeable future.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. It is also possible that potential plaintiffs may file lawsuits relating to the Opus Acquisition, as litigation and related claims frequently follow the announcement and completion of business transactions, including mergers like the one we consummated. Litigation often is expensive and diverts management's attention and resources, which could seriously harm our business. The outcome of any future litigation is uncertain and, if not resolved we may incur significant costs and damages to our reputation.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable to our Company.

Item 5. Other Information

Other than as set forth below, during the quarter ended September 30, 2024, none of the Company's directors or officers has adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K under the Exchange Act).

Item 6. Exhibits

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
2.1	Agreement and Plan of Merger, dated as of October 22, 2024, by and among the Company, Former Opus, Orange Merger Sub I, Inc., and Orange Merger Sub II, LLC (incorporated by reference to Exhibit 2.1 to Registrant's Current Report on Form 8-K, filed on October 22, 2024).
3.1	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock, effective as of October 22, 2024 (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed on October 22, 2024).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of the Company, effective as of October 23, 2024 (incorporated by reference to Exhibit 3.2 to Registrant's Current Report on Form 8-K, filed on October 22, 2024).
3.3	Amended and Restated Bylaws, dated as of June 11, 2024 (incorporated by reference to Exhibit 3.3 to Registrant's Current Report on Form 8-K, filed on October 22, 2024).
10.1**+	Employment Agreement, dated as of October 22, 2024, by and between the Company and Dr. Benjamin Yerxa.
10.2**+	Consulting Agreement, dated as of October 22, 2024, by and between the Company and Dr. Jean Bennett.
10.3**+	Second Amendment to 2021 Inducement Plan
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Documents are furnished not filed.

** Indicates exhibits that are being filed herewith.

\+ Indicates management contract or compensatory plan.

Opus Genetics, Inc.
Form 10-Q

SIGNATURES

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

Dated: November 12, 2024

Opus Genetics, Inc.

By: /s/ George Magrath
George Magrath
Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Nirav Jhaveri
Nirav Jhaveri
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "***Agreement***") by and between **OCUPHIRE PHARMA, INC.**, a Delaware corporation (the "***Company***"), and Benjamin R. Yerxa, Ph.D. (the "***Executive***") is signed by the Company and the Executive on October 22, 2024 (the "***Effective Date***").

RECITALS

WHEREAS, the Executive and Opus Genetics Inc. ("***Opus***") are parties to that certain Employment Agreement, dated August 23, 2023 (the "***Prior Agreement***"), pursuant to which Opus retained the Executive as its President and Chief Executive Officer;

WHEREAS, the Company acquired Opus pursuant to a merger (the "***Merger***") with Opus ceasing to exist pursuant to that certain Agreement and Plan of Merger, by and among the Company, **Orange Merger Sub I, Inc.** a Delaware corporation and wholly owned subsidiary of the Company ("***First Merger Sub***"), **Orange Merger II, LLC,** a Delaware limited liability company and wholly owned subsidiary of the Company ("***Second Merger Sub***" and together with First Merger Sub, "***Merger Subs***") and Opus, dated October 22, 2024 (the "***Merger Agreement***");

WHEREAS, the Company and the Executive desire to enter into this Agreement to embody the terms of the Executive's relationship as the President of the Company following the Effective Date and to amend, restate and supersede the terms and conditions of the Prior Agreement in its entirety on the Effective Date on the terms and conditions set forth in this Agreement; and

WHEREAS, this Agreement shall represent the entire understanding and agreement between the parties with respect to the Executive's employment with the Company.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration, including the respective covenants and agreements set forth below and in the Confidentiality Agreement (as defined below), the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. EMPLOYMENT PERIOD AND CONSULTING PERIOD.

(a) Employment Period. Subject to the remainder of this Agreement, the Company hereby agrees to continue to employ the Executive, and the Executive hereby agrees to continue to be employed by the Company, subject to the terms and conditions of this Agreement, commencing on the Effective Date and ending on October 22 2025 (the "***Expiration Date***"). For purposes of this Agreement, "***Employment Period***" includes the period commencing on the Effective Date and continuing until the earlier of (i) the Expiration Date and (ii) the date on which the Executive's employment with the Company is terminated by either party for any reason.

(b) Consulting Period. For a period of three years following the Expiration Date or the Termination Date (provided that the Executive's employment is not terminated by the Company for Cause or by the Executive pursuant to Section 3(b) of this Agreement or because of the Executive's death or Disability) (the "***Consulting Period****")*, the Executive agrees to provide consulting services to the Company, when and as reasonably requested by the Company, and will receive a payment in the amount of $400,000 per year for such services, which amount shall be paid to the Executive in cash in equal quarterly installments, within thirty (30) days following the end of each quarter during each year of the Consulting Period, subject to the Executive's continued service with the Company through the last day of the applicable quarterly period; provided, that in the Company's sole discretion and in consultation with Executive, up to 50% (or such greater amount as may be mutually agreed upon by the parties) of the annual amount payable to the Executive may be paid in the form of restricted stock units with respect to the Company's common stock, which restricted stock units shall be granted in the first week of the applicable quarter, with the number of shares subject to the restricted stock unit award determined based on the closing market price of the Company's common stock as of the applicable grant date and with such restricted stock units to vest on the last day of the applicable quarterly period, subject to the Executive's continued service through the last day of the applicable quarterly period and with the shares subject to the restricted stock unit award to be settled within thirty (30) days following the end of the applicable quarterly period; provided, further, that the Company may elect to accelerate the grant of all of the restricted share unit awards for any year in the Consulting Period to the first week of the applicable year, with the award to vest in four equal quarterly installments based on the Executive's continued service through the last day of the applicable quarterly period and to be settled within thirty (30) days following the end of the applicable quarterly period. Such services will include assisting with such reasonable requests for information or other assistance that the Chief Executive Officer of the Company (the "***CEO***") or the board of directors of the Company (the "***Board***") may request. In connection with the foregoing, the Company and the Executive agree that on or about the Expiration Date or Termination Date they will enter into a consulting agreement, in the form attached hereto as Exhibit A, to memorialize the foregoing terms.

2. Terms Of Employment.

(a) Position and Duties.

(i) During the Employment Period, the Executive shall serve as the President of the Company on a full time basis, and in such other position or positions with the Company and its subsidiaries as are consistent with the Executive's position as President of the Company, and shall have such duties and responsibilities as are assigned to the Executive by the Board or the CEO consistent with the Executive's position as President. If elected, the Executive agrees to serve as a member of the Board during the Employment Period. The Executive shall perform his job duties principally from the Executive's home office in North Carolina, provided that the Executive shall be required to work from time to time at the principal executive offices of the Company and such other locations as needed or reasonably requested from time to time by the CEO.

(ii) During the Employment Period, and excluding any periods of vacation and sick leave to which the Executive is entitled, the Executive agrees to devote substantially all of his time and attention to the business and affairs of the Company, to discharge the responsibilities assigned to the Executive hereunder, and to use the Executive's best efforts to perform faithfully and efficiently such responsibilities. During the Employment Period, it shall not be a violation of this Agreement for the Executive to (A) be employed by the Company or any of its subsidiaries or Affiliates, (B) serve on civic or charitable boards, committees, or advisory boards, (C) deliver lectures, fulfill speaking engagements or teach at educational institutions, (D) manage personal investments, (E) serve on the boards of directors of not-for-profit organizations, (F) serve on the boards of directors of Clearside Biomedical, Nacuity Pharmaceuticals, NC Biotech Center, and Sharefish, or (G) serve on the boards of directors of other entities as approved by the Board, so long as such activities do not interfere with the performance of the Executive's responsibilities as an employee of the Company in accordance with this Agreement.

(iii) **Company Policies**. The Executive's employment will be subject to the terms of the Company's employee handbook (as amended from time to time).

(b) **Compensation**.

(i) ***Base Salary***. During the Employment Period, the Executive shall receive an annualized base salary (the "***Base Salary***") equal to $425,000 subject to applicable withholding taxes, which shall be paid in accordance with the Company's normal payroll practices for senior executive officers of the Company as in effect from time to time. During the Employment Period, the Base Salary shall be subject to review by the Board or the Compensation Committee of the Board (the "***Compensation Committee***") and may be adjusted based upon the Company's normal performance review practices for senior executive officers. The Base Salary shall not be reduced (unless otherwise agreed to by the Executive or pursuant to a salary reduction program applicable generally to the Company's similarly situated employees). The term "Base Salary" as utilized in this Agreement shall refer to the Base Salary as so increased or adjusted.

(ii) ***Performance Bonus***. In addition to the Base Salary, for each fiscal year during the Employment Period, the Executive shall be eligible for an annual cash bonus of up to 35% of the Base Salary actually paid to the Executive in such fiscal year (the "***Performance Bonus***"), based upon the Company and the Executive achieving performance goals and objectives for such fiscal year, as determined by the Compensation Committee or the Board (in their sole and absolute discretion) and as determined in accordance with the policies and practices generally applicable to other senior executive officers of the Company. No Performance Bonus amount is guaranteed and, in addition to the other conditions for earning such Performance Bonus, the Executive must remain an employee in good standing of the Company on (A) the Performance Bonus payment date to earn and be eligible to receive a Performance Bonus with respect to calendar year 2024 and (ii) the Expiration Date to earn and be eligible to receive a Performance Bonus with respect to calendar year 2025. The Board (or the Compensation Committee) will determine whether the Executive has earned the Performance Bonus and the amount of any Performance Bonus based upon achievement of milestones which shall be determined in sole discretion of the Board (or the Compensation Committee). If earned, each such Performance Bonus awarded to the Executive shall be paid within the first two and half months of the fiscal year next following the fiscal year for which the Performance Bonus is awarded. For the avoidance of doubt, any Performance Bonus earned by the Executive during calendar years 2024 and 2025 shall be prorated by the number of days during which the Executive was employed by the Company in the calendar year of 2024 or 2025, respectively, which, for the avoidance of doubt shall not include any days that the Executive served as a consultant of the Company pursuant to Section 1(b) of this Agreement.

(iii) ***Initial Equity Award***. As an inducement for Executive to enter into this Agreement and subject to the terms of the Company's 2021 Inducement Plan (as such plan may be amended, modified or replaced, the "***Inducement Plan***") and the form of Restricted Stock Unit Grant Notice and award agreement issued thereunder (collectively, the "***Equity Documents***"), promptly following the Effective Date and approval by the Board, the Company will issue the Executive a Restricted Stock Unit Award (as defined in the Inducement Plan) with respect to 332,800 shares of the Company's common stock (the "***Initial Inducement Award***"). The Initial Inducement Award shall include the following additional terms: (1) subject to the Executive's continued employment with or service as a consultant or independent contractor for the Company and the terms and conditions of the Inducement Plan, the Initial Inducement Award shall vest in four (4) equal consecutive annual installments of 25% of the Initial Inducement Award, commencing on the first anniversary of the Effective Date and continuing on each consecutive anniversary of the Effective Date so that all Restricted Stock Units will be vested on the four-year anniversary of the Effective Date, subject to the Executive's continuous service with the Company or an Affiliate (as an employee or consultant or independent contractor) through such vesting dates; and (2) in the event that during the Employment Period or any period during which Employee is serving the Company as a consultant or independent contractor the Company consummates a Change in Control (as defined below) and the Initial Inducement Award is not assumed, continued or substituted by the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) in such Change in Control in the manner contemplated by Section 9(c)(i) and (ii) of the Inducement Plan, then 100% of the unvested portion of the Initial Inducement Award shall fully vest immediately prior to the effectiveness of such Change in Control, subject to the Executive's continued employment with or service as a consultant or independent contractor for the Company as of such date and as further provided in the terms and conditions of this Agreement, the Initial Inducement Award and the Inducement Plan. For the avoidance of doubt, in the event of any conflict between the terms of this Section 2(b)(iii) of this Agreement and the terms of the Inducement Plan and Equity Documents, the terms of the Plan and Equity Documents shall control.

(iv) ***Welfare Benefit Plans***. During the Employment Period, the Executive and/or the Executive's family, as the case may be, shall be eligible for participation in and shall receive all benefits under welfare benefit plans, practices, policies and programs provided by the Company and its Affiliates (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other senior executive officers of the Company. Notwithstanding the foregoing, the Company may amend or discontinue any such welfare benefit plans, practices, policies and programs at any time in its sole discretion.

(v) ***Expenses***. During the Employment Period, the Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by the Executive in accordance with the plans, practices, policies and programs of the Company.

(vi) ***Vacation***. During the Employment Period, the Executive shall be entitled to paid vacation in accordance with the plans, practices, policies and programs of the Company consistent with the treatment of other senior executive officers of the Company.

3. Termination Of Employment.

(a) The Employment Period shall end upon the earliest to occur of (i) the Executive's death, (ii) a termination due to Disability (as defined below), (iii) a termination for Cause (as defined below), (iv) the Termination Date specified in connection with any exercise by the Company of its Termination Right (as defined below), (v) a termination for Good Reason (as defined below) by the Executive, (vi) the termination of this Agreement by Executive pursuant to Section 3(b), or (vii) the Expiration Date. Upon termination of the Executive's employment for any reason, the Executive will be deemed to have automatically resigned, effective as of the Termination Date, from any and all positions that the Executive holds as an officer, director, manager and/or member of any governing body (or a committee thereof), in any case, of the Company or any of its Affiliates (as defined below).

(b) This Agreement may be terminated by the Executive at any time upon thirty (30) days prior written notice to the Company or upon such shorter period as may be agreed upon between the Executive and the Board or the CEO. In the event of a termination by the Executive other than a termination for Good Reason, the Company shall be obligated only to continue to pay the Executive's Base Salary and provide other benefits provided by this Agreement up to the date of the termination.

(c) Benefits Payable Under Termination.

(i) ***By the Company for Cause or because of Executive's Death or Disability or by Executive Without Good Reason.*** If Executive's employment and this Agreement are terminated by the Company in a termination for Cause or in the event of the Executive's death or a termination due to Disability, or by Executive other than a termination for Good Reason pursuant to Section 3(b), then the Company's obligation to compensate Executive ceases on the Termination Date except as to: (A) amounts of Base Salary earned but unpaid as of the effective termination date; (B) accrued but unused vacation; (C) accrued but unpaid bonus amounts; and (D) unreimbursed eligible business expenses (collectively, the "***Accrued Amounts***"). Executive shall comply with this Agreement after a termination of employment.

(ii) ***By the Company without Cause or by the Executive for Good Reason.*** Notwithstanding any other provision contained herein, if Executive's employment hereunder is terminated by Executive for Good Reason or by the Company without Cause, in each case within twelve (12) months following the "Closing Date" (as such term is defined in the Merger Agreement), Executive shall be entitled to receive the Accrued Amounts and subject to Executive's compliance with this Agreement and Executive's execution of a release as specified in Section 3(c)(iii), Executive shall be entitled to receive:

(A) a lump sum payment equal to 0.5 times the sum of (i) the annual Base Salary as in effect as of the Termination Date and (ii) an amount equal to a prorated portion of the Performance Bonus for the year in which the Termination Date occurs, with such prorated amount determined by multiplying the Executive's target Performance Bonus for the year in which the Termination Date occurs by a fraction, the numerator of which is the number of full months during such year in which the Executive was employed and the denominator of which is twelve (12), and payable within 60 days following the effective date of the Executive's termination of employment (provided, however, that if following or within three (3) months prior to the effective date of a Change in Control occurring during the twelve (12) months following the Closing Date, the Executive effects a termination for Good Reason or the Company terminates the Executive's employment other than due to the Executive's death, a termination for Cause or a termination due to a Disability (a **"*CIC Qualifying Termination*"**), then subject to Executive's compliance with this Agreement and Executive's execution of a release as specified in Section 3(c)(iii), the Company shall pay to the Executive, in a lump sum in cash within sixty (60) days after the Termination Date, an amount equal to 0.5 times the sum of (i) the annual Base Salary as in effect as of the Termination Date and (ii) the Executive's target Performance Bonus for the year in which the Termination Date occurs), provided that in the case of a CIC Qualifying Termination within three (3) months prior to the effective date of the Change in Control, the enhanced severance due upon a CIC Qualifying Termination shall be payable within sixty (60) days after the effective date of the Change in Control (which, for the avoidance of doubt, will be reduced by any severance payable under this section absent the occurrence of a Change in Control); and

(B) notwithstanding the terms of any equity incentive plan or award agreements, as applicable, all outstanding unvested equity awards with respect to the Company held by Executive shall become fully vested and exercisable for the remainder of their full term, with any equity awards other than outstanding stock options, settled within 60 days following the effective date of the Executive's termination of employment or such later date as required to comply with Section 409A of the Internal Revenue Code of 1986, as amended (***"Section 409A"***).

(C) if, to the extent applicable, the Executive timely elects continued health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (***"COBRA"***) or applicable state law and the Company's group health plans following the Termination Date, then the Company shall pay 100% of the COBRA premiums necessary to continue the Executive's and the Executive's covered dependents' health insurance coverage in effect for the Executive (and the Executive's covered dependents) on the Termination Date until the earliest of: (A) twelve (12) months following the Termination Date; (B) the date when the Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment; or (C) if applicable, the date the Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the Termination Date through the earlier of (A)-(C) (the ***"COBRA Payment Period"***). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on the Executive's behalf could result in a violation of applicable law or the imposition of penalties or taxes, or is not available for other reasons, then in lieu of paying COBRA premiums pursuant to this Section 3(c)(ii)(C), the Company shall pay the Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the premium for such month, subject to applicable tax withholding, for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive the Executive of the Executive's rights under COBRA for benefits under plans and policies arising under the Executive's employment by the Company.

(iii) ***Required Release.*** Notwithstanding any provision of this Agreement to the contrary, the Company's obligation to provide the payments under Section 3(c)(ii) is conditioned upon Executive's execution and non-revocation of an enforceable release of claims in a form provided to him by the Company and his compliance with this Agreement. If Executive chooses not to execute such release, revokes his execution of such release, or fails to comply with this Agreement, then the Company shall have no obligation to provide the payments under Section 3(c)(ii). The release of claims shall be provided to Executive no later than seven (7) days following his separation from service and Executive must execute it within the time period specified in the release (which shall not be longer than forty-five (45) days from the date of receipt). Such release shall not be effective until any applicable revocation period has expired.

(iv) ***Benefits in Lieu of Other Severance.*** Executive is not entitled to receive any compensation or benefits upon his termination except as: (A) set forth in this Agreement; or (B) otherwise required by law. Moreover, the terms and conditions afforded Executive under this Agreement are in lieu of any severance benefits to which he otherwise might be entitled pursuant to any severance plan, policy and practice of the Company, including any severance entitlement set forth in the Prior Agreement.

(v) ***Additional Distribution Rules***. Notwithstanding any other payment date or schedule provided in this Agreement to the contrary, if the Executive is deemed on the Termination Date of the Executive's employment to be a "specified employee" within the meaning of that term under Section 409A, then each of the following shall apply:

(A) With regard to any payment that is considered "nonqualified deferred compensation" under Section 409A and payable on account of a "separation from service" (within the meaning of Section 409A and as provided in Section 3(f) of this Agreement), such payment shall not be made prior to the date which is the earlier of (1) the expiration of the six (6)-month period measured from the date of the Executive's "separation from service," and (2) the date of the Executive's death (the "***Delay Period***") to the extent required under Section 409A. Upon the expiration of the Delay Period, all payments delayed pursuant to this Section 3(c)(v)(A) (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid to the Executive in a lump sum, and all remaining payments due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein; and

(B) To the extent that benefits to be provided during the Delay Period are considered "nonqualified deferred compensation" under Section 409A provided on account of a "separation from service," the Executive shall pay the cost of such benefits during the Delay Period, and the Company shall reimburse the Executive, to the extent that such costs would otherwise have been paid or reimbursed by the Company or to the extent that such benefits would otherwise have been provided by the Company at no cost to the Executive, for the Company's share of the cost of such benefits upon expiration of the Delay Period, and any remaining benefits shall be paid, reimbursed or provided by the Company in accordance with the procedures specified herein.

The foregoing provisions of this Section 3(c)(v)(A) and (B) shall not apply to any payments or benefits that are excluded from the definition of "nonqualified deferred compensation" under Section 409A, including, without limitation, payments excluded from the definition of "nonqualified deferred compensation" on account of being separation pay due to an involuntary separation from service under Treasury Regulation 1.409A-1(b)(9)(iii) or on account of being a "short-term deferral" under Treasury Regulation 1.409A-1(b)(4).

(d) **Definitions**. For purposes of this Agreement, the following terms shall have the meanings ascribed to them below:

(i) "***Affiliate***" means any corporation, partnership, limited liability company, trust or other entity which directly, or indirectly through one or more intermediaries, controls, is under common control with, or is controlled by, the Company.

(ii) "***Business Partners***" is any person or entity who or which, at any time during Executive's employment with the Company: (A) contracted for, was billed for, or received any product, service, or other offering from the Company; (B) contracted for, billed for, or provided any product, service, or other offerings to the Company; (C) was in contact with Executive or in contact with any other employee or agent of the Company, of which contact Executive was or should have been aware, concerning the sale or purchase of, or contract for, any product, service, or other offering of the Company; or (D) was solicited by the Company in an effort in which Executive was involved or of which Executive was aware.

(iii) **"*Cause*"** means any of the following: (A) the Executive's commission of a felony or other crime involving moral turpitude or the commission of any other act or omission involving misappropriation, disloyalty, fraud, or breach of fiduciary duty, (B) the Executive's repeated failure to perform duties as reasonably directed by the Company, (C) the Executive's gross negligence or willful misconduct in the performance of the Executive's job duties, (D) the Executive violating any of the material terms of the Company's established rules or policies, or (E) any other material breach of this Agreement or any other agreement between the Executive and the Company which, if curable, is not cured to the Company's reasonable satisfaction within fifteen (15) days after written notice thereof to the Executive.

(iv) "***Change in Control***" shall have the meaning ascribed to such term in the Company's 2020 Equity Incentive Plan (the "***Plan***").

(v) "***Code***" means the Internal Revenue Code of 1986, as amended and the rules and regulations promulgated thereunder.

(vi) "***Competitive Business***" is defined as a business or enterprise that is developing any ophthalmic gene therapy with a mechanism of action that is similar to a mechanism of action that is a feature of any product under development by the Company.

(vii) "***Disability***" means the Executive's physical or mental inability to substantially perform Executive's duties and responsibilities under this Agreement, with or without reasonable accommodation, for a period of ninety (90) days, whether or not consecutive, during any 365-day period, as determined in the Company's reasonable discretion. The Company shall give Executive written notice of a termination due to Disability and the termination shall be effective as of the Termination Date specified in such notice.

(viii) **"*Good Reason*"** means the occurrence of any of the following without Executive's express prior written consent: (A) a reduction in Executive's salary by more than 5% other than as part of an across-the-board salary reduction that applies in the same manner to all senior executives of the Company; (B) the removal of Executive from the position of President of the Company other than due to a termination for Cause, death or termination due to Disability; (C) a material reduction in Executive's responsibilities, duties, or authority as President of the Company unless agreed to in writing by the Executive; or (D) the Company's material breach of this Agreement; provided, however, that prior to a termination for Good Reason, Executive must provide written notice to the Company briefly describing the condition giving rise to the termination for Good Reason within thirty (30) days of Executive's knowledge of its initial existence and must give the Company thirty (30) days from such notice to cure the condition alleged to give rise to the termination for Good Reason and, if such condition is not cured, Executive must terminate his employment within thirty (30) days from the end of the cure period. For the avoidance of doubt, by entering into this Agreement, the Executive acknowledges that Executive shall not have a right to terminate for Good Reason under the Prior Agreement or as a result of the Merger.

(ix) "***Termination Date***" means the earlier to occur of (A) the date the Company specifies in writing to the Executive in connection with the exercise of its Termination Right; (B) the date the Executive specifies in writing to the Company in connection with any notice to effect a termination for Good Reason; (C) the date on which the Employment Period ends pursuant to Section 3(b); (D) death; or (E) the Expiration Date. Notwithstanding the foregoing, a termination of employment will not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits subject to Section 409A upon or following a termination of employment unless such termination is also a "separation from service" (within the meaning of Section 409A), and notwithstanding anything contained herein to the contrary, the date on which such separation from service takes place will be the Termination Date.

(x) "***Termination Right***" means the right of the Company, in its sole, absolute and unfettered discretion, to terminate the Executive's employment under this Agreement for any reason or no reason whatsoever. For the avoidance of doubt, any termination for Cause effected by the Company shall not constitute the exercise of its Termination Right.

(e) **Conflict with Plan**. As permitted under the terms of the Plan, the Company and the Executive agree that the definitions of Cause or Good Reason set forth in this Section 3 shall apply in place of any similar definition or comparable concept applicable under the Plan (or any similar definition in any successor plan).

(f) **Section 409A**. It is intended that payments and benefits under this Agreement either be excluded from or comply with the requirements of Section 409A and the guidance issued thereunder and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted consistent with such intent. In the event that any provision of this Agreement is subject to but fails to comply with Section 409A, the Company may revise the terms of the provision to correct such noncompliance to the extent permitted under any guidance, procedure or other method promulgated by the Internal Revenue Service now or in the future or otherwise available that provides for such correction as a means to avoid or mitigate any taxes, interest or penalties that would otherwise be incurred by the Executive on account of such noncompliance. *Provided, however*, that in no event whatsoever shall the Company be liable for any additional tax, interest or penalty imposed upon or other detriment suffered by the Executive under Section 409A or damages for failing to comply with Section 409A. Solely for purposes of determining the time and form of payments due the Executive under this Agreement (including any payments due under Sections 3(c)) or otherwise in connection with the Executive's termination of employment with the Company, the Executive shall not be deemed to have incurred a termination of employment unless and until the Executive shall incur a "separation from service" within the meaning of Section 409A. The parties agree, as permitted in accordance with the final regulations thereunder, a "separation from service" shall occur when the Executive and the Company reasonably anticipate that the Executive's level of bona fide services for the Company (whether as an employee or an independent contractor) will permanently decrease to no more than forty (40) percent of the average level of bona fide services performed by the Executive for the Company over the immediately preceding thirty-six (36) months (or the period of Executive's employment if Executive has been employed with the Company less than thirty-six (36) months at the time of the Executive's termination). The determination of whether and when a separation from service has occurred shall be made in accordance with this subparagraph and in a manner consistent with Treasury Regulation 1.409A-1(h). All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement (and the in-kind benefits to be provided) during a calendar year may not affect the expenses eligible for reimbursement (and the in-kind benefits to be provided) in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement (or in-kind benefits) is not subject to set off or liquidation or exchange for any other benefit. For purposes of Section 409A, the Executive's right to any installment payments under this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., "payment shall be made within ninety (90) days following the date of termination"), the actual date of payment within the specified period shall be within the sole discretion of the Company.

4. **Executive Remedy**. The Executive acknowledges and agrees that the payment and rights provided under Section 3 are fair and reasonable, and are the Executive's sole and exclusive remedy, in lieu of all other remedies at law or in equity, for termination of the Executive's employment by the Company upon exercise of its Termination Right pursuant to this Agreement or upon a termination for Good Reason.

5. **Section 280G.**

(a) If any payment or benefit (whether or not pursuant to this Agreement) the Executive would receive in connection with a Change in Control from the Company or otherwise (the "***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this paragraph, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Executive shall have the option to select one of the following two alternative forms of payment: (A) payment in full of the entire amount of the Payment, or (B) payment of only a part of the Payment so that the Executive receives the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"). If Executive elects to receive a Reduced Payment, the reduction in payments and/or benefits shall occur in the following order: (A) reduction of cash payments in the reverse chronological order in which otherwise payable; (B) cancellation of accelerated vesting of equity awards other than stock options; (C) cancellation of accelerated vesting of stock options; and (D) reduction of other benefits paid to Executive in the reverse chronological order in which otherwise payable. In the event that acceleration of compensation from the Executive's equity awards is to be reduced, such acceleration of vesting shall be canceled in the reverse order of the date of grant and, in the case of a particular grant, in the reverse chronological order in which the grant would otherwise vest.

(b) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control, or a nationally recognized law firm, shall make all determinations required to be made under this Section 5. If the independent registered public accounting firm or nationally recognized law firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint an independent registered public accounting firm or nationally recognized law firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(c) The independent registered public accounting firm or law firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and the Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the accounting firm or law firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

6. Restrictive Covenants.

(a) Non-Competition. In consideration of the payments and benefits described in Section 3 and other sections of this Agreement, to which the Executive was not entitled prior to the Effective Date hereof, the Executive agrees that, throughout the term of the Executive's employment with the Company and for one (1) year immediately following the Termination Date (the "***Restricted Period***"), the Executive shall not, directly or indirectly, without the prior written consent of the Board, own, manage, operate, control, finance or participate in the ownership, management, operation, control or financing of, or provide services as an officer, director, executive, partner, employee, principal, agent, representative, consultant, licensor, licensee or otherwise to, for, or on behalf of, any Competitive Business*;* provided, however, that the Executive (i) may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (but without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange, and (ii) may provide services or work for any Competitive Business in any area of its business that does not develop or commercialize gene therapies for the treatment of ophthalmic disorders and diseases with respect to a product that would be in direct competition with a similar product of the Company. In recognition of the broad geographic scope of the Company's business and of the ease of competing with that business from any location throughout the world, the restrictions in this Section 6(a) are intended to cover the following geographic areas (collectively, the "***Territory***"): (A) the United States; (B) all states (including the District of Columbia, if applicable) in which the Company provided goods or services, had employees or customers, or otherwise conducted business at any time during Executive's employment; or (C) all states (including the District of Columbia, if applicable) in which Executive performed services for the Company or had a material presence or influence, or over which Executive had managerial responsibilities. If a court or arbitrator determines that the Territory described above in clause (A) is too restrictive, then the parties agree that the Territory shall be the area specified in clause (B). If a court or arbitrator determines that the Territory described above in clauses (A) and (B) are too restrictive, then the parties agree the Territory shall be reduced to the area specified in clause (C). If the court determines that all of the areas mentioned above are too restrictive, then the parties agree the court or arbitrator may reduce or limit the area to enable the intent of this Section 6(a) to be enforced in the largest acceptable area. The Executive hereby represents and warrants that the Executive has disclosed previously to the CEO all other employment or other commercial business activities that the Executive already undertakes or intends to undertake (to the extent currently known by the Executive), during the Executive's period of employment with the Company.

(b) Non-Solicitation of Business Partners. Executive agrees that during the Restricted Period, Executive will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, except on behalf of the Company: (i) solicit, induce or attempt to induce any Business Partners to terminate, diminish, or materially alter in a manner harmful to the Company its relationship with the Company; or (ii) solicit or assist in the solicitation of any Business Partners to induce or attempt to induce such Business Partners to contract with, or order from, a Competitive Business.

(c) Reasonableness of Restrictions. Executive agrees that Executive has read Section 6 of this Agreement and understand its terms. Executive agrees that those restrictions are reasonable, proper, and necessitated by the Company's legitimate business interests, based on Executive's role and access to and use of the Company's trade secrets and proprietary and confidential information. If any restrictions set forth in Section 6 of this Agreement are found by any court of competent jurisdiction or arbitrator to be unenforceable because they extend for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

(d) Employee Proprietary Information, Inventions Assignment, and Non-Solicitation Agreement. In connection with this Agreement, and as a condition of the Executive's employment with the Company, the Executive shall sign and abide by the Employee Proprietary Information, Inventions Assignment and Non-Solicitation Agreement ("***Confidentiality Agreement***"), a copy of which is attached as Exhibit B to this Agreement. The Confidentiality Agreement may be amended by the parties from time to time without regard to this Agreement and contain provisions that are intended by the parties to survive and do survive termination or expiration of this Agreement.

(e) Notice of Immunity from Liability For Confidential Disclosure of a Trade Secret. Pursuant to 18 USC § 1833(b), an individual may not be held criminally or civilly liable under any federal or state trade secret law for disclosure of a trade secret: (i) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law; and/or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Additionally, an individual suing an employer for retaliation based on the reporting of a suspected violation of law may disclose a trade secret to his or her attorney and use the trade secret information in the court proceeding, so long as any document containing the trade secret is filed under seal and the individual does not disclose the trade secret except pursuant to court order. Nothing in this Agreement or the Invention Assignment Agreement is intended to limit any rights under this federal law.

(f) Exclusions. Notwithstanding anything to the contrary in this Agreement or the Confidentiality Agreement, the Executive understands that nothing in this Agreement, the Confidentiality Agreement, or any other agreement between the Executive and the Company prohibits the Executive, confidentially or otherwise, from communicating, cooperating, or filing a charge or complaint with a governmental enforcement or regulatory entity (an "Agency") or participating in an Agency investigation, in each case without receiving prior authorization from, or having to disclose any such conduct to, the Company. Nothing in this Agreement or the Confidentiality Agreement shall (i) be construed to limit the Executive's right to receive an award for information provided to any Agency, including under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010; nor (ii) prohibit the Executive from discussing or disclosing information that is expressly prohibited from being the subject of employee nondisclosure obligations under applicable law, such as information about unlawful acts in the workplace, including harassment or any other conduct that the Executive has reason to believe is unlawful or in violation of public policy, or from speaking with an attorney regarding the same. Notwithstanding the foregoing, in making any such disclosures or communications, the Executive agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Proprietary Information to any parties other than the Agencies. The Executive further understands that the Executive is not permitted to disclose the Company's attorney-client privileged communications or attorney work product.

7. Successors.

(a) This Agreement is personal to the Executive and without the prior written consent of the Company shall not be assignable by the Executive otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by the Executive's legal representatives.

(b) This Agreement shall inure to the benefit of and be binding upon the Company and its successors and assigns and any party acting in the form of a receiver or trustee capacity.

(c) The Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company to assume expressly and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. As used in this Agreement, "Company" shall mean the Company as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law, or otherwise.

8. MISCELLANEOUS.

(a) This Agreement shall be construed, and the rights and obligations of the parties hereunder determined, in accordance with the substantive laws of the State of Michigan, without regard to its conflict-of-laws principles. For the purposes of any suit, action or proceeding based upon, arising out of or relating to this Agreement or the negotiation, execution or performance hereof, the parties hereby expressly submit to the jurisdiction of all federal and state courts sitting within the confines of the Federal Eastern District of Michigan (the "***Venue Area***") and consent that any order, process, notice of motion or other application to or by any such court or a judge thereof may be served within or without such court's jurisdiction by registered mail or by personal service in accordance with Section 8(b). The parties agree that such courts shall have the exclusive jurisdiction over any such suit, action or proceeding commenced by either or both of said parties. Each party hereby irrevocably waives any objection that it may now or hereafter have to the laying of venue of any suit, action or proceeding based upon, arising out of or relating to this Agreement or the negotiation, execution or performance hereof, brought in any federal or state court sitting within the confines of the Venue Area and hereby further irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. The captions of this Agreement are not part of the provisions hereof and shall have no force or effect. This Agreement may not be amended or modified otherwise than by a written agreement executed by the parties hereto or their respective successors and legal representatives.

(b) All notices and other communications hereunder shall be in writing and shall be given by hand delivery to the other party or by registered or certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Executive:	At Executive's address as it appears in the Company's books and records or at such other place as Executive shall have designated by notice as herein provided to the Company
If to the Company:	Ocuphire Pharma, Inc. Attn: George Magrath, M.D. 37000 Grand River Ave Suite 120 Farmington Hills, MI 48335
with a copy to:	Sidley Austin LLP Attn: Asher Rubin 2850 Quarry Lake Drive Suite 280 Baltimore, MD 21209; (410) 559-2881 Arubin@sidley.com Sidley Austin LLP Attn: Andrea Reed One South Dearborn Street Chicago, IL 60603; (312) 853-7881 andrea.reed@sidley.com

or to such other address as either party shall have furnished to the other in writing in accordance herewith. Notice and communications shall be effective when actually received by the addressee.

(c) The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.

(d) From and after the Effective Date, the Company shall cover the Executive under directors' and officers' liability insurance both during and, while potential liability exists, after the Employment Period in the same amount and to the same extent as the Company covers its other executive officers and directors.

(e) The Company hereby agrees to indemnify the Executive and hold the Executive harmless to the extent provided under the Amended and Restated Certificate of Incorporation of the Company, the Amended and Restated Bylaws of the Company, and any Indemnification Agreement entered into by and between the Company and the Executive against and in respect of any and all actions, suits, proceedings, claims, demands, judgments, costs, expenses (including reasonable attorney's fees), losses, and damages resulting from the Executive's good faith performance of the Executive's duties and obligations with the Company. For clarity, the Executive shall not be entitled to any indemnification in any proceeding brought by the Company against the Executive or his affiliates or any proceeding relating to or arising out of conduct that could form the basis for a termination for Cause. This obligation shall survive the termination of the Executive's employment with the Company.

(f) The Company may withhold from any amounts payable under this Agreement such Federal, state, local or foreign taxes that the Company determines are required to be withheld pursuant to any applicable law or regulation.

(g) The Executive's or the Company's failure to insist upon strict compliance with any provision of this Agreement or the failure to assert any right the Executive or the Company may have hereunder shall not be deemed to be a waiver of such provision of right or any other provision or right of this Agreement.

(h) This Agreement, the Confidentiality Agreement, and all agreements, documents, instruments, schedules, exhibits or certificates prepared in connection herewith, and as of the Effective Date represent the entire understanding and agreement between the parties with respect to the subject matter hereof, supersede all prior understandings, agreements or negotiations between such parties, whether written or oral (including, for the avoidance of doubt, the Prior Agreement), and may be amended, supplemented or changed only by an agreement in writing which makes specific reference to this Agreement or the agreement or document delivered pursuant hereto, as the case may be, and which is signed by the party against whom enforcement of any such amendment, supplement or modification is sought.

(i) This Agreement may be executed in one or more counterparts and by facsimile, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Signatures of the parties transmitted by facsimile or via .pdf format shall be deemed to be their original signatures for all purposes. The words "execution," "signed," "signature," and words of like import shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the Michigan Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a facsimile machine or electronic mail (any such delivery, an "***Electronic Delivery***"), will be treated in all manner and respects as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such agreement or instrument, each other party hereto or thereto will re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such agreement or instrument will raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such party forever waives any such defense, except to the extent such defense related to lack of authenticity.

Signatures on the Following Page

In Witness Whereof, the Company and the Executive have executed this Agreement as of the date first above written.

The Executive:

/s/ Benjamin R. Yerxa

Benjamin R. Yerxa, Ph.D.

The Company:

Ocuphire Pharma, Inc.

By: /s/ George Magrath

Name: Dr. George Magrath

Title: Chief Executive Officer

Exhibit A

Form of Consulting Agreement

CONSULTING AGREEMENT

This **Consulting Agreement** (this ***"Agreement"***) is made as of October 22, 2024 (the ***"Effective Date"***), between **Ocuphire Pharma, Inc.**, a Delaware corporation, having a principal place of business at 37000 Grand River Avenue, Suite 120, Farmington Hills, Michigan 48335 (the ***"Company"***), and **Benjamin R. Yerxa, Ph.D.** having an address at _____ (***"Consultant"***).

Background

The Company desires to retain Consultant, and Consultant desires to be engaged by the Company, to perform certain consulting services in the field of ophthalmology pursuant to the terms and conditions of this Agreement.

Terms and Conditions

Now, Therefore, in consideration of the foregoing and the terms, conditions and covenants hereinafter set forth, the Company and Consultant agree as follows:

1. Certain Definitions. Capitalized terms used in this Agreement and not otherwise defined shall have the following meanings:

(a) ***"Company Documents and Materials"*** means documents or other media, whether in tangible or intangible form, that contain or embody Proprietary Information or any other information concerning the Inventions or the business, operations, or plans of the Company, prepared by Consultant in the performance of the Services. Company Documents and Materials include, without limitation, blueprints, drawings, photographs, charts, graphs, notebooks, computer disks, tapes or printouts, sound recordings and other printed, electronic, typewritten or handwritten documents or information, sample products, prototypes and models.

(b) ***"Company Representative"*** means George Magrath, M.D., or his successor as Chief Executive Officer of the Company.

(c) ***"Inventions"*** means, without limitation, all software programs or subroutines, source or object code, algorithms, improvements, inventions, works of authorship, trade secrets, technology, designs, formulas, ideas, processes, techniques, know-how and data, whether or not patentable or copyrightable, made or discovered or conceived or reduced to practice or developed by Consultant, either alone or jointly with others.

(d) ***"Proprietary Information"*** means information developed, created, or discovered by or on behalf of the Company, which is disclosed by Company to Consultant, whether during or before the term of this Agreement, that is not generally known in Consultant's trade or industry and will include, without limitation, information about data, results, ideas, processes, techniques, formulae, know-how, improvements, discoveries, developments and design, tangible and intangible information relating to biological materials (such as cell lines, antibodies, tissue samples, proteins, nucleic acids and the like), assays and assay components and media, procedures and formulations for producing any such assays or assay components, and pre-clinical and clinical data, test, results, developments or experiments, plans for research, development and new therapeutics, technical information, tools, diagrams, plans, specifications, trade secrets, inventions, invention disclosures, concepts, structures, products, patentspending, patent applications, prototypes, processes, works in process, works of authorship, copyright applications, software programs and subroutines, source and object code, algorithms, trade secrets, designs, technology, know-how, processes, data, ideas, techniques, inventions, works of authorship, formulae, business and product development plans, customer lists, terms of compensation and performance levels of the Company's employees and consultants, the Company's customers and other information concerning the Company's actual or anticipated business, research or development, or which is received in confidence by or for the Company from any other person or entity.

(e) ***"Services"*** means the consulting services in the field of ophthalmology to be performed by Consultant on behalf of the Company described on Exhibit A attached hereto.

2. Services. The Company hereby engages Consultant, and Consultant accepts such engagement, to perform the Services. Consultant will be free of control and direction from the Company (other than general oversight and control over the scope of work, results of the Services and timing of deliverables), and will have exclusive control over the manner and means of performing the Services, including the choice of place and time. The expected hours shall not exceed eighty (80) hours per month. Consultant shall not be required to work any specified schedule but Consultant agrees to proceed with diligence and promptness. Consultant hereby represents and warrants that the Services shall be performed in accordance with the highest professional standards in the field to the satisfaction of the Company.

3. Term. The term of this Agreement shall commence on October 22, 2025 (or, if earlier, the first day following the termination of Consultant's employment with the Company other than (i) by the Executive pursuant to Section 3(b) of the Employment Agreement, by and between Consultant and the Company, effective October 22, 2024 (the "***Employment Agreement***"), (ii) by the Company for Cause (as defined in the Employment Agreement), or (iii) because of Consultant's death or Disability (as defined in the Employment Agreement) (the day on which the term actually commences, the "***Start Date***") and terminate on October 21, 2028 (the "***Consulting Period***") unless the parties mutually agree in writing to extend the term of this Agreement. Notwithstanding the foregoing, (a) either party may terminate this Agreement for any reason upon giving not less than thirty (30) days' notice to the other party, (b) the Company may terminate this Agreement immediately in the event of any embezzlement, non-performance of the Services, fraud or deceit in Consultant's performance of Consultant's obligations hereunder, or Consultant's violation of law, and (c) either party may terminate this Agreement immediately upon occurrence of any of the following events: (i) the breach of this Agreement by the other party, which breach is not cured within ten (10) business days after the breaching party's receipt of written notice of such breach from the non-breaching party, or (ii) the dissolution, voluntary or involuntary bankruptcy of either party, or assignment by either party of all or substantially all of its assets for the benefit of creditors. The rights and obligations of the parties hereto under Sections 6 through 28 of this Agreement shall survive the expiration or termination of this Agreement. If the Company terminates this Agreement pursuant to Section 3(a) above, or Consultant terminates this Agreement pursuant to Section 3(c)(i) above, all compensation due or unvested under this Agreement will accelerate and be immediately payable to Consultant within sixty (60) days following such termination of this Agreement. Such compensation shall be calculated by subtracting the amount of compensation paid or which vested pursuant to this Agreement from October 22, 2025 to the date of termination from $1,200,000.00, with the value of any equity-based awards to be calculated based on the number of shares subject to such awards multiplied by the closing stock price on the applicable grant date; provided, that if all or any portion of such compensation would constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "**Code**"), and would, but for this Section 3, be subject to the excise tax imposed under Section 4999 of the Code (the "**Excise Tax**"), then such compensation shall be reduced (but not below zero), in reverse chronological order, to the extent necessary to ensure that no Excise Tax is due. Any determination required by the preceding sentence shall be made in writing by an independent accounting firm selected by the Company and Consultant.

4. Compensation. In consideration of Consultant's performance of the Services, the Company shall pay Consultant at a rate of $400,000 per year during the Consulting Period, which amount shall be paid to the Consultant in cash in equal quarterly installments, within thirty (30) days following the end of each quarter during each year of the Consulting Period, subject to the Consultant's continued service with the Company through the last day of the applicable quarterly period; provided, that in the Company's sole discretion and in consultation with the Consultant, up to 50% (or such greater amount as may be mutually agreed upon by the parties) of the annual amount payable to the Consultant may be paid in the form of restricted stock units with respect to the Company's common stock, which restricted stock units shall be granted in the first week of the applicable quarter, with the number of shares subject to the restricted stock unit award determined based on the closing market price of the Company's common stock as of the applicable grant date and with such restricted stock units to vest on the last day of the applicable quarterly period, subject to the Consultant's continued service through the last day of the applicable quarterly period and with the shares subject to the restricted stock unit award to be settled within thirty (30) days following the end of the applicable quarterly period; provided, further, the Company may elect to accelerate the grant of all of the restricted share unit awards for any year in the Consulting Period to the first week of the applicable year, with the award to vest in four equal quarterly installments based on the Consultant's continued service through the last day of the applicable quarterly period and to be settled within thirty (30) days following the end of the applicable quarterly period. For the Services rendered during any calendar month during the term of this Agreement, Consultant will submit invoices to the Company on the last day of each calendar month or within fifteen (15) calendar days thereafter, containing at a minimum an accounting of activities performed and corresponding hours spent during that month. In addition, subject to the prior written approval of the Company Representative, the Company will pay or reimburse Consultant for all reasonable travel-related expenses incurred by Consultant in attending meetings and like events requested by the Company and any other expenses approved by the Company Representative in advance. All such expense reimbursements shall be subject to submission of appropriate documentation or receipts in accordance with the Company's Consultant & Contractor Reimbursable Expense Policy in effect from time to time, and must be submitted to the Company for reimbursement within thirty (30) calendar days after such expenses were incurred by Consultant. Payment to Consultant of undisputed fees and expenses will be due thirty (30) days following the Company's receipt of the invoice or expense reimbursement request with appropriate documentation.

5. **Expenses and Liabilities**. Consultant agrees that as an independent contractor, Consultant is solely responsible for all expenses Consultant incurs in connection with the performance of the Services, except for expenses that are pre-approved by the Company Representative in writing. The Company shall have no obligation to reimburse Consultant for expenses that were not approved in advance by the Company. Consultant understands that Consultant will not be provided any office equipment or supplies to perform the Services and shall not be reimbursed for any supplies, equipment, or operating costs, nor will these costs of doing business be defrayed in any way by the Company.

6. **Disclosure.** Pursuant to applicable governmental laws, rules and regulations, Consultant understands and acknowledges that the Company may be required to disclose to relevant governmental authorities the payments made by or on behalf of the Company to Consultant under this Agreement, as well as the purpose and nature of such payments. Consultant shall keep accurate records regarding payments made and expenses incurred in connection with this Agreement and shall provide the Company with such information upon request. The Company will have the right to disclose (including on the Company's website) and report, as may be required by applicable law (including the Physician Payment Sunshine Act set forth in Section 6002 of the Patient Protection and Affordable Care Act of 2010, and similar state reporting laws), or as otherwise desired by the Company (a) information relating to the Services, including without limitation, all payments, reimbursement for expenses, or other transfers of value made in other than monetary form, (b) identifying information concerning Consultant, and any other information relating to this Agreement.

7. **Confidentiality of Proprietary Information.**

(a) **Nature of Information.** Consultant understands that the Company possesses and will possess Proprietary Information which is important to its business. Consultant understands that Consultant's engagement creates a relationship of confidence and trust between the Company and Consultant with respect to Proprietary Information.

(b) **Property of the Company.** Consultant acknowledges and agrees that all Company Documents and Materials, Proprietary Information, and all patents, patent rights, copyrights, trade secret rights, trademark rights and other rights (including, without limitation, intellectual property rights) anywhere in the world in connection therewith is and shall be the sole property of the Company. Consultant hereby assigns to the Company any and all rights, title and interest Consultant may have or acquire in any Proprietary Information, or Company Documents and Materials.

(c) **Confidentiality.** At all times during the term of this Agreement and thereafter, Consultant shall keep in confidence and trust and shall not use or disclose any Proprietary Information or anything relating to it without the prior written consent of the Company Representative, except as may be necessary in the ordinary course of performing the Services. The obligations of confidentiality and non-disclosure set forth herein shall not apply to any information that:

(i) was already known to Consultant prior to receipt hereunder as evidenced by Consultant's written records;

(ii) is or later becomes publicly available other than through a breach of this Agreement by Consultant;

(iii) is lawfully disclosed to Consultant by a third party under no confidentiality obligations; and/or

(iv) Consultant is given written permission to disclose by an authorized representative of Company.

(d) Compelled Disclosure. In the event that Consultant is requested in any proceeding to disclose any Proprietary Information, Consultant shall give the Company prompt notice of such request so that the Company may seek an appropriate protective order. If, in the absence of a protective order, Consultant is nonetheless compelled by any court or tribunal of competent jurisdiction to disclose Proprietary Information, Consultant may disclose such information without liability hereunder; provided, however, that Consultant gives the Company notice of the Proprietary Information to be disclosed as far in advance of its disclosure as is practicable and uses Consultant's best efforts to obtain assurances that confidential treatment will be accorded to such Proprietary Information.

(e) Records. Consultant agrees to make and maintain adequate and current written records, in a form specified by the Company, of all Inventions, trade secrets and works of authorship assigned or to be assigned to the Company pursuant to this Agreement.

(f) Handling of the Company Documents and Materials. Consultant agrees that during Consultant's engagement by the Company, Consultant shall not remove any Company Documents and Materials from the business premises of the Company or deliver any Company Documents and Materials to any person or entity outside the Company, except as Consultant may be required to do in connection with performing the Services. Consultant further agrees that, immediately upon the termination of Consultant's engagement for any reason, or during Consultant's engagement if so requested by the Company, Consultant shall return all Company Documents and Materials, apparatus, equipment and other physical property, or any reproduction of such property, excepting only Consultant's copy of this Agreement.

(g) Notice of Immunity from Liability For Confidential Disclosure of a Trade Secret. Pursuant to 18 USC § 1833(b), if Consultant is an individual, Consultant may not be held criminally or civilly liable under any federal or state trade secret law for disclosure of a trade secret: (a) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law; and/or (b) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Additionally, In addition, if Consultant is an individual and Consultant files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Consultant may disclose the trade secret to Consultant's attorney and may use the trade secret information in the court proceeding, if Consultant (X) files any document containing the trade secret under seal; and (Y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to limit any rights under this federal law.

8. INVENTIONS.

(a) Disclosure. Consultant shall promptly disclose in writing to the Company any and all Inventions. Such disclosures shall be received by the Company in confidence. Consultant shall promptly disclose in writing to the Company Representative or to such person designated by the Company Representative all Inventions made during the term of Consultant's engagement with the Company related to the Services. Consultant shall also disclose to the Company Representative all Inventions made, discovered, conceived, reduced to practice or developed by Consultant either alone or jointly with others, within six (6) months after the termination of Consultant's engagement with the Company which resulted, in whole or in part, from Consultant's prior engagement with the Company and are related to the Services. Such disclosures shall be received by the Company in confidence, to the extent such Inventions are not assigned to the Company pursuant to subsection (b) below, and do not extend the assignments made in such subsection.

(b) Assignment of Inventions to the Company. Consultant agrees that all Inventions which Consultant makes, discovers, conceives, reduces to practice or develops (in whole or in part, either alone or jointly with others) during Consultant's engagement related to the Services, including, but not limited to, conceptions or ideas derived prior to Consultant's engagement but related to the Services and reduced to practice or developed (in whole or in part, either alone or jointly with others) during Consultant's engagement with the Company, shall be the sole property of the Company to the maximum extent permitted by law. Consultant hereby irrevocably and exclusively assigns to the Company in perpetuity, without further consideration, all of Consultant's right, title and interest (including, without limitation, all patent rights, copyrights, trademark rights, trade secret rights and other proprietary and/or intellectual property rights, and all renewals thereof) throughout the United States and in all other countries or jurisdictions, free and clear of all liens and encumbrances, in and to all such Inventions. If in the course of Consultant's engagement with the Company, Consultant incorporates into a Company Invention, product, process, or machine a prior Invention or improvement not related to the Services that is owned by Consultant or in which Consultant has an interest, Consultant hereby does assign all rights and interest in such prior Invention to the Company. To the extent that any such prior Invention is not deemed to be assignable as provided in this Section 8(b), the Company is hereby granted and shall have a non-exclusive, royalty-free, irrevocable, perpetual, sublicensable, worldwide license to make, have made, modify, use, market, sell and distribute such prior Invention as part of or in connection with such product, process or machine.

(c) Ownership of Copyrightable Inventions. Consultant agrees that the Company shall be the sole owner of all patents, patent rights, copyrights, trade secret rights, trademark rights and all other intellectual property or other rights in connection with Inventions related to the Services. Consultant further acknowledges and agrees that such Inventions related to the Services that are copyrightable Inventions were created by or for Consultant (whether alone or with others) on behalf of the Company or for the benefit of the Company and shall be the sole and complete property of the Company, and any and all copyrights to such Inventions shall belong exclusively and perpetually to the Company throughout the world. Consultant shall not attempt to register any works created by Consultant pursuant to this Agreement at the U.S. Copyright Office, the U.S. Patent & Trademark Office, or any foreign copyright, patent, or trademark registry.

(d) Cooperation. Consultant agrees to perform, during and after Consultant's engagement, all acts deemed necessary or desirable by the Company to permit and assist it, at the Company's expense, in further evidencing and perfecting the assignments made to the Company under this Agreement and in obtaining, maintaining, defending and enforcing patents, patent rights, copyrights, trademark rights, trade secret rights or any other rights in connection with such Inventions and improvements related to the Services in any and all countries. Such acts may include, without limitation, execution of documents and assistance or cooperation in legal proceedings. Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents, as Consultant's agents and attorney-in-fact, coupled with an interest, to act for and on Consultant's behalf and in Consultant's place and stead, to execute and file any documents, applications or related findings and to do all other lawfully permitted acts strictly limited to furthering the purposes set forth above in this Section 8(d), including, without limitation, the perfection of assignment and the prosecution and issuance of patents, patent applications, filing with the FDA, copyright applications and registrations, trademark applications and registrations or other rights in connection with such Inventions and improvements related to the Services with the same legal force and effect as if executed by Consultant.

(e) Assignment or Waiver of Moral Rights. Any assignment of copyright hereunder (and any ownership of a copyright as a work made for hire) includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "Moral Rights" (collectively, ***"Moral Rights"***). To the extent such Moral Rights cannot be assigned under applicable law and to the extent the following is allowed by the law in the various countries where Moral Rights exist, Consultant hereby waives such Moral Rights and consents to any action of the Company that would violate such Moral Rights in the absence of such consent.

(f) Holdover Assignment.

(i) Consultant agrees to, after the termination of Consultant's engagement with the Company for any reason, (1) disclose immediately to the Company all Inventions related to the Services, patentable or not; (2) assist, at the Company's expense, such applications for United States patents and foreign patents covering such Inventions related to the Services as the Company may request; (3) assign to the Company without further compensation to Consultant the entire title and rights to all such Inventions and applications related to the Services that Consultant may have; and (4) execute, acknowledge, deliver, or act as otherwise necessary at the request of the Company all such papers, including but not limited to patent applications, assignments, power of attorney, as necessary to secure the Company the full rights to such Inventions and applications related to the Services.

(ii) The Inventions related to the Services which shall come under this Section 8(f) shall include all Inventions related to the Services that (1) Consultant conceives, reduces to practice, or otherwise makes or develops, either solely or jointly with others, within one year after the termination of this Agreement; (2) are in any way based on any trade secret or confidential or proprietary information that Consultant learned during Consultant's engagement with the Company; (3) result from any work performed by Consultant for the Company under this Agreement; or (4) are in any way related to the subject matter or activities of Consultant's engagement with the Company.

9. Non-Solicitation or Hire of the Company Employees. During the term of this Agreement and for one year thereafter, Consultant shall not encourage or solicit any employee of the Company to leave the Company for any reason or to accept employment with Consultant or any other entity. As part of this restriction, Consultant shall not (a) interview or provide any input to any third party regarding any such employee during such time period, or (b) retain or hire in any capacity, either individually or for any person or entity by which Consultant may be engaged or with which Consultant may be affiliated, any person who is or was employed by the Company at any time during the term of this Agreement and six (6) months after the termination of this Agreement.

10. Non-Solicitation of Non-Employees. During the term of this Agreement and for one year thereafter, Consultant shall not interfere with or attempt to impair the relationship between the Company and any of its non-employee consultants and advisors, nor shall Consultant attempt, directly or indirectly, to solicit, entice, hire or otherwise induce any non-employee consultant or advisor of the Company to terminate association with the Company.

11. Company Authorization for Publication. Prior to Consultant's submitting or disclosing for possible publication or dissemination outside the Company any material prepared by Consultant that incorporates information that concerns the Company's business or anticipated research, Consultant agrees to deliver a copy of such material to the Company Representative for review. Within twenty (20) days following such submission, the Company agrees to notify Consultant in writing whether the Company believes such material contains any Proprietary Information or Inventions related to the Services, and Consultant agrees to make such deletions and revisions as are reasonably requested by the Company to protect its Proprietary Information and Inventions related to the Services. Consultant further agrees to obtain the written consent of the Company prior to any review of such material by persons outside the Company.

12. Former Employer Information. Consultant represents and certifies to the Company that Consultant's performance of all the terms of this Agreement and engagement as a consultant of the Company do not and shall not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by Consultant in confidence or in trust prior to Consultant's engagement by the Company, or violate the terms of any covenant not to compete between Consultant and any third party. Consultant shall not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employers of Consultant or any other third party.

13. Independent Contractor. The Company and Consultant mutually understand and agree that Consultant shall perform the Services under this Agreement as an independent contractor. Nothing in this Agreement is intended to allow the Company to exercise control or direction over the manner or method by which Consultant performs the Services. Nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture, or employment relationship between Client and Consultant. Consultant is not authorized to make any representation, contract or commitment on behalf of the Company. Consultant will not be entitled to any of the benefits that the Company may make available to its employees (including, but not limited to, group health or life insurance, profit sharing or retirement benefits), and agrees that Consultant is excluded from participating in any such benefit plans or programs as a result of the performance of the Services, without regard to Consultant's independent contractor status. The parties agree that the Company will not withhold any sums for income tax, unemployment insurance, social security, or any other withholding pursuant to any law or requirement of any governmental body on behalf of Consultant. Consultant is solely responsible for, and will file, on a timely basis, all tax returns and payments required to be filed with, or made to, any foreign, federal, state or local tax authority with respect to the performance of Services and receipt of fees under this Agreement, and Consultant agrees to indemnify the Company from any and all damages, costs, claims, expenses or other liability (including attorneys' fees) arising from or related to Consultant's failure to comply with any of the foregoing.

14. COMPLIANCE.

(a) Consultant will become familiar with and comply with the Company's written rules, regulations policies applicable to the Services that are provided to Consultant by the Company in advance of the performance of the Services.

(b) Both parties to this Agreement agree to comply with all applicable federal, state, and local laws and regulations in performing their obligations under this Agreement. Both parties to this Agreement expressly acknowledge that the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), prohibits the payment or receipt of remuneration as an inducement or reward for the referral, purchase, or ordering of items or services for which payment may be made in whole or in part under a federal health care program. It is the intention of the parties that this Agreement be performed in accordance with such anti-kickback statute. If any portion of this Agreement is found, by any court or agency with jurisdiction over the subject matter of the Agreement, not to be in compliance with such anti-kickback statute, that portion of the Agreement shall be deemed to be retroactively amended and reformed as necessary to comply with the statute, and the parties shall cooperate in taking any steps necessary to ensure such compliance.

15. WARRANTIES.

(a) Consultant represents and warrants that Consultant: (i) is skilled and experienced in providing the Services, and will perform the Services in a professional and workmanlike manner customary in the industry; (ii) has, and will maintain throughout the term of this Agreement, all training, licenses, certifications, and information necessary for safely and properly performing the Services; (iii) will perform the Services in accordance with the terms and conditions of this Agreement and all applicable laws, ordinances and regulations; (iv) has not been found by any agency to have violated any statutes, rules, or regulations concerning the conduct of clinical research or services substantially similar to the Services; nor has received any agency letter alleging the same; (v) has not been terminated from any investigation or research project by a sponsor or agency for misconduct; and (vi) has not been subject to any disciplinary actions by any applicable boards of medicine, institutional review boards, or other similar agencies, nor been subject to any other restrictions or sanctions related to allegations of research or professional misconduct.

(b) Consultant further represents and warrants that (i) Consultant has the full and unrestricted right to disclose any information, know-how, materials, knowledge or data disclosed by Consultant to the Company in the performance of this Agreement; and (ii) the data and Inventions will not infringe any third party intellectual property rights. Consultant agrees to promptly notify Company in writing in the event that any of the foregoing warranties change.

(c) Consultant further represents and certifies that Consultant has never been, is not currently, and during the term of this Agreement will not be: (i) excluded, debarred, suspended, or otherwise ineligible to participate in any federal health care program (e.g., Medicare, Medicaid, Tricare) or any U.S. government procurement or non-procurement program (i.e., listed on the Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities, www.oig.hhs.gov/exclusions, or the General Services Administration's System for Award Management, www.sam.gov); (ii) debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application; (iii) the subject of an FDA debarment investigation or proceeding (or similar proceeding of a foreign equivalent); (iv) convicted of or under indictment for a crime for which an individual or entity could be debarred under 21 U.S.C. § 335a(a) or (b); or (v) convicted of or under indictment for a criminal offense (A) bearing on trustworthiness or (B) that falls within the scope of 42 U.S.C. §§ 1320a-7, 1395ccc, 1395c-5, and/or regulations promulgated thereunder.

(d) Consultant shall promptly notify the Company in writing if, at any time during the term of this Agreement, any representation or certification of Consultant contained in this Agreement shall no longer be true and correct.

16. Non-Referral. The parties agree that Consultant is under no obligation to solicit, refer or solicit referrals of patients for any of the Company's business or products or to recommend the Company's products to patients, colleagues or other third parties. Consultant will not receive any benefit whatsoever for making patient referrals or for prescribing, purchasing, leasing or ordering any products or services from the Company. Consultant shall at all times act independently and exercise his own professional medical judgment in connection with his clinical and patient care work.

17. Publicity. Neither party shall use the name, symbols or marks of the other party or its officers or employees in any advertising or promotional material without the prior written consent of the other party. Consultant shall not make any public disclosure, whether to the press or otherwise, regarding the Services, without the prior written consent of the Company, unless required by applicable regulation or law.

18. Maintenance of Records. During the term of this Agreement and until the expiration of five (5) years after the furnishing of the Services pursuant to this Agreement, Consultant shall make available, upon written request of the Company or its designee, any records maintained by Consultant regarding any of the Services performed hereunder by Consultant.

19. No Authority to Bind. Neither party shall have power or authority to execute any agreements or contracts for or on behalf of the other party or to bind the other party in any other manner.

20. No Assignment. This Agreement may not be assigned by either party without the written consent of the other party; provided, however, that the Company may assign this Agreement to any purchaser of all or substantially all of its assets or business (by merger, asset sale, equity sale or otherwise) without Consultant's consent, provided that the Company notifies Consultant in writing of any such assignment. Any attempted pledge by Consultant of any of the rights under this Agreement or assignment of this Agreement without the prior consent of the Company shall be void.

21. Severability. The parties agree that if one or more provisions of this Agreement are held to be unenforceable under applicable law, such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

22. Binding Effect. This Agreement shall inure to the benefit of and be binding upon, the parties and their respective successors and permitted assigns.

23. Amendment. This Agreement may not be amended except by mutual written Agreement of the parties.

24. Equitable Relief. Each party acknowledges that a breach by the other party of this Agreement may cause the non-breaching party irreparable harm, for which an award of damages may not be adequate compensation and agrees that, in the event of such a breach or threatened breach, the non-breaching party will be entitled to seek equitable relief, including in the form of a restraining order, orders for preliminary or permanent injunction, specific performance, and any other relief that may be available from any court[, and the parties hereby waive any requirement for the securing or posting of any bond or the showing of actual monetary damages in connection with such relief. These remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available under this Agreement at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

25. Notices. All notices, requests, demands and other communications shall be in writing and shall be deemed to have been duly given or made if delivered by hand, in which case notice will be deemed effective upon receipt, or, if delivered by certified or registered mail, with postage prepaid to the address of such party set forth in the introductory paragraph of this Agreement or to such address directed by a party in writing, in which case notice will be deemed effective upon mailing. The return receipt, the delivery receipt, or the affidavit of messenger will be deemed conclusive but not exclusive evidence of delivery; delivery will also be presumed at such time as delivery is refused by the addressee upon presentation.

26. Entire Agreement. This Agreement shall constitute the entire agreement between the parties and supersedes any and all other written or oral agreements between Consultant and the Company with respect to the subject matter of this Agreement.

27. Governing Law; Consent to Jurisdiction; Waiver of Jury Trial. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to its principles of conflicts of laws. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the state and federal courts of the State of Delaware for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. EACH OF THE PARTIES HERETO WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.

28. **Counterparts/Electronic Execution and Delivery.** This Agreement may be executed in one or more counterparts and by facsimile, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Signatures of the parties transmitted by facsimile or via .pdf format shall be deemed to be their original signatures for all purposes. The words "execution," "signed," "signature," and words of like import shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the Michigan Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a facsimile machine or electronic mail (any such delivery, an ***"Electronic Delivery"***), will be treated in all manner and respects as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such agreement or instrument, each other party hereto or thereto will re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such agreement or instrument will raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such party forever waives any such defense, except to the extent such defense related to lack of authenticity.

Signatures on the Following Page

In Witness Whereof, the Company and Consultant have made this Agreement effective as of the date first set forth above.

CONSULTANT:

THE COMPANY:

Ocuphire Pharma, Inc.

EXHIBIT A

DESCRIPTION OF SERVICES

The Services shall include the following, the scope of which will be mutually agreed from time to time:

- Provide input on high-level strategies to improve organizational success in pipeline development
- Assit in finding ways to increase the profitability and success of the company
- Represents the company at internal and external events
- Support team with input on key business development initiatives
- Participates in business development initiative such as investments, fundraising, mergers and acquisitions, and strategic alliances

Exhibit B

Employee Proprietary Information, Inventions Assignment and Non-Solicitation Agreement

EMPLOYEE PROPRIETARY INFORMATION, INVENTIONS ASSIGNMENT AND NON-SOLICITATION AGREEMENT

THIS EMPLOYEE PROPRIETARY INFORMATION, INVENTIONS ASSIGNMENT AND NON-SOLICITATION AGREEMENT (this ***"Agreement"***) is made as of the date set forth below between **Ocuphire Pharma, Inc.**, a Delaware corporation (the ***"Company"***), and the undersigned employee of the Company (***"Employee"***).

This Agreement confirms certain terms of Employee's employment with the Company, which Employee acknowledges are a material part of the consideration for Employee's employment by the Company, and the compensation received by Employee from the Company from time to time.

1. **Definitions.** The following capitalized terms used in this Agreement shall have the following meanings:

   (a) ***"Company Documents and Materials"*** means documents or other media, whether in tangible or intangible form, that contain or embody Proprietary Information or any other information concerning the business, operations or plans of the Company, whether such documents or media have been prepared by Employee or by others. Company Documents and Materials include, without limitation, blueprints, drawings, photographs, charts, graphs, notebooks, tests, test results, experiments, customer lists, computer disks, tapes or printouts, sound recordings and other printed, electronic, typewritten or handwritten documents or information, sample products, prototypes and models.

   (b) ***"Inventions"*** means, without limitation, all software programs or subroutines, source or object code, algorithms, improvements, inventions, works of authorship, trade secrets, technology, designs, formulas, ideas, processes, techniques, know-how and data, whether or not patentable or copyrightable, made or discovered or conceived or reduced to practice or developed by Employee, either alone or jointly with others.

   (c) ***"Proprietary Information"*** means information that was or will be developed, created, or discovered by or on behalf of the Company, or which became or will become known to, or was or is conveyed to the Company, which has commercial value in the Company's business, whether or not patentable or copyrightable, including, without limitation, information about software programs and subroutines, source and object code, algorithms, trade secrets, designs, technology, know-how, processes, data, ideas, techniques, inventions, works of authorship, formulas, business and product development plans, customer lists, terms of compensation and performance levels of the Company's employees and consultants, the Company's customers and other information concerning the Company's actual or anticipated business, research or development, or which is received in confidence by or for the Company from any other person or entity.

   (j) **2. Confidentiality of Proprietary Information.**

   a. **Nature of Information.** Employee understands that the Company possesses and will possess Proprietary Information which is important to its business. Employee understands that Employee's engagement creates a relationship of confidence and trust between the Company and Employee with respect to Proprietary Information.

   b. **Property of the Company.** Employee acknowledges and agrees that all Company Documents and Materials, Proprietary Information and all patents, patent rights, copyrights, trade secret rights, trademark rights and other rights (including, without limitation, intellectual property rights) anywhere in the world in connection therewith is and shall be the sole property of the Company. Employee hereby assigns to the Company any and all rights, title and interest Employee may have or acquire in the Proprietary Information or any Company Documents and Materials.

c. **Confidentiality.** At all times, both during the term of Employee's engagement by the Company and after Employee's termination, Employee shall keep in confidence and trust and shall not use or disclose any Proprietary Information or anything relating to it without the prior written consent of the President or other duly designated officer of the Company, except as may be necessary in the ordinary course of performing Employee's duties for the Company; provided, however, that Employee shall have no such obligation with respect to Proprietary Information that (i) was already known to Employee at the time of its disclosure to Employee by or on behalf of the Company, as evidenced by written records (ii) at the time of disclosure to Employee was generally available to the public or otherwise in the public domain, or (iii) subsequent to such disclosure becomes generally available to the public without fault on Employee's part.

d. **Compelled Disclosure.** In the event that Employee is requested in any proceeding to disclose any Proprietary Information, Employee shall give the Company prompt notice of such request so that the Company may seek an appropriate protective order. If, in the absence of a protective order, Employee is nonetheless compelled by any court or tribunal of competent jurisdiction to disclose Proprietary Information, Employee may disclose such information without liability hereunder; provided, however, that Employee gives the Company notice of the Proprietary Information to be disclosed as far in advance of its disclosure as is practicable and uses Employee's best efforts to obtain assurances that confidential treatment will be accorded to such Proprietary Information.

e. **Records.** Employee agrees to make and maintain adequate and current written records, in a form specified by the Company, of all Inventions, trade secrets and works of authorship assigned or to be assigned to the Company pursuant to this Agreement.

f. **Handling of the Company Documents and Materials.** Employee agrees that during Employee's employment by the Company, Employee shall not remove any Company Documents and Materials from the business premises of the Company or deliver any Company Documents and Materials to any person or entity outside the Company, except as Employee may be required to do in connection with performing the duties of Employee's employment. Employee further agrees that, immediately upon the termination of Employee's employment by Employee or by the Company for any reason, or during Employee's employment if so requested by the Company, Employee shall return all Company Documents and Materials, apparatus, equipment and other physical property, or any reproduction of such property, excepting only (i) Employee's personal copies of personnel records and records relating to Employee's compensation; and (ii) Employee's copy of this Agreement.

g. **Notice of Immunity from Liability For Confidential Disclosure of a Trade Secret.** Pursuant to 18 USC § 1833(b), an individual may not be held criminally or civilly liable under any federal or state trade secret law for disclosure of a trade secret: (a) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law; and/or (b) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Additionally, an individual suing an employer for retaliation based on the reporting of a suspected violation of law may disclose a trade secret to his or her attorney and use the trade secret information in the court proceeding, so long as any document containing the trade secret is filed under seal and the individual does not disclose the trade secret except pursuant to court order. Nothing in this Agreement is intended to limit any rights under this federal law.

h. **Exclusions**. Notwithstanding anything in this Agreement to the contrary, Employee understands that nothing in this Agreement or any other agreement between Employee and the Company prohibits Employee, confidentially or otherwise, from communicating, cooperating, or filing a charge or complaint with a governmental or regulatory entity, participating in a governmental or regulatory entity investigation, or giving other disclosures to a governmental or regulatory entity, in each case without receiving prior authorization from, or having to disclose any such conduct to, the Company. Nothing in this Agreement shall (i) restrict or impede Employee from discussing the terms and conditions of Employee's employment or otherwise exercising Employee's rights under Section 7 of the National Labor Relations Act as protected by applicable law or (ii) be construed to limit Employee's right to receive an award for information provided to any governmental agency, including under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Further, nothing in this Agreement prohibits Employee from discussing or disclosing information that is expressly prohibited from being the subject of employee nondisclosure obligations under applicable law, such as information about unlawful acts in the workplace, including harassment or any other conduct that Employee has reason to believe is unlawful or in violation of public policy, or from speaking with an attorney regarding the same. Notwithstanding, in making any such disclosures or communications, Employee agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Proprietary Information to any parties other than the government agencies. Employee further understands that Employee is not permitted to disclose the Company's attorney-client privileged communications or attorney work product.

(k) 3. INVENTIONS.

(a) Disclosure. Employee shall promptly disclose in writing to Employee's immediate supervisor or to such other person designated by the Company all Inventions made during the term of Employee's employment. Employee shall also disclose to Employee's immediate supervisor or such designee all Inventions made, discovered, conceived, reduced to practice or developed by Employee either alone or jointly with others, within six (6) months after the termination of Employee's employment with the Company which resulted, in whole or in part, from Employee's prior employment by the Company. Such disclosures shall be received by the Company in confidence, to the extent such Inventions are not assigned to the Company pursuant to subsection (b) below, and do not extend the assignments made in such subsection.

(b) Assignment of Inventions to the Company. Except as provided in Sections 3(c) and 3(d), Employee agrees that all Inventions which Employee makes, discovers, conceives, reduces to practice or develops (in whole or in part, either alone or jointly with others) during Employee's employment, including, but not limited to, conceptions or ideas derived prior to employment and reduced to practice or developed (in whole or in part, either alone or jointly with others) during employment, shall be the sole property of the Company to the maximum extent permitted by law and Employee agrees to assign and hereby does assign to the Company all right title and interest to the Inventions.

(c) Works Made for Hire. Employee agrees that the Company shall be the sole owner of all patents, patent rights, copyrights, trade secret rights, trademark rights and all other intellectual property or other rights in connection with Inventions. Employee further acknowledges and agrees that such Inventions, including, without limitation, any computer programs, programming documentation and other works of authorship, are "works made for hire" for purposes of the Company's rights under copyright laws. Employee hereby assigns to the Company any and all rights, title and interest Employee may have or acquire in such Inventions. If in the course of Employee's employment with the Company, Employee incorporates into a Company product, process or a machine a prior Invention or improvement owned by Employee or in which Employee has an interest, and listed in Exhibit 1, the Company is hereby granted and shall have a non-exclusive, royalty-free, irrevocable, perpetual, sublicensable, worldwide license to make, have made, modify, use, market, sell and distribute such prior Invention as part of or in connection with such product process or machine. Pursuant to Section 3(d), if in the course of Employee's employment with the Company, Employee incorporates into a Company product, process or a machine a prior Invention or improvement owned by Employee or in which Employee has an interest, but not listed in Exhibit 1, Employee agrees to assign and hereby does assign all rights and interest in the Invention to the Company.

(d) List of Inventions. Employee has attached hereto as Exhibit 1 a complete list of all Inventions or improvements to which Employee claims ownership or in which Employee has an interest and that Employee desires to remove from the operation of this Agreement. Employee acknowledges and agrees that such list is complete. If no such list is attached to this Agreement or such Exhibit has not been completed and signed by Employee, Employee represents to the Company and agrees that Employee has no such Inventions or improvements at the time of signing this Agreement.

(e) Cooperation. Employee agrees to perform, during and after Employee's employment, all acts deemed necessary or desirable by the Company to permit and assist it, at the Company's expense, in further evidencing and perfecting the assignments made to the Company under this Agreement and in obtaining, maintaining, defending and enforcing patents, patent rights, copyrights, trademark rights, trade secret rights or any other rights in connection with such Inventions and improvements in any and all countries. Such acts may include, without limitation, execution of documents and assistance or cooperation in legal proceedings. Employee hereby irrevocably designates and appoints the Company and its duly authorized officers and agents, as Employee's agents and attorney-in-fact, coupled with an interest, to act for and on Employee's behalf and in Employee's place and stead, to execute and file any documents, applications or related findings and to do all other lawfully permitted acts to further the purposes set forth above in this Section, including, without limitation, the perfection of assignment and the prosecution and issuance of patents, patent applications, filing with the FDA, copyright applications and registrations, trademark applications and registrations or other rights in connection with such Inventions and improvements with the same legal force and effect as if executed by Employee.

(f) Assignment or Waiver of Moral Rights. Any assignment of copyright hereunder (and any ownership of a copyright as a work made for hire) includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "Moral Rights" (collectively, ***"Moral Rights"***). To the extent such Moral Rights cannot be assigned under applicable law and to the extent the following is allowed by the law in the various countries where Moral Rights exist, Employee hereby waives such Moral Rights and consents to any action of the Company that would violate such Moral Rights in the absence of such consent.

(g) Holdover Assignment.

i. Employee agrees to, after the termination of Employee's employment with the Company for any reason, (1) disclose immediately to the Company all Inventions, patentable or not; (2) assist, at the Company's expenses such applications for United States patents and foreign patents covering such Inventions as the Company may request; (3) assign to the Company without further compensation to Employee the entire title and rights to all such Inventions and applications that Employee may have, and (4) execute, acknowledge, deliver, or act as otherwise necessary at the request of the Company all such papers, including but not limited to patent applications, assignments, power of attorney, as necessary to secure the Company the fully rights to such Inventions and applications.

ii. The Inventions which shall come under this Section 3(g) shall include all Inventions that (1) Employee conceives, reduces to practice, or otherwise makes or develops, either solely or jointly with others, within one year after the termination of Employee's employment with the Company; and (2) are in any way based on any trade secret or confidential or proprietary information that Employee learned during employment at the Company; or result from any work performed by Employee for the Company; or are in any way related to the subject matter or activities of Employee's employment at the Company. If Employee believes that any Inventions Employee conceives, reduces to practice, or otherwise makes or develops, either solely or jointly with others, within one year after the termination of Employee's employment with the Company is not an Invention covered by Section 3(g)(ii)(2) of this Agreement, then Employee will disclose such Invention, along with all information and records pertaining to the Invention, and the Company will examine the disclosure in confidence to determine if in fact it is an Invention subject to this Agreement.

(l) 4. Non-Solicitation or Hire of Company Employees . During the term of Employee's employment and for one (1) year thereafter, Employee shall not encourage or solicit any employee of the Company to leave the Company for any reason or to accept employment with any other person or entity. As part of this restriction, Employee shall not (a) interview or provide any input to any third party regarding any such person during such time period, or (b) retain or hire in any capacity, either individually or for any company by which Employee may be employed or with which Employee may be affiliated, any person who is or was employed by the Company at any time during the time of Employee's employment with Company and six (6) months after the termination of Employee's employment with the Company. Notwithstanding the foregoing, the restrictions of this Section shall not apply with respect to the *bona fide* hiring and firing of the Company personnel to the extent such acts are part of Employee's duties for the Company.

(m) 5. Non-Solicitation of Non-Employees. During the term of this Agreement and for one (1) year thereafter, Employee shall not interfere with or attempt to impair the relationship between the Company and any of its non-employee consultants and advisors or customers, nor shall Employee attempt, directly or indirectly, to solicit, entice, hire or otherwise induce any non-employee consultant or advisor or customer of the Company to terminate association with Company.

(n) 6. Reasonableness of Terms. The Company and Employee agree that the terms contained in Sections 2-5 of this Agreement are reasonable in all respects and that the restrictions contained therein are designed to ensure that Employee does not engage in unfair competition with the Company. In the event a court determines that any of the terms or provisions of this Agreement are unreasonable, the court may limit the application of any provision or term, or modify any provision or term, and proceed to enforce this Agreement as so limited or modified.

(o) 7. Remedies. Employee acknowledges that a violation of the terms of this Agreement may give rise to irreparable injury to the Company inadequately compensable in damages, and accordingly, agrees that the Company may seek injunctive relief against such breach or threatened breach, in addition to any other legal remedies which may be available, including recovery of monetary damages. In any action successfully brought by the Company to enforce the rights of the Company against Employee under this Agreement, the Company shall also be entitled to recover reasonable attorneys' fees and costs of the action, and the period of the restrictions above shall be deemed to commence upon the entry of the court's order for relief.

(p) 8. GENERAL.

a. Severability. Employee agrees that if one or more provisions of this Agreement are held to be unenforceable under applicable law, such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

b. **Authorization to Notify New Employer.** Employee hereby authorizes the Company to notify Employee's new employer about Employee's rights and obligations under this Agreement following the termination of Employee's employment with the Company.

c. **Entire Agreement.** This Agreement sets forth the entire agreement and understanding between the Company and Employee relating to the subject matter herein and supersedes all prior discussions between them and any and all statements made by any officer, employee or representative of the Company regarding the Company's financial condition or future prospects. Employee understands and acknowledges that, except as set forth in this Agreement and in the offer letter from the Company to Employee, (i) no other representation or inducement has been made to Employee, (ii) Employee has relied on Employee's own judgment and investigation in accepting Employee's employment with the Company, and (iii) Employee has not relied on any representation or inducement made by any officer, employee or representative of the Company.

d. **Amendment.** No modification of or amendment to this Agreement nor any waiver of any rights under this Agreement shall be effective unless in a writing signed by the President of the Company and Employee. Employee understands and agrees that any subsequent change or changes in Employee's duties, salary or compensation shall not affect the validity or scope of this Agreement.

e. **Effective Date and Binding Effect.** This Agreement shall be effective as of the first day of Employee's employment with the Company and shall be binding upon Employee, Employee's heirs, executor, assigns and administrators and shall inure to the benefit of the Company, its subsidiaries, successors and assigns.

f. **Governing Law; Consent to Jurisdiction.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of Michigan, without regard to its principles of conflicts of laws. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the state and federal courts of the State of Michigan for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. BY SIGNING THIS AGREEMENT EMPLOYEE ALSO WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.

EMPLOYEE HAS READ THIS AGREEMENT CAREFULLY AND UNDERSTANDS AND ACCEPTS THE OBLIGATIONS WHICH IT IMPOSES UPON EMPLOYEE WITHOUT RESERVATION. NO PROMISES OR REPRESENTATIONS HAVE BEEN MADE TO EMPLOYEE TO INDUCE EMPLOYEE TO SIGN THIS AGREEMENT. EMPLOYEE SIGNS THIS AGREEMENT VOLUNTARILY AND FREELY.

[Signature Page Follows]

THE COMPANY: OCUPHIRE PHARMA, INC.

By:

Name: Amy Rabourn

Title: SVP of Finance

Date: October 22, 2024

EMPLOYEE:

Benjamin R. Yerxa, Ph.D.

Date: October 22, 2024

EXHIBIT 1

The following is a complete list of all Inventions or improvements relevant to the subject matter of Employee's employment by the Company that have been made or discovered or conceived or first reduced to practice by Employee either alone or jointly with others prior to Employee's employment by the Company that Employee desires to remove from the operation of the Company's Employee Proprietary Information, Inventions Assignment and Non-Solicitation Agreement:

No Inventions or improvements.

See below: Any and all Inventions regarding:

Additional sheets attached.

Employee proposes to bring to Employee's employment the following materials and documents of a former employer:

No materials or documents

See below:

Date:

Exhibit 10.2

CONSULTING AGREEMENT

This **Consulting Agreement** (this ***"Agreement"***) is made as of October 22, 2024 (the ***"Effective Date"***), between **Ocuphire Pharma, Inc.**, a Delaware corporation, having a principal place of business at 37000 Grand River Avenue, Suite 120, Farmington Hills, Michigan 48335 (the ***"Company"***), and **Jean Bennett, M.D., Ph.D.**, having an address at 182 Fishers Road, Bryn Mawr, PA 19010 (***"Consultant"***).

Background

The Company desires to retain Consultant, and Consultant desires to be engaged by the Company, to perform certain consulting services in the Field (as defined below) pursuant to the terms and conditions of this Agreement.

Terms and Conditions

Now, Therefore, in consideration of the foregoing and the terms, conditions and covenants hereinafter set forth, the Company and Consultant agree as follows:

1. Certain Definitions. Capitalized terms used in this Agreement and not otherwise defined shall have the following meanings:

(a) ***"Company Documents and Materials"*** means documents or other media, whether in tangible or intangible form, that contain or embody Proprietary Information or any other information concerning the Inventions or the business, operations, or plans of the Company, prepared by Consultant in the performance of the Services. Company Documents and Materials include, without limitation, blueprints, drawings, photographs, charts, graphs, notebooks, computer disks, tapes or printouts, sound recordings and other printed, electronic, typewritten or handwritten documents or information, sample products, prototypes and models.

(b) ***"Company Representative"*** means George Magrath, M.D., Chief Executive Officer.

(c) ***"Inventions"*** means, without limitation, all software programs or subroutines, source or object code, algorithms, improvements, inventions, works of authorship, trade secrets, technology, designs, formulas, ideas, processes, techniques, know-how and data, whether or not patentable or copyrightable, made or discovered or conceived or reduced to practice or developed by Consultant, either alone or jointly with others in connection with the Services.

(d) ***"Proprietary Information"*** means information developed, created, or discovered by or on behalf of the Company, which is disclosed by Company to Consultant, whether during or before the term of this Agreement, that is not generally known in Consultant's trade or industry and will include, without limitation, information about data, results, ideas, processes, techniques, formulae, know-how, improvements, discoveries, developments and design, tangible and intangible information relating to biological materials (such as cell lines, antibodies, tissue samples, proteins, nucleic acids and the like), assays and assay components and media, procedures and formulations for producing any such assays or assay components, and pre-clinical and clinical data, test, results, developments or experiments, plans for research, development and new therapeutics, technical information, tools, diagrams, plans, specifications, trade secrets, inventions, invention disclosures, concepts, structures, products, patents pending, patent applications, prototypes, processes, works in process, works of authorship, copyright applications, software programs and subroutines, source and object code, algorithms, trade secrets, designs, technology, know-how, processes, data, ideas, techniques, inventions, works of authorship, formulae, business and product development plans, customer lists, terms of compensation and performance levels of the Company's employees and consultants, the Company's customers and other information concerning the Company's actual or anticipated business, research or development, or which is received in confidence by or for the Company from any other person or entity.

(e) ***"Services"*** means the consulting services to be performed by Consultant on behalf of the Company described on Exhibit A attached hereto which relate only to the development of an oral platform for diabetic retinopathy that blocks new blood vessel formation and local non gene therapy treatment for geographic atrophy (the "***Field***").

2. Services. The Company hereby engages Consultant, and Consultant accepts such engagement, to perform the Services. Consultant will be free of control and direction from the Company (other than general oversight and control over the scope of work, results of the Services and timing of deliverables), and will have exclusive control over the manner and means of performing the Services, including the choice of place and time. The expected hours shall not exceed forty (40) hours per month. Consultant shall not be required to work any specified schedule but Consultant agrees to proceed with diligence and promptness. Consultant hereby represents and warrants that the Services shall be performed in accordance with the highest professional standards in the field to the reasonable satisfaction of the Company.

3. Term. The term of this Agreement shall commence on the Effective Date and terminate on October 21, 2025 (the "***Separation Date***") unless the parties mutually agree in writing to extend the term of this Agreement. Notwithstanding the foregoing, (a) either party may terminate this Agreement for any reason upon giving not less than thirty (30) days' notice to the other party, (b) the Company may terminate this Agreement immediately in the event of any embezzlement, non-performance of the Services, fraud or deceit in Consultant's performance of Consultant's obligations hereunder, or Consultant's violation of law, and (c) either party may terminate this Agreement immediately upon occurrence of any of the following events: (i) the breach of this Agreement by the other party, which breach is not cured within ten (10) business days after the breaching party's receipt of written notice of such breach from the non-breaching party, or (ii) the dissolution, voluntary or involuntary bankruptcy of either party, or assignment by either party of all or substantially all of its assets for the benefit of creditors. The rights and obligations of the parties hereto under Sections 6 through 28 of this Agreement shall survive the expiration or termination of this Agreement.

4. Compensation. As Consultant's sole consideration for the Services rendered pursuant to this Agreement, promptly following the Effective Date and approval by the Board, the Company shall grant Consultant a restricted stock unit award with respect to 100,000 shares of the Company's common stock, which award shall fully vest on the Separation Date or, if this Agreement is terminated prior to the Separation Date by the Company pursuant to Section 3(a) above or by the Consultant pursuant to Section 3(c)(i) above, then the award shall fully vest on the effective date of such termination, subject to Consultant's continued service with the Company through and including the Separation Date or effective date of termination, as applicable, and the terms and conditions set forth in the applicable award agreement and the Ocuphire Pharma, Inc. 2020 Equity Incentive Plan.[1] In addition, subject to the prior written approval of the Company Representative, the Company will pay or reimburse Consultant for all reasonable travel-related expenses incurred by Consultant in attending meetings and like events requested by the Company and any other expenses approved by the Company Representative in advance. All such expense reimbursements shall be subject to submission of appropriate documentation or receipts in accordance with the Company's Consultant & Contractor Reimbursable Expense Policy in effect from time to time (see Exhibit B attached hereto), and must be submitted to the Company for reimbursement within thirty (30) calendar days after such expenses were incurred by Consultant. Payment to Consultant of undisputed expenses will be due thirty (30) days following the Company's receipt of the expense reimbursement request with appropriate documentation.

5. Expenses and Liabilities. Consultant agrees that as an independent contractor, Consultant is solely responsible for all expenses Consultant incurs in connection with the performance of the Services, except for expenses that are pre-approved by the Company Representative in writing as described in Section 4 above. Notwithstanding the foregoing, (i) the Company will approve business class or first class for all domestic flights of five (5) hours or more, and for all international flights; (ii) all airline tickets will be the lowest cost refundable fare; and (iii) the Company shall pay for meeting registration and meeting housing in connection with situations where the primary function of Consultant is performance of Services. The Company shall have no obligation to reimburse Consultant for expenses that were not approved in advance by the Company. Consultant understands that Consultant will not be provided any office equipment or supplies to perform the Services and shall not be reimbursed for any supplies, equipment, or operating costs, nor will these costs of doing business be defrayed in any way by the Company.

6. Disclosure. Pursuant to applicable governmental laws, rules and regulations, Consultant understands and acknowledges that the Company may be required to disclose to relevant governmental authorities the payments made by or on behalf of the Company to Consultant under this Agreement, as well as the purpose and nature of such payments. Consultant shall keep accurate records regarding payments made and expenses incurred in connection with this Agreement and shall provide the Company with such information upon request. The Company will have the right to disclose (including on the Company's website) and report, as may be required by applicable law (including the Physician Payment Sunshine Act set forth in Section 6002 of the Patient Protection and Affordable Care Act of 2010, and similar state reporting laws), or as otherwise desired by the Company (a) information relating to the Services, including without limitation, all payments, reimbursement for expenses, or other transfers of value made in other than monetary form, (b) identifying information concerning Consultant, and any other information relating to this Agreement.

7. Confidentiality of Proprietary Information.

(a) Nature of Information. Consultant understands that the Company possesses and will possess Proprietary Information which is important to its business. Consultant understands that Consultant's engagement creates a relationship of confidence and trust between the Company and Consultant with respect to Proprietary Information.

(b) Property of the Company. Consultant acknowledges and agrees that all Company Documents and Materials, Proprietary Information, and all patents, patent rights, copyrights, trade secret rights, trademark rights and other rights (including, without limitation, intellectual property rights) anywhere in the world in connection therewith is and shall be the sole property of the Company. Consultant hereby assigns to the Company any and all rights, title and interest Consultant may have or acquire in any Proprietary Information, or Company Documents and Materials.

(c) Confidentiality. At all times during the term of this Agreement and thereafter, Consultant shall keep in confidence and trust and shall not use or disclose any Proprietary Information or anything relating to it without the prior written consent of the Company Representative, except as may be necessary in the ordinary course of performing the Services. The obligations of confidentiality and non-disclosure set forth herein shall not apply to any information that:

(i) was already known to Consultant prior to receipt hereunder as evidenced by Consultant's written records;

(ii) is or later becomes publicly available other than through a breach of this Agreement by Consultant;

(iii) is lawfully disclosed to Consultant by a third party under no confidentiality obligations; and/or

(iv) Consultant is given written permission to disclose by an authorized representative of Company.

(d) Compelled Disclosure. In the event that Consultant is requested in any proceeding to disclose any Proprietary Information, Consultant shall give the Company prompt notice of such request so that the Company may seek an appropriate protective order. If, in the absence of a protective order, Consultant is nonetheless compelled by any court or tribunal of competent jurisdiction to disclose Proprietary Information, Consultant may disclose such information without liability hereunder; provided, however, that Consultant gives the Company notice of the Proprietary Information to be disclosed as far in advance of its disclosure as is practicable and uses Consultant's best efforts to obtain assurances that confidential treatment will be accorded to such Proprietary Information.

(e) Records. Consultant agrees to make and maintain adequate and current written records, in a form specified by the Company, of all Inventions, trade secrets and works of authorship assigned or to be assigned to the Company pursuant to this Agreement.

(f) Handling of the Company Documents and Materials. Consultant agrees that during Consultant's engagement by the Company, Consultant shall not remove any Company Documents and Materials from the business premises of the Company or deliver any Company Documents and Materials to any person or entity outside the Company, except as Consultant may be required to do in connection with performing the Services. Consultant further agrees that, immediately upon the termination of Consultant's engagement for any reason, or during Consultant's engagement if so requested by the Company, Consultant shall return all Company Documents and Materials, apparatus, equipment and other physical property, or any reproduction of such property, excepting only Consultant's copy of this Agreement.

(g) Notice of Immunity from Liability For Confidential Disclosure of a Trade Secret. Pursuant to 18 USC § 1833(b), if Consultant is an individual, Consultant may not be held criminally or civilly liable under any federal or state trade secret law for disclosure of a trade secret: (a) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law; and/or (b) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Additionally, In addition, if Consultant is an individual and Consultant files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Consultant may disclose the trade secret to Consultant's attorney and may use the trade secret information in the court proceeding, if Consultant (X) files any document containing the trade secret under seal; and (Y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to limit any rights under this federal law.

8. INVENTIONS.

(a) Disclosure. Consultant shall promptly disclose in writing to the Company Representative or to such person designated by the Company Representative all Inventions made during the term of Consultant's engagement with the Company related to the Services. Consultant shall also disclose to the Company Representative all Inventions made, discovered, conceived, reduced to practice or developed by Consultant either alone or jointly with others, within six (6) months after the termination of Consultant's engagement with the Company which resulted, in whole or in part, from Consultant's prior engagement with the Company and are related to the Services. Such disclosures shall be received by the Company in confidence, to the extent such Inventions are not assigned to the Company pursuant to subsection (b) below, and do not extend the assignments made in such subsection.

(b) Assignment of Inventions to the Company. Consultant agrees that all Inventions which Consultant makes, discovers, conceives, reduces to practice or develops (in whole or in part, either alone or jointly with others) during Consultant's engagement related only to the Services, including, but not limited to, conceptions or ideas derived prior to Consultant's engagement but related to the Services and reduced to practice or developed (in whole or in part, either alone or jointly with others) during Consultant's engagement with the Company, shall be the sole property of the Company to the maximum extent permitted by law. Consultant hereby irrevocably and exclusively assigns to the Company in perpetuity, without further consideration, all of Consultant's right, title and interest (including, without limitation, all patent rights, copyrights, trademark rights, trade secret rights and other proprietary and/or intellectual property rights, and all renewals thereof) throughout the United States and in all other countries or jurisdictions, free and clear of all liens and encumbrances, in and to all such Inventions. If in the course of Consultant's engagement with the Company, Consultant incorporates into a Company Invention, product, process, or machine a prior Invention or improvement not related to the Services that is owned by Consultant or in which Consultant has an interest, Consultant hereby does assign all rights and interest in such prior Invention to the Company. To the extent that any such prior Invention is not deemed to be assignable as provided in this Section 8(b), the Company is hereby granted and shall have a non-exclusive, royalty-free, irrevocable, perpetual, sublicensable, worldwide license to make, have made, modify, use, market, sell and distribute such prior Invention as part of or in connection with such product, process or machine.

(c) Ownership of Copyrightable Inventions. Consultant agrees that the Company shall be the sole owner of all patents, patent rights, copyrights, trade secret rights, trademark rights and all other intellectual property or other rights in connection with Inventions related to the Services. Consultant further acknowledges and agrees that such Inventions related to the Services that are copyrightable Inventions were created by or for Consultant (whether alone or with others) on behalf of the Company or for the benefit of the Company and shall be the sole and complete property of the Company, and any and all copyrights to such Inventions shall belong exclusively and perpetually to the Company throughout the world. Consultant shall not attempt to register any works created by Consultant pursuant to this Agreement at the U.S. Copyright Office, the U.S. Patent & Trademark Office, or any foreign copyright, patent, or trademark registry.

(d) Cooperation. Consultant agrees to perform, during and after Consultant's engagement, all acts deemed necessary or desirable by the Company to permit and assist it, at the Company's expense, in further evidencing and perfecting the assignments made to the Company under this Agreement and in obtaining, maintaining, defending and enforcing patents, patent rights, copyrights, trademark rights, trade secret rights or any other rights in connection with such Inventions and improvements related to the Services in any and all countries. Such acts may include, without limitation, execution of documents and assistance or cooperation in legal proceedings. If the Company is unable after reasonable efforts to locate Consultant or Consultant fails to timely respond to the Company's requests regarding execution of documents relating to the assignments authorized under this Agreement, Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents, as Consultant's agents and attorney-in-fact, coupled with an interest, to act for and on Consultant's behalf and in Consultant's place and stead, to execute and file any documents, applications or related findings and to do all other lawfully permitted acts strictly limited to furthering the purposes set forth above in this Section 8(d), including, without limitation, the perfection of assignment and the prosecution and issuance of patents, patent applications, filing with the FDA, copyright applications and registrations, trademark applications and registrations or other rights in connection with such Inventions and improvements related to the Services with the same legal force and effect as if executed by Consultant.

(e) Assignment or Waiver of Moral Rights. Any assignment of copyright hereunder (and any ownership of a copyright as a work made for hire) includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "Moral Rights" (collectively, ***"Moral Rights"***). To the extent such Moral Rights cannot be assigned under applicable law and to the extent the following is allowed by the law in the various countries where Moral Rights exist, Consultant hereby waives such Moral Rights and consents to any action of the Company that would violate such Moral Rights in the absence of such consent.

(f) Holdover Assignment.

(i) Consultant agrees to, after the termination of Consultant's engagement with the Company for any reason, (1) disclose immediately to the Company all Inventions related to the Services, patentable or not; (2) assist, at the Company's expense, such applications for United States patents and foreign patents covering such Inventions related to the Services as the Company may request; (3) assign to the Company without further compensation to Consultant the entire title and rights to all such Inventions and applications related to the Services that Consultant may have; and (4) execute, acknowledge, deliver, or act as otherwise necessary at the request of the Company all such papers, including but not limited to patent applications, assignments, power of attorney, as necessary to secure the Company the full rights to such Inventions and applications related to the Services.

(ii) The Inventions related to the Services which shall come under this Section 8(f) shall include all Inventions related to the Services that (1) Consultant conceives, reduces to practice, or otherwise makes or develops, either solely or jointly with others, within one year after the termination of this Agreement; (2) are in any way based on any trade secret or confidential or proprietary information that Consultant learned during Consultant's engagement with the Company; (3) result from any work performed by Consultant for the Company under this Agreement; or (4) are in any way related to the Field.

9. Non-Solicitation or Hire of the Company Employees. During the term of this Agreement and for one (1) year thereafter, Consultant shall not encourage or solicit any employee of the Company to leave the Company for any reason or to accept employment with Consultant or any other entity. As part of this restriction, Consultant shall not (a) interview or provide any input to any third party regarding any such employee during such time period, or (b) retain or hire in any capacity, either individually or for any person or entity by which Consultant may be engaged or with which Consultant may be affiliated, any person who is or was employed by the Company at any time during the term of this Agreement and six (6) months after the termination of this Agreement.

10. Non-Solicitation of Non-Employees. During the term of this Agreement and for one (1) year thereafter, Consultant shall not interfere with or attempt to impair the relationship between the Company and any of its non-employee consultants and advisors, nor shall Consultant attempt, directly or indirectly, to solicit, entice, hire or otherwise induce any non-employee consultant or advisor of the Company to terminate association with the Company.

11. Company Authorization for Publication. Prior to Consultant's submitting or disclosing for possible publication or dissemination outside the Company any material prepared by Consultant that incorporates information that concerns the Company's business or anticipated research, Consultant agrees to deliver a copy of such material to the Company Representative for review. Within twenty (20) days following such submission, the Company agrees to notify Consultant in writing whether the Company believes such material contains any Proprietary Information or Inventions related to the Services, and Consultant agrees to make such deletions and revisions as are reasonably requested by the Company to protect its Proprietary Information and Inventions related to the Services. Consultant further agrees to obtain the written consent of the Company prior to any review of such material by persons outside the Company.

12. Former Employer Information. Consultant represents and certifies to the Company that Consultant's performance of all the terms of this Agreement and engagement as a consultant of the Company do not and shall not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by Consultant in confidence or in trust prior to Consultant's engagement by the Company, or violate the terms of any covenant not to compete between Consultant and any third party. Consultant shall not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employers of Consultant or any other third party.

13. Independent Contractor. The Company and Consultant mutually understand and agree that Consultant shall perform the Services under this Agreement as an independent contractor. Nothing in this Agreement is intended to allow the Company to exercise control or direction over the manner or method by which Consultant performs the Services. Nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture, or employment relationship between Client and Consultant. Consultant is not authorized to make any representation, contract or commitment on behalf of the Company. Consultant will not be entitled to any of the benefits that the Company may make available to its employees (including, but not limited to, group health or life insurance, profit sharing or retirement benefits), and agrees that Consultant is excluded from participating in any such benefit plans or programs as a result of the performance of the Services, without regard to Consultant's independent contractor status. The parties agree that the Company will not withhold any sums for income tax, unemployment insurance, social security, or any other withholding pursuant to any law or requirement of any governmental body on behalf of Consultant. Consultant is solely responsible for, and will file, on a timely basis, all tax returns and payments required to be filed with, or made to, any foreign, federal, state or local tax authority with respect to the performance of Services and receipt of fees under this Agreement, and Consultant agrees to indemnify the Company from any and all damages, costs, claims, expenses or other liability (including attorneys' fees) arising from or related to Consultant's failure to comply with any of the foregoing.

14. COMPLIANCE.

(a) Consultant will become familiar with and comply with the Company's written rules, regulations and policies applicable to the Services that are provided to Consultant by the Company in advance of the performance of the Services.

(b) Both parties to this Agreement agree to comply with all applicable federal, state, and local laws and regulations in performing their obligations under this Agreement. Both parties to this Agreement expressly acknowledge that the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), prohibits the payment or receipt of remuneration as an inducement or reward for the referral, purchase, or ordering of items or services for which payment may be made in whole or in part under a federal health care program. It is the intention of the parties that this Agreement be performed in accordance with such anti-kickback statute. If any portion of this Agreement is found, by any court or agency with jurisdiction over the subject matter of the Agreement, not to be in compliance with such anti-kickback statute, that portion of the Agreement shall be deemed to be retroactively amended and reformed as necessary to comply with the statute, and the parties shall cooperate in taking any steps necessary to ensure such compliance.

15. WARRANTIES.

(a) Consultant represents and warrants that Consultant: (i) is skilled and experienced in providing the Services, and will perform the Services in a professional and workmanlike manner customary in the industry; (ii) has, and will maintain throughout the term of this Agreement, all training, licenses, certifications, and information necessary for safely and properly performing the Services; (iii) will perform the Services in accordance with the terms and conditions of this Agreement and all applicable laws, ordinances and regulations; (iv) has not been found by any agency to have violated any statutes, rules, or regulations concerning the conduct of clinical research or services substantially similar to the Services; nor has received any agency letter alleging the same; (v) has not been terminated from any investigation or research project by a sponsor or agency for misconduct; and (vi) has not been subject to any disciplinary actions by any applicable boards of medicine, institutional review boards, or other similar agencies, nor been subject to any other restrictions or sanctions related to allegations of research or professional misconduct.

(b) Consultant further represents and warrants that (i) Consultant has the full and unrestricted right to disclose any information, know-how, materials, knowledge or data disclosed by Consultant to the Company in the performance of this Agreement; and (ii) the data and Inventions will not infringe any third party intellectual property rights. Consultant agrees to promptly notify Company in writing in the event that any of the foregoing warranties change.

(c) Consultant further represents and certifies that Consultant has never been, is not currently, and during the term of this Agreement will not be: (i) excluded, debarred, suspended, or otherwise ineligible to participate in any federal health care program (e.g., Medicare, Medicaid, Tricare) or any U.S. government procurement or non-procurement program (i.e., listed on the Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities, www.oig.hhs.gov/exclusions, or the General Services Administration's System for Award Management, www.sam.gov); (ii) debarred by the FDA pursuant to 21 U.S.C. § 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application; (iii) the subject of an FDA debarment investigation or proceeding (or similar proceeding of a foreign equivalent); (iv) convicted of or under indictment for a crime for which an individual or entity could be debarred under 21 U.S.C. § 335a(a) or (b); or (v) convicted of or under indictment for a criminal offense (A) bearing on trustworthiness or (B) that falls within the scope of 42 U.S.C. §§ 1320a-7, 1395ccc, 1395c-5, and/or regulations promulgated thereunder.

(d) Consultant shall promptly notify the Company in writing if, at any time during the term of this Agreement, any representation or certification of Consultant contained in this Agreement shall no longer be true and correct.

16. Non-Referral. The parties agree that Consultant is under no obligation to solicit, refer or solicit referrals of patients for any of the Company's business or products or to recommend the Company's products to patients, colleagues or other third parties. Consultant will not receive any benefit whatsoever for making patient referrals or for prescribing, purchasing, leasing or ordering any products or services from the Company. Consultant shall at all times act independently and exercise his own professional medical judgment in connection with his clinical and patient care work.

17. Publicity. Neither party shall use the name, symbols or marks of the other party or its officers or employees in any advertising or promotional material without the prior written consent of the other party. Consultant shall not make any public disclosure, whether to the press or otherwise, regarding the Services, without the prior written consent of the Company, unless required by applicable regulation or law.

18. Maintenance of Records. During the term of this Agreement and until the expiration of five (5) years after the furnishing of the Services pursuant to this Agreement, Consultant shall make available, upon written request of the Company or its designee, any records maintained by Consultant regarding any of the Services performed hereunder by Consultant.

19. No Authority to Bind. Neither party shall have power or authority to execute any agreements or contracts for or on behalf of the other party or to bind the other party in any other manner.

20. No Assignment. This Agreement may not be assigned by either party without the written consent of the other party; provided, however, that the Company may assign this Agreement to any purchaser of all or substantially all of its assets or business (by merger, asset sale, equity sale or otherwise) without Consultant's consent, provided that the Company notifies Consultant in writing of any such assignment. Any attempted pledge by Consultant of any of the rights under this Agreement or assignment of this Agreement without the prior consent of the Company shall be void.

21. Severability. The parties agree that if one or more provisions of this Agreement are held to be unenforceable under applicable law, such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

22. Binding Effect. This Agreement shall inure to the benefit of and be binding upon, the parties and their respective successors and permitted assigns.

23. Amendment. This Agreement may not be amended except by mutual written Agreement of the parties.

24. Equitable Relief. Each party acknowledges that a breach by the other party of this Agreement may cause the non-breaching party irreparable harm, for which an award of damages may not be adequate compensation and agrees that, in the event of such a breach or threatened breach, the non-breaching party will be entitled to seek equitable relief, including in the form of a restraining order, orders for preliminary or permanent injunction, specific performance, and any other relief that may be available from any court, and the parties hereby waive any requirement for the securing or posting of any bond or the showing of actual monetary damages in connection with such relief. These remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available under this Agreement at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

25. Notices. All notices, requests, demands and other communications shall be in writing and shall be deemed to have been duly given or made if delivered by hand, in which case notice will be deemed effective upon receipt, or, if delivered by certified or registered mail, with postage prepaid to the address of such party set forth in the introductory paragraph of this Agreement or to such address directed by a party in writing, in which case notice will be deemed effective upon mailing. The return receipt, the delivery receipt, or the affidavit of messenger will be deemed conclusive but not exclusive evidence of delivery; delivery will also be presumed at such time as delivery is refused by the addressee upon presentation.

26. Entire Agreement. This Agreement shall constitute the entire agreement between the parties and supersedes any and all other written or oral agreements between Consultant and the Company with respect to the subject matter of this Agreement.

27. **Governing Law; Consent to Jurisdiction; Waiver of Jury Trial.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of Michigan, without regard to its principles of conflicts of laws. Each of the parties hereto irrevocably submits to the exclusive jurisdiction of the state and federal courts of the State of Michigan for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement and the transactions contemplated hereby. Each of the parties hereto irrevocably consents to the jurisdiction of any such court in any such suit, action or proceeding and to the laying of venue in such court. Each party hereto irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. EACH OF THE PARTIES HERETO WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.

28. **Counterparts/Electronic Execution and Delivery.** This Agreement may be executed in one or more counterparts and by facsimile, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Signatures of the parties transmitted by facsimile or via .pdf format shall be deemed to be their original signatures for all purposes. The words "execution," "signed," "signature," and words of like import shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the Michigan Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a facsimile machine or electronic mail (any such delivery, an ***"Electronic Delivery"***), will be treated in all manner and respects as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such agreement or instrument, each other party hereto or thereto will re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such agreement or instrument will raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each such party forever waives any such defense, except to the extent such defense related to lack of authenticity.

Signatures on the Following Page

In Witness Whereof, the Company and Consultant have made this Agreement effective as of the date first set forth above.

CONSULTANT:	**THE COMPANY:**
	Ocuphire Pharma, Inc.
/s/ Jean Bennett	/s/ George Magrath
Jean Bennett, M.D. Ph.D.	George Magrath, M.D. CEO

EXHIBIT A

DESCRIPTION OF SERVICES

The Services shall include the following, the scope of which will be mutually agreed from time to time:

Providing scientific consulting on the manufacturing, development, and clinical trials for the IRD programs.

EXHIBIT B

Consultant & Contractor
Reimbursable Expense Policy

1. GENERAL

1. **Introduction**
The Reimbursable Expense Policy should be used as a basis for submitting expenses relating to any Consultant and/or Contractor Agreement for the Ocuphire Pharma. This policy also pertains to all reimbursable expenses by sub- consultants/ contractors on any Ocuphire Pharma project.

2. **Policy**
Official reimbursable expenses shall be properly authorized, processed, conducted, reported, and reimbursed in accordance to this Policy.

Consultants/Contractors are expected to exercise good judgment in the type and amount of expense incurred.

The Consultant/Contractor is responsible for becoming familiar with and adhering to the Policy as applicable for each reimbursable expense submitted.

For travel expenses, Consultants/Contractors are expected to plan in advance of the departure date to obtain lowest cost fares, rates and accommodations. In addition, Consultant/Contractors are encouraged to use all practical means, including internet discounters, to obtain the lowest cost fares, rates, and accommodations.

3. **Definitions**

The following definitions apply to this Policy:

Domestic Travel – Travel between business points within the continental United States (CONUS).

Actual and Reasonable Expenses – The specific, itemized expenses incurred, based on original receipts up to the amount judged by the Ocuphire employee managing the consultant and the Head of Human Resources to justifiable under the circumstances.

Official Travel Time – For computing per diem allowances, official travel starts at the day (time) the consultant leaves their home, office, or other authorized point and ends on the day (time) the consultant returns home, to the office, or other authorized point.

3. **Definitions *continued***

Travel Expenses – Includes meals, lodging, transportation and incidental expenses for less than 30 consecutive days.

Extended Travel Expenses - Includes meals, lodging, transportation and incidental expenses for 30 or more consecutive days.

Reimbursable expenses – those official expenses directly related to a project or assignment related to an executed contract or agreement.

4. **Reimbursements**

Expenses incurred by the Consultant/Contractor performed outside the scope of the Consultant/Contractor Agreement will be denied. This includes, but is not limited to, expenses incurred:

- Prior to the execution of the Agreement;
- After the expiration of the Agreement;
- At a location not included in the Agreement;
- At a cost in excess of those costs allowed within the Agreement and/or within this Policy.
- In connection with other agreements the Consultant/Contractor has with other clients.

Only those expenses which are ordinary and necessary, and within the allowable budget, to accomplish the official business purpose are eligible for reimbursement.

Entertainment expenses, including alcohol, are not reimbursable.

Consultants/Contractors will be responsible for all unapproved travel and related expenses.

5. **Interrupted Itinerary**

If official business travel is interrupted for personal convenience, any resulting expense shall be borne by the Consultant/Contractor.

1. **Guideline**
   Consultants must utilize the most economical mode of transportation and the most usually traveled route consistent with the business purpose of the trip.

2. **Official Travel Time**
   Travel time will be paid at 50% of the hourly rate

3. **Air Travel**
   Lowest Available Airfare

   Airfare reimbursement shall not exceed the lowest practical, available cost of competing airfare. When all considerations are equal (e.g. travel time dates, times, destination, and work impacted by travel), the consultant must choose the lowest fare available at that time, regardless of personal preferences for air carrier.

   Use of Business or First Class

   No reimbursement will be made for Business or First Class travel without advance written approval from the Ocuphire Contracting Director (or designee).

   (Note: Business or First Class accommodations obtained through use of frequent flyer programs or at Consultant's expense will not require advance approval.

   However, Consultant must be able to the lowest available price of Coach accommodations in order to be reimbursed from that portion of the expense.) First Class travel may be approved under the following circumstances:

   - Required to accommodate a disability or special medical need (requires proof from a medical doctor);
   - No other class of service (coach or business) is available within 24 hours of the proposed departure or arrival time.

   Business Class travel may be approved under the following circumstances:

   - No other class of service is provided on regularly scheduled flights between origin and destination.
   - Required to accommodate a disability or special medical need.
   - An overall savings (subsistence costs, overtime, lost productivity time) compared to waiting for coach class.

Extended Travel to Save Costs
The additional expenses associated with travel that includes an extended stay (e.g. Saturday night stay) may be reimbursed when the overall savings is at least $150 compared to the cost if the Consultant had not extended the trip.

The additional expenses that must be considered for the extended stay savings include but not limited to are, additional cost of lodging, rental car, meals and parking.

4. **Travel by Private Automobile**

Reimbursement for Travel by Private Automobile
When a private automobile is used *due to business necessity*, actual mileage will be reimbursed at the most current rate allowable by the Internal Revenue Service. The number of miles driven must be documented by the Consultant. No additional reimbursement is made for expenses related to the use of the automobile. Routine repairs, cleaning, detailing, tires, gasoline, or other automobile expense items are not reimbursed for privately owned automobiles.

When two or more persons share a privately owned automobile, only the driver may claim the reimbursement for mileage. Two or more persons traveling to the same destination, for the same purpose, and same or approximately the same time span on the same days or days shall be expected to share a privately owned automobile whenever possible.

Charges for parking and toll roads are allowed; however receipts must be provided.

Reimbursement for Travel by Private Automobile in Lieu of Air Travel

When a private automobile is used instead of available air travel for the personal convenience of the Consultant, reimbursement of transportation costs by private automobile shall not exceed the documented amount of airfare Consultant would have paid had the Consultant traveled by air.

Reimbursement for Travel To or From a Common Carrier Terminal
When a Consultant drives a privately owned automobile to or from a common carrier terminal, the mileage and tolls for one round trip, plus parking for the duration of the trip may be claimed for reimbursement.

Documented miles driven and receipts must be provided. Consultant is expected to use the lowest, reasonable cost parking option available.

Rental Vehicles

Rental cars may be used for transportation to or from a common carrier terminal. Rental cars may also be used upon arrival at the official business destination when the use of public transportation or other transportation such as taxis is not practical when cost, number of miles to be traveled and other factors are taken into consideration. Only commercial agencies may be used. Consultants are strongly encouraged to request the lowest available rate when making rental car reservations.

Reimbursement

Reimbursement is limited to standard sedans or a vehicle commensurate with the requirements of the trip. The cost of the rental car and gasoline will be reimbursed. Documented miles driven and receipts are must be provided.

The car must be turned in promptly. Daily charges, outside Official Travel Time, will not be reimbursed.

Insurance

The Consultant assumes all risks and expenses associated with obtaining insurance deemed necessary when using a rental car. Car rental insurance, including collision damage waivers, is not reimbursable

Ground Transportation
The following guidelines apply to ground transportation to or from a common carrier terminal at the business point.

Taxis

The cost of the taxi ride plus gratuity will be reimbursed. Receipts must be provided.

Airport Shuttle Service

The cost of the airport shuttle ride plus gratuity will be reimbursed. Receipts must be provided.

Local Buses and Subways

Local bus and subway fares are reimbursable; however, receipts are not required.

Lodging

Lodging expenses for travel within the Continental United States (CONUS) are reimbursed at actual cost, up to the maximum rate established in the U.S. General Services Administration (GSA) Federal Travel Regulation Domestic Per Diem Rates. Lodging taxes, although not included in the GSA per diem rate for lodging, are additionally reimbursable. Consultants are strongly encouraged to request the lowest available rate when making the lodging reservations.

Hotel bills should show the hotel name and locations, dates room was occupied and the rate per day. Other items appearing on the hotel bill should be identified as to the business reason for the charges.

Consultant will not be reimbursed for the following expenses appearing on the hotel bill:

- Alcohol (alone or part of meal)
- Entertainment
- Personal services in general
- Laundry/Dry cleaning if travel is less than five days

When accommodations are shared with other than an official Consultant, reimbursement is limited to the cost that would have been incurred had the Consultant been traveling alone.

Non-Commercial Lodging
Consultants lodging in non-commercial facilities such as house trailers or field camping are reimbursed actual expenses up to the maximum applicable GSA lodging rate. No reimbursement for housing as a guest in a private home.

Meals Expense
Meals expense for travel within the Continental United States (CONUS) are reimbursed at actual cost, up to the maximum rate established in the U. S. General Services Administration (GSA) Federal Travel Regulation Domestic Per Diem Rate

Meals expense for the first and last day of travel are reimbursed at the lower of actual costs or the pro-rated GSA per diem rate listed below:

Beginning of "Official Travel Time" Date of Departure		Ending of "Official Travel Time" Date of Departure	
Prior to 11:00 am	100% per diem	Prior to 11:00 am	33% per diem
11:01 am to 5:00 pm	66% per diem	11:01 am to 5:00 pm	66% per diem
After 5:00 pm	33% per diem	After 5:00 pm	100% per diem

For travel of more than 12 hours but less than 24 hours; meals are reimbursed at the pro-rated GSA per diem rates defined above.

Daily expenses incurred within the vicinity of the Consultant's primary work site shall not be reimbursed.

Incidental Expenses
Payments for tolls, parking charges, cab fares can be reimbursed with proper documentation. Reasonable laundry and dry cleaning expenses will be allowed if travel is over a period of 5 consecutive days. Additionally, reasonable gratuities shall be reimbursed.

Expenses for entertainment and personal convenience items such as alcohol, in-room movies, reading materials and clothing are not reimbursable.

Daily Allowance and Lodging Allowance for Extended Travel A Consultant remaining at one location for 30 days or more but not more than six months shall be considered extended travel. The 30 days begins on the first day at the assignment location. The Consultant's return home for weekends does not break the continuity of an extended travel assignment.

The maximum reimbursable rate for extended travel will be the lesser of actual costs of lodging (housekeeping, utilities and furniture rental), meals, and incidentals (as previously outlined above) **or** 60% of the maximum rate established in the U. S. General Services Administration (GSA) Federal Travel Regulation Domestic Per Diem Rates.

All extended travel must be approved in advance by the Contracting Director or designee prior to Consultant committing to any extended lodging arrangement

Daily Allowance and Lodging Allowance for Extended Travel

Consultants are encouraged to require employees to relocate to the primary work site, when practical, to avoid excessive Extended Travel and/or repetitive Travel for weekly commute to the primary work site from Consultant or Consultant's employees'

4. Miscellaneous Expenses

General

Miscellaneous expenses that are ordinary and necessary to accomplish the official business purpose of the trip are reimbursable. Receipts are required for all miscellaneous expenses. The most common of these expenses are as follows:

- Use of computers, printers, faxing machines, and scanners.
- Postage and delivery.
- Office supplies specific to the project.

Expenses that will not be reimbursed will be items for personal use or items that do not have a direct business reason or benefit to the project. Examples of these expenses are:

- Business gifts.
- Snacks or other entertainment items for staff meetings and/or meetings with sub-consultants.
- Mileage expense for purchase of items, where the direct project related item was purchased was not the sole reason for the trip.
- Carrying cases for cell phones or computers.
- Items that could be used on more than one project.

Telephone Calls

Telephone calls should be made in the most economical method possible. Claims for phone call require a statement of the date, person called, phone number, and business reason for the call.

Personal phone calls are not reimbursable.

Reimbursement

A travel expense statement must be prepared and submitted with the appropriate supporting documents. Expenses should be itemized chronologically according to the nature and type of travel expense (i.e. airfare, hotel, meals, etc.). The completed and supported travel expense statement should be submitted within 30 days of the travel. Any expense submitted beyond this time will not be reimbursed.

Exhibit 10.3

SECOND AMENDMENT TO

OCUPHIRE PHARMA, INC.

2021 INDUCEMENT PLAN

WHEREAS, Ocuphire Pharma, Inc. (the "***Company***") has heretofore adopted the Ocuphire Pharma, Inc. 2021 Inducement Plan, as amended (the "***Plan***"); and

WHEREAS, the Company wishes to amend the Plan to increase the number of shares of common stock of the Company, par value $0.0001 per share, available for issuance under the Plan;

NOW, THEREFORE, the Plan shall be amended, effective as the date hereof, as follows:

1. The first sentence of Section 3(a) is deleted and replaced with the following:

Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed 2,625,258 shares (the ***"Share Reserve"***).

2. Except as modified herein, the remaining terms of the Plan shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the undersigned officer of the Company, acting pursuant to authority granted to the officer by the Board of Directors of the Company, has executed this instrument on this 20th day of October, 2024.

OCUPHIRE PHARMA, INC.

By: /s/ George Magrath

Name: Dr. George Magrath
Title: Chief Executive Officer

Exhibit 31.1

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

I, George Magrath, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Opus Genetics, Inc., a Delaware corporation formerly known as Ocuphire Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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 12, 2024

/s/ George Magrath

Name: George Magrath
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Nirav Jhaveri, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Opus Genetics, Inc., a Delaware corporation formerly known as Ocuphire Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ Nirav Jhaveri

Name: Nirav Jhaveri
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Report") of Opus Genetics, Inc., a Delaware corporation formerly known as Ocuphire Pharma, Inc. (the "Company"), as filed with the Securities and Exchange Commission, George Magrath, as Chief Executive Officer of the Company, and Nirav Jhaveri, as Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of his knowledge and belief:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and

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

/s/ George Magrath

George Magrath
Chief Executive Officer
(Principal Executive Officer)

/s/ Nirav Jhaveri

Nirav Jhaveri
Chief Financial Officer
(Principal Financial Officer)

Dated: November 12, 2024