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, 2025

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 No.)
8 Davis Drive, Suite 220 Durham, NC	**27713**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (984) 884-6030

N/A
(Former name or former address, if changed since last report)

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

Title of each class	Trading Symbol	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 10, 2025 was 68,964,208.

OPUS GENETICS, INC.
FORM 10-Q
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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Opus Genetics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share amounts and par value)

	As of	
	September 30, 2025	December 31, 2024
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 30,815	$ 30,321
Accounts receivable	2,916	3,563
Contract assets and unbilled receivables (Note 11)	1,364	2,209
Prepaids and other current assets	815	515
Short-term investments	—	2
Total current assets	35,910	36,610
Property and equipment, net	212	252
Total assets	$ 36,122	$ 36,862
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,395	$ 3,148
Accrued expenses and other liabilities	5,367	8,147
Warrant liabilities	21,325	—
Total current liabilities	29,087	11,295
Long-term funding agreement, related party	1,068	—
Total liabilities	30,155	11,295
Commitments and contingencies (Note 4 and Note 10)		
Series A preferred stock, par value $0.0001; 14,146 shares were designated as of September 30, 2025 and December 31, 2024; zero and 14,145.374 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively.	—	18,843
Stockholders' equity:		
Preferred stock, par value $0.0001; 9,985,854 shares authorized as of September 30, 2025 and December 31, 2024; no shares issued and outstanding at September 30, 2025 and December 31, 2024.	—	—
Common stock, par value $0.0001; 125,000,000 shares authorized as of September 30, 2025 and December 31, 2024; 64,544,096 and 31,574,657 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively.	6	3
Additional paid-in capital	178,027	145,719
Accumulated deficit	(172,066)	(138,998)
Total stockholders' equity	5,967	6,724
Total liabilities, Series A preferred stock and stockholders' equity	$ 36,122	$ 36,862

See accompanying notes

Opus Genetics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
License and collaborations revenue	$ 3,079	$ 3,867	$ 10,331	$ 6,690
Operating expenses:				
General and administrative	4,981	2,894	17,093	10,918
Research and development	6,409	8,982	20,384	19,817
Total operating expenses	11,390	11,876	37,477	30,735
Loss from operations	(8,311)	(8,009)	(27,146)	(24,045)
Fair value change in warrant and other derivative liabilities	(9,525)	—	(5,803)	—
Financing costs	—	—	(1,337)	—
Interest expense	(68)	—	(68)	—
Other income, net	450	483	1,286	1,648
Loss before income taxes	(17,454)	(7,526)	(33,068)	(22,397)
Benefit (provision) for income taxes	—	—	—	—
Net loss	(17,454)	(7,526)	(33,068)	(22,397)
Other comprehensive loss, net of tax	—	—	—	—
Comprehensive loss	$ (17,454)	$ (7,526)	$ (33,068)	$ (22,397)
Net loss per share:				
Basic and diluted	$ (0.25)	$ (0.29)	$ (0.59)	$ (0.88)
Number of shares used in per share calculations:				
Basic and diluted	70,636,887	26,145,080	56,100,689	25,501,117

See accompanying notes.

Opus Genetics, Inc.
Condensed Consolidated Statements of Changes in Series A Preferred Stock and Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Series A Preferred Stock		Common Stock		Additional Paid–In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
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	—	456
Issuance costs	—	—	—	—	(42)	—	(42)
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
Balance at December 31, 2024	14,145.374	$ 18,843	31,574,657	$ 3	$ 145,719	$ (138,998)	$ 6,724
Issuance of common stock and pre-funded warrants in connection with the March 2025 offering and private placement	—	—	13,396,207	1	5,979	—	5,980
Issuance of common stock in connection with at-the-market program	—	—	352,953	1	408	—	409
Issuance costs	—	—	—	—	(728)	—	(728)
Stock-based compensation		—	186,919	—	913	—	913
Share repurchases for the payment of employee taxes	—	—	(31,913)	—	(36)	—	(36)
Exercise of stock options	—	—	5,000	—	5	—	5
Net and comprehensive loss	—	—	—	—	—	(8,194)	(8,194)
Balance at March 31, 2025	14,145.374	18,843	45,483,823	5	152,260	(147,192)	5,073
Conversion of preferred stock	(14,145.374)	(18,843)	14,145,374	1	18,842	—	18,843
Stock-based compensation	—	—	278,858	—	896	—	896
Issuance cost, net credit	—	—	—	—	81	—	81
Net and comprehensive loss	—	—	—	—	—	(7,420)	(7,420)
Balance at June 30, 2025	—	—	59,908,055	6	172,079	(154,612)	17,473
Issuance of common stock in connection with private placement and at-the-market program	—	—	4,611,041	—	5,217	—	5,217
Issuance costs	—	—	—	—	(107)	—	(107)
Stock-based compensation	—	—	—	—	816	—	816
Exercise of stock options	—	—	25,000	—	22	—	22
Net and comprehensive loss	—	—	—	—	—	(17,454)	(17,454)
Balance at September 30, 2025	—	$ —	64,544,096	$ 6	$ 178,027	$ (172,066)	$ 5,967

See accompanying notes.

Opus Genetics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	For the Nine Months Ended September 30,	
	2025	**2024**
Operating activities		
Net loss	$ (33,068)	$ (22,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,625	2,567
Depreciation	40	—
Fair value change in warrant and other derivative liabilities	5,803	—
Non-cash interest	68	—
Unrealized loss from short-term investments	2	12
Warrant financing costs	1,337	—
Change in assets and liabilities:		
Accounts receivable	647	(931)
Contract assets and unbilled receivables	845	(61)
Prepaids and other current assets	(300)	670
Accounts payable	(797)	(1,319)
Accrued expenses	(2,622)	3,321
Net cash used in operating activities	(25,420)	(18,138)
Investing activities		
Net cash used in investing activities	—	—
Financing activities		
Proceeds from issuance of common stock and pre-funded warrants in connection with the March 2025 offering and March 2025 private placement	5,980	—
Proceeds from issuance of warrants in connection with the March 2025 offering and March 2025 private placement	15,520	—
Proceeds from issuance of common stock in connection with the at-the-market program, private placement and purchase agreement	5,626	4,497
Proceeds from funding agreement, related party	1,000	—
Issuance costs	(2,203)	(186)
Exercise of stock options	27	—
Share repurchases for the payment of employee taxes	(36)	(42)
Net cash provided by financing activities	25,914	4,269
Net increase (decrease) in cash and cash equivalents	494	(13,869)
Cash and cash equivalents at beginning of period	30,321	50,501
Cash and cash equivalents at end of period	$ 30,815	$ 36,632
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ —	$ —
Supplemental non-cash financing transactions:		
Conversion of Series A preferred stock into common stock	$ 18,843	$ —
Change in unpaid issuance costs	$ 112	$ 46

See accompanying notes.

Notes to Condensed Consolidated Financial Statements

1. Company Description and Summary of Significant Accounting Policies

Nature of Business and Basis of Presentation

Opus Genetics, Inc. (the "Company" or "Opus"), a Delaware corporation formerly known as Ocuphire Pharma, Inc. (the "Company" or "Opus"), is a clinical-stage biopharmaceutical company developing gene therapies for the treatment of inherited retinal diseases ("IRDs") and small molecule therapies for other ophthalmic disorders. The Company's headquarters is located in Durham, North Carolina.

On October 22, 2024, the Company acquired a private corporation then operating under the name of "Opus Genetics, Inc." ("Private 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, Private Opus, and certain merger subsidiaries party thereto.

The Company's pipeline includes assets from the adeno-associated virus ("AAV") based gene therapy portfolio of Private Opus that address mutations in genes that cause different forms of Leber congenital amaurosis ("LCA"), bestrophinopathy, 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. More specifically, we are developing OPGx-LCA5 to treat LCA5-associated inherited retinal disease ("IRD"), an early-onset retinal degeneration, and an open-label, dose-escalation Phase 1/2 clinical trial is ongoing. OPGx-BEST1 is another gene therapy candidate in the Company's portfolio. This asset is being developed for the treatment of IRDs associated with mutations in the BEST1 gene, which can lead to legal blindness. Apart from gene therapies, the Company's pipeline also includes Phentolamine Ophthalmic Solution 0.75%, a non-selective alpha-1 and alpha-2 adrenergic antagonist to reduce pupil size as well as APX3330, a novel small-molecule inhibitor of Ref-1 designed to slow the progression of non-proliferative diabetic retinopathy.

In November 2022, the Company entered into a license and collaboration agreement (as amended, the "Viatris License Agreement") with 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% ("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 is also developing PS for the treatment of presbyopia, an ophthalmic disorder that involves the progressive loss of ability to focus on close objects that results in blurred near vision, difficulty seeing in dim light, and eye strain. Additionally, the Company is currently developing PS for decreased vision under mesopic (low) light conditions following keratorefractive surgery, pursuant to a received FDA agreement under Special Protocol Assessment ("SPA").

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and include the accounts of the Company's subsidiary. All intercompany transactions and balances have been eliminated in consolidation. 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 Company's fiscal year begins on January 1 and ends on December 31.

The December 31, 2024 condensed consolidated 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. The accompanying condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2024 included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2025.

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.

The derivative liability line item reflected on the December 31, 2024 consolidated balance sheet in the prior year was reclassified to the accrued expenses and other liabilities line item in the amount of $2,000.

Liquidity

Since its inception, the Company has devoted substantially all of its resources to drug development and clinical trials.

The Company expects that its cash and cash equivalents as of September 30, 2025 of $30.8 million will be sufficient to fund its operations for at least the next 12 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 issue debt financing, may provide additional liquidity in the future, however these actions are not solely within the control of the Company and the Company is unable to predict the outcome of these actions to generate the liquidity ultimately required.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated 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 are 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. 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 condensed consolidated 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.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 1, *"Company Description and Summary of Significant Accounting Policies*" to the consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2024, that was filed with the SEC, on March 31, 2025. Since the date of those financial statements, except as set forth below under "Warrant liabilities", there have been no material changes to the Company's significant accounting policies.

Warrant liabilities

The Company issued warrants to purchase equity securities in connection with the March 2025 financings and are recorded under the warrant liabilities line item in the accompany condensed consolidated balance sheets (See Note 8 – Financings). The Company accounts for these warrants as a liability at fair value when the valuation inputs are not fixed and determinable. Additionally, issuance costs associated with the warrant liability were expensed as incurred and reflected as financing costs in the accompanying condensed consolidated statements of comprehensive loss. The Company adjusts the liability for changes in fair value until the earlier of; 1) the exercise or 2) expiration of the warrants. Any future change in fair value of the warrant liabilities, when outstanding, is recognized in the condensed consolidated statements of comprehensive loss under the fair value change in warrant and other derivative liabilities line item.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("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 has determined that the adoption of this guidance will augment its income tax disclosures related mainly to categorical detail in the rate reconciliation and jurisdictional detail associated with income taxes paid.

In November 2024, the FASB issued ASU 2024-03 *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses. This ASU is intended to improve the disclosures related to expenses and provide investors more detailed information about certain types of expenses. This ASU is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the potential impact that this new standard will have on our consolidated financial statements and related disclosures.

2. Mergers

Acquisition of Opus Genetics

As described in Note 1 – Company Description and Summary of Significant Accounting Policies, on October 22, 2024, the Company completed the stock purchase of Private Opus. Under the terms of the Merger Agreement, at the closing of the Opus Acquisition, the Company issued to the security holders of Private Opus 5,237,063 shares of the Company's common stock, par value $0.0001 per share ("common stock"), 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 was convertible into 1,000 shares of common stock, subject to stockholder approval, which was obtained at the Company's Annual Meeting of Stockholders held on April 30, 2025. Following the closing of the Opus Acquisition, the Company had 31,435,507 shares of common stock and 14,145.374 shares of Series A preferred stock outstanding. The total consideration in connection with the Opus Acquisition was $25.8 million. The transaction was accounted for as an asset acquisition in accordance with ASC 805, *Business Combinations*, as one asset, the underlying intellectual property associated with the IRD therapies, comprised more than 90% of Private Opus's assets.

Merger with Rexahn

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

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 (as defined in the CVR Agreement) and the payment of all amounts payable thereunder. As of September 30, 2025, 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 of September 30, 2025, as there were no potential milestones yet considered probable beyond those previously reported.

3. 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, 2025 and December 31, 2024, 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 long-term funding agreement, related party line item was determined on an amortized cost basis, based on an effective rate of interest.

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 liabilities associated with the equity line financing facility and the March 2025 Warrants and March 2025 Private Placement Warrants (as defined below) are 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 and market interest rates (See Note 8 – Financings). There were no transfers between fair value hierarchy levels during the three and nine months ended September 30, 2025 and 2024.

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

	As of September 30, 2025			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ —*	$ —*	$ —	$ —
Total assets at fair value	$ —*	$ —*	$ —	$ —
Liabilities:				
Warrant liabilities	$ 21,325	$ —	$ —	$ 21,325
Other derivative liabilities	—	—	—	—
Total liabilities at fair value	$ 21,325	$ —	$ —	$ 21,325

**De minimis* value

	As of December 31, 2024			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 2	$ 2	$ —	$ —
Total assets at fair value	$ 2	$ 2	$ —	$ —
Liabilities:				
Other derivative liabilities	$ 2	$ —	$ —	$ 2
Total liabilities at fair value	$ 2	$ —	$ —	$ 2

The following table provides a roll-forward of short-term investments measured at fair value on a recurring basis using observable level 1 inputs for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	**2024**
Short-term investments		
Balance as of beginning of period	$ 2	$ 15
Unrealized loss	(2)	(12)
Balance as of end of period	$ —*	$ 3

**De minimis* value

The following table provides a roll-forward of liabilities measured at fair value on a recurring basis using unobservable level 3 inputs for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Warrant liabilities		
Balance as of beginning of period	$ —	$ —
Issuance of March 2025 Warrants and March 2025 Private Placement Warrants	15,520	—
Change in fair value	5,805	—
Balance as of end of period	$ 21,325	$ —

	Nine Months Ended September 30,	
	2025	2024
Other derivative liabilities		
Balance as of beginning of period	$ 2	$ 74
Change in fair value	(2)	—
Balance as of end of period	$ —	$ 74

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

4. 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 10 – Apexian Sublicense Agreement). As of September 30, 2025, 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.

University of Pennsylvania LCA5/RDH12 License Agreement

On June 15, 2022, Opus entered into an amended and restated license agreement (the "LCA5/RDH12 Agreement") with the Trustees of the University of Pennsylvania ("Penn") pursuant to which it was granted an exclusive, royalty-bearing license to certain patents and a non-exclusive license to certain information relating to products directed towards treatment or correction of mutation of the LCA5 or RDH12 genes. In return for these rights, the Company is obligated to make certain development, regulatory and commercial milestone payments up to a maximum potential aggregate amount of $2.6 million and royalty payments on future net sales of such products. Until the Company is required to pay royalties under the LCA5/RDH12 Agreement, the Company must pay a *de minimis* annual license maintenance fee to Penn. The Company is also obligated to make payments on any sublicense income, with such percentage depending on the stage of product development, which there was no sublicense income for any of the periods presented. During the quarter ended September 30, 2025, the first development milestone under the LCA5/RDH12 Agreement was satisfied and the related amount payable was included in accrued expenses and other liabilities as of September 30, 2025 and research and development expense for the three and nine months ended September 30, 2025.

Iveric Asset Purchase Agreement – BEST1 and RHO Programs

On December 23, 2022, Opus entered into an asset purchase agreement (the "Iveric Agreement") with a subsidiary of Iveric Bio, Inc. ("Iveric") pursuant to which the Company acquired certain assets, including the BEST1 License (as defined below), relating to the BEST1 and RHO products. In return for these rights, the Company is obligated to make payments to Iveric upon the achievement of specified development and commercial milestones, the maximum potential aggregate amount of such payments being $111.7 million. As of September 30, 2025, the Company determined that none of the future obligations under the agreement were probable and therefore no liabilities were recorded related to the agreement.

Penn and University of Florida BEST1 License Agreement

On April 10, 2019, Iveric entered into an exclusive patent license agreement (as amended, the "BEST1 License") with Penn and the University of Florida Research Foundation ("UF"), which agreement was assigned to Opus under the terms of the Iveric Agreement. Under the BEST1 License, Opus received exclusive patent rights and non-exclusive knowhow and data rights with regard to products to treat diseases associated with mutations in the BEST1 gene. In return for these rights, the Company is obligated to make payments to Penn upon the achievement of certain clinical, regulatory and commercial milestones, the maximum potential aggregate amount of such payments being $76.4 million. The Company is also obligated to make royalty payments on future net sales of licensed BEST1 products. Until the Company is required to pay royalties under the BEST1 License, the Company must pay a *de minimis* annual license maintenance fee to UF and Penn. The Company must also make payments on any sublicense income, with such percentage depending on the stage of product development, which there was no sublicense income during any of the periods presented. In consideration for Penn and UF's consent to the assignment of the BEST1 License to us under the Iveric Agreement, the Company will also pay Penn a percentage of each milestone payment that we are required to pay to Iveric under the Iveric Agreement. As of September 30, 2025, the Company determined that none of the future obligations under the agreement were probable and therefore no liabilities were recorded related to the agreement.

Penn and UF RHO License Agreement

On June 6, 2018, Iveric entered into an exclusive patent license agreement (the "RHO License") by and between Penn and UF pursuant to which the Company has exclusive patent rights and non-exclusive knowhow and data rights with regard to products to treat rhodopsin-mediated diseases as a result of the Iveric Agreement as defined above. In return for these rights, the Company is obligated to make development and commercial milestone payments, the maximum potential aggregate amount of such payments being $93.5 million and royalty payments on future sales of such products. As of September 30, 2025, the Company determined that none of the future obligations under the agreement were probable and therefore no liabilities were recorded related to the agreement.

Massachusetts Eye and Ear Infirmary License Agreement

On November 9, 2021, Opus entered into a license agreement with the Massachusetts Eye and Ear Infirmary ("MEEI"), granting an exclusive worldwide license of MEEI patents for use in the NMNAT1 program for all products and processes including the treatment of retinal disease in humans, and a non-exclusive worldwide license to technological information. In return for these rights, the Company is obligated to make development milestone payments, the maximum potential aggregate amount of such payments being $0.4 million and royalty payments on future sales of such products. As of September 30, 2025, the Company determined that none of the future obligations under the agreement were probable and therefore no liabilities were recorded related to the agreement.

Facility and Other Leases

On January 1, 2025, the Company relocated its headquarters to Durham, North Carolina. On July 1st, 2025, the Company amended the lease for its headquarters in Durham, North Carolina for three months through September 30, 2025, and the lease is currently in place on a month-to-month basis. The headquarters lease qualifies for the short-term exception under ASC 842, *Leases*.

The Company also leases additional laboratory space in Durham, North Carolina on a month-to-month basis. Upon the Opus Acquisition, the Company assumed a number of equipment leases that expired in July 2025 and are now on a month-to-month basis. Both the laboratory space and equipment leases qualify for the short-term exception under ASC 842, *Leases*.

The rent expense associated with all leases amounted to $0.1 million and less than $0.1 million during the three months ended September 30, 2025 and 2024, respectively and $0.2 million and less than $0.1 million during the nine months ended September 30, 2025 and 2024, respectively.

Other

In the ordinary course of business, from time to time, the Company may be subject to a broad range of claims and legal proceedings that relate to contractual allegations, patent infringement and other claims. In addition, the Company from time to time may be potentially committed to reimburse third parties for costs incurred associated with business development related transactions upon the achievement of certain milestones. The Company establishes accruals when applicable for matters and commitments for which it believes losses are probable and can be reasonably estimated.

Notes to Condensed Consolidated Financial Statements

5. Supplemental Balance Sheet Information

Accrued expenses and other liabilities

Accrued expenses and other liabilities consist of the following (in thousands):

	As of	
	September 30, 2025	December 31, 2024
Research and development services and supplies	$ 2,821	$ 4,452
Compensation and benefits	1,422	1,481
Professional services	856	1,608
Other	268	606
Total	$ 5,367	$ 8,147

6. Related Party Transactions

Consulting Agreements with Dr. Pepose

On April 11, 2024, the Company entered into a consulting agreement (the "Pepose Consulting Agreement") with Dr. Pepose, a former director of the Company. Pursuant to the Pepose Consulting Agreement, Dr. Pepose was paid a monthly consulting fee and 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 vested in 12 equal monthly installments that began on May 11, 2024 and concluded on April 11, 2025. On November 21, 2024, the Pepose Consulting Agreement was amended to continue through April 11, 2026.

For the agreements with Dr. Pepose described above, the Company incurred related consulting expenses of $0.1 million and $0.4 million during the three and nine months ended September 30, 2025, respectively, and the Company incurred related consulting expenses of $0.1 million and $0.3 million during the three and nine months ended September 30, 2024, respectively.

March 2025 Subscription Agreements with Dr. George Magrath and Cam Gallagher

On March 21, 2025, the Company entered into a subscription agreement with each of Dr. George Magrath, the Company's Chief Executive Officer, and Cam Gallagher, the chairman of the Company's board of directors (the "Board"), in connection with a private offering of our securities. For more information, see Note 8 – Financings.

August 2025 Subscription Agreements with Cam Gallagher and Sean Ainsworth

On August 25, 2025, the Company entered into subscription agreements pursuant to which the Company agreed to issue and sell in a private placement (the "August 2025 Private Placement") to certain investors 3,138,338 shares of its common stock for gross proceeds of approximately $3.5 million.

The August 2025 Private Placement was led by Cam Gallagher, Chair of the Company's Board, with an investment of $1.0 million, along with participation by Sean Ainsworth, the lead independent director of the Board, in the amount of $0.1 million, and other investors for the balance of the Private Placement. For more information, see Note 8 – Financings.

Consulting Agreement with Dr. Jean 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 the Company's common stock, which award vested on October 22, 2025. The Company incurred no consulting expenses, beyond the stock-based compensation associated with the restricted stock unit award, during the three and nine months ended September 30, 2025, respectively.

Letter Agreement and Strategic Partnership—FFB

On August 25, 2022, Private Opus entered into a binding letter of agreement ("2022 Binding Letter Agreement") with Foundation Fighting Blindness ("FFB") and the Jaeb Center for Health Research (the "JCHR") to collaborate on natural history studies involving individuals with retinal dystrophies associated with mutations in multiple genes of interest. Under the terms of the 2022 Binding Letter Agreement, FFB and the JCHR had the sole responsibility and authority to design and conduct the study, with input from the Company. Subject to certain conditions, the 2022 Binding Letter Agreement required that the Company provide FFB with a total of $2.0 million of funding to support the study, such amount being payable in an initial installment of $0.4 million at the time of submission of the final study protocol to the Institutional Review Board of the JCHR and, subject to certain conditions, in four annual installments of $0.4 million on the anniversaries of such submission. On May 27, 2025, the Company entered into a binding letter of agreement ("2025 Letter Agreement") with FFB and the JCHR, which superseded and canceled the 2022 Binding Letter Agreement. As of September 30, 2025 a total of $0.4 million was paid by the Company under the 2022 Binding Letter Agreement and no more payments were due under the 2022 Binding Letter Agreement.

Under the 2025 Letter Agreement, the Company will collaborate with FFB and the JCHR on portions of a study involving individuals with retinal dystrophies associated with mutations in the RDH12 or BEST1 genes (the "Study"). The term of this 2025 Letter Agreement ends on the date that is two months from the Study's completion. FFB and the JCHR, as its designee, shall have the sole responsibility and authority to design and conduct the Study, with input from the Company. Under the 2025 Letter Agreement, the Company is obligated to make two payments to FFB: (1) $0.3 million on or before June 30, 2025 and (2) $0.3 million on or before January 31, 2027 upon receipt of semi-annual reports from FFB outlining the progress being made in the Study, including visit completion status and publication plans, and the ability for the Company to provide ongoing comments and suggestions regarding possible changes to the Study. Such payments shall constitute the sole compensation paid to FFB in return for Company access to research materials and datasets.

The Company paid the initial $0.3 million due on or before June 30, 2025 under the 2025 Letter Agreement which was recorded as research and development expense. As of September 30, 2025, the Company is required to fund one additional installment in the aggregate of $0.3 million upon receipt of future semi-annual reports.

RDF Agreement

On June 13, 2025, the Company entered into a funding agreement (the "RDF Agreement") with the Foundation Fighting Blindness Retinal Degeneration Fund ("RDF"), whose sole member is FFB, a significant stockholder of the Company, relating to the Company's program to develop gene therapies to treat patients impacted by retinitis pigmentosa caused by pathogenic variants in the Mer proto-oncogene tyrosine kinase (MERTK) gene (the "MERTK Program"). The RDF Agreement provides for nondilutive funding by RDF of up to $2.0 million to support the development of the MERTK Program, $1.0 million of which was disbursed to the Company in June 2025 and up to $1.0 million of which may be disbursed to the Company upon achievement of a specified development milestone subject to RDF's receipt of eligible funds.

Under the RDF Agreement, the Company is subject to certain diligence obligations to develop and commercialize a product under the MERTK Program. If the Company is unable to achieve certain milestones by certain dates, or otherwise fails to meet its diligence obligations, the Company will be obligated to collaborate with RDF to out-license or otherwise make applicable rights available to a third party.

Notes to Condensed Consolidated Financial Statements

In addition, the Company will pay a milestone payment equal to the total amounts funded by RDF under the RDF Agreement upon the achievement of a regulatory milestone. The Company will also make tiered royalty payments to RDF in low-to-mid single percentages until RDF has received aggregate royalty payments equal to 300% of the amounts funded by RDF under the Agreement. In the event of a change of control of the Company or a sale or exclusive license of the MERTK Program, RDF will have the option to require the Company to buy out RDF's interest under the Agreement for an amount equal to 100% of the funds disbursed to the Company under the Agreement. The Agreement may be terminated by either party for cause, including material breach or bankruptcy, subject to a cure period.

The RDF Agreement was accounted for as debt under ASC 470, *Debt*. ASC 470 requires interest expense to be recorded under an effective interest rate method. During the three and nine months ended September 30, 2025, interest expense was $0.1 million based on an effective rate of interest of 22.3% and was recorded as interest expense in the accompanying condensed consolidated statements of comprehensive loss. The accreted liability in connection with the RDF Agreement was $1.1 million as of September 30, 2025 and was recorded under the long-term funding agreement, related party line item in the accompanying condensed consolidated balance sheets.

7. Series A Preferred Stock

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 authorization of 14,146 shares of Series A preferred stock, of which 14,145.374 Series A preferred stock were issued upon close of the Opus Acquisition. On April 30, 2025, the Company held its 2025 Annual Meeting of Stockholders. During the 2025 Annual Meeting, the Company's stockholders voted to approve the conversion of each share of Series A preferred stock into 1,000 shares of common stock. Subsequently, on May 5, 2025, all shares of Series A preferred stock were converted into 14,145,374 shares of common stock.

8. Financings

August 2025 Private Placement

On August 25, 2025, the Company entered into subscription agreements pursuant to which the Company agreed to issue and sell in the August 2025 Private Placement to certain investors 3,138,338 shares of its common stock for gross, and net, proceeds of approximately $3.5 million.

The Company intends to use the net proceeds of the August 2025 Private Placement to expedite manufacturing process development, including scale-up of clinical and commercial production and testing, to ensure sufficient supply of cGMP material for its gene therapy candidates, OPGx-LCA5 and OPGx-BEST1. No underwriting discounts or commissions were paid with respect to the August 2025 Private Placement.

The August 2025 Private Placement was led by Cam Gallagher, Chair of the Board, along with participation by Sean Ainsworth, the lead independent director of the Board, and other investors. See Note 6 – Related Party Transactions.

March 2025 Financings

On March 21, 2025, the Company entered into an underwriting agreement with Craig-Hallum Capital Group, LLC, as the sole underwriter. Pursuant to the underwriting agreement, the Company agreed to issue and sell, in an underwritten public offering (the "March 2025 Offering"), 12,219,736 shares of common stock and warrants to purchase up to 21,052,631 shares of common stock (the "March 2025 Warrants"). Each share of common stock was sold together with one March 2025 Warrant to purchase one share of common stock, at a price to the public of $0.95 per share and related March 2025 Warrant. The Company also issued 8,832,895 pre-funded warrants ("Pre-Funded Warrants") at a price to the public of $0.9499 per Pre-funded Warrant.

On March 21, 2025, the Company entered into a subscription agreement (the "Subscription Agreement") with each of Dr. George Magrath, the Company's Chief Executive Officer, and Cam Gallagher, the chairman of the Board. Pursuant to the Subscription Agreement, the Company agreed to issue and sell, in a private offering (the "March 2025 Private Placement"), a total of 392,157 shares of common stock to Mr. Magrath and 784,314 shares of common stock to Mr. Gallagher, as well as 392,157 warrants to purchase shares of common stock to Mr. Magrath and 784,314 warrants to purchase shares of common stock to Mr. Gallagher ("March 2025 Private Placement Warrants"). Each March 2025 Private Placement Warrant has an initial exercise price of $1.15, expires on the five-year anniversary of the original issuance date and may be called by the Company 30 days following the release of the Company's OPGx-BEST1 DUO-1001 Cohort 1 data upon achievement of a volume weighted average price of our common stock for 30 consecutive trading days of over $1.725 per share and the trading average daily volume for such 30 day period exceeds $150,000 per trading day. See Note 6 – Related Party Transactions.

The combined gross proceeds from the March 2025 Offering and the March 2025 Private Placement, which both closed on March 24, 2025 (the "Closing Date"), were approximately $21.5 million, before deducting underwriting discounts and commissions and offering expenses payable by the Company in the amount of $1.8 million.

March 2025 Warrants

The March 2025 Warrants have an initial exercise price equal to $0.95 per share of common stock and are exercisable for five years from the date of issuance. The exercise prices and numbers of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. A holder may not exercise the March 2025 Warrant if, after giving effect to such exercise, the holder (together with its affiliates) would beneficially own (as determined in accordance with the terms of the March 2025 Warrants) more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after giving effect to the exercise. Lastly, certain volatility provisions in the event of a fundamental transaction precluded the March 2025 Warrants from being considered indexed to the Company's own stock, and as such, were classified on the condensed consolidated balance sheets as warrant liabilities.

The March 2025 Warrants are callable by the Company in certain circumstances. Subject to certain exceptions, in the event that the March 2025 Warrants are outstanding, if, after the Closing Date, (i) the Company has announced OPGx-BEST1 DUO-1001 Cohort 1 data, (ii) the volume weighted average price of the common stock for 30 consecutive trading days ("Warrant Measurement Period"), which 30 consecutive trading day period shall not have commenced until after the initial exercise date) exceeds $1.425 (subject to adjustment), (iii) the trading average daily volume for such Warrant Measurement Period exceeds $150,000 per trading day and (iv) the March 2025 Warrant holder is not in possession of any information that constitutes or might constitute material non-public information which was provided by the Company, its subsidiaries or any of its officers, directors, employees, agents or affiliates, then the Company may, within one trading day of the end of such Warrant Measurement Period, upon notice, call for cancellation of all or any portion of the March 2025 Warrants for which a notice of exercise has not yet been delivered for consideration equal to $0.001 per March 2025 Warrant share.

In the event of a fundamental transaction, as defined in the Form of Warrant, the holders of the March 2025 Warrants will be entitled to receive upon exercise the kind and amount of securities, cash or other property that the holders would have received had they exercised immediately prior to such fundamental transaction. Additionally, as more fully described in the Form of Warrant, in the event of certain fundamental transactions, the holders of the March 2025 Warrants will be entitled to receive consideration in an amount equal to the Black Scholes Value of the remaining unexercised portion of the March 2025 Warrants on the date of consummation of such fundamental transaction.

The fair value of the March 2025 Warrants at the time of issuance was $14.7 million and were recorded in the warrant liabilities line item in the accompanying condensed consolidated balance sheets upon issuance. The fair value change during the three and nine months ended September 30, 2025 was an expense of $9.0 million and $5.5 million, respectively. The fair value of these instruments were based on a Monte Carlo simulation incorporating a volatility rate of 72.5% and 80.0% as of September 30, 2025 and March 24, 2025, respectively, a risk free rate of 3.6% and 4.0% as of September 30, 2025 and March 24, 2025, respectively, the market price of the Company's common stock at $1.65 and $1.15 per share as of September 30, 2025 and March 24, 2025, respectively, and other factors over a simulated term of 4.5 years and 5 years at September 30, 2025 and March 24, 2025, respectively. As of September 30, 2025 the transaction costs attributed to the March 2025 Warrants amounted to approximately $1.3 million and were recorded in the accompanying condensed consolidated statements of comprehensive loss under financing costs.

March 2025 Private Placement Warrants

The March 2025 Private Placement Warrants have an initial exercise price equal to $1.15 per share of common stock and are exercisable for five years from the date of issuance. The March 2025 Private Placement Warrants are callable by the Company in certain circumstances. Subject to certain exceptions, in the event that the March 2025 Private Placement Warrants are outstanding, if, after the Closing Date, (i) the Company announced OPGx-BEST1 DUO-1001 Cohort 1 data, (ii) the volume weighted average price of the common stock for 30 consecutive trading days (the "Private Placement Measurement Period", which 30 consecutive trading day period shall not have commenced until after the initial exercise date) exceeds $1.725 (subject to adjustment), (iii) the trading average daily volume for such Private Placement Measurement Period exceeds $150,000 per trading day and (iv) the March 2025 Private Placement Warrant holder is not in possession of any information that constitutes or might constitute material non-public information which was provided by the Company, its subsidiaries or any of its officers, directors, employees, agents or affiliates, then the Company may, within one trading day of the end of such Private Placement Measurement Period, upon notice, call for cancellation of all or any portion of the March 2025 Private Placement Warrants for which a notice of exercise has not yet been delivered for consideration equal to $0.001 per March 2025 Private Placement Warrant share. Other terms under the March 2025 Private Placement Warrants are generally identical to the terms of the March 2025 Warrants discussed above. Lastly, certain volatility provisions in the event of a fundamental transaction precluded the March 2025 Private Placement Warrants from being considered indexed to the Company's own stock, and as such, were classified on the condensed consolidated balance sheets as warrant liabilities.

The fair value of the March 2025 Private Placement Warrants at the time of issuance was $0.8 million and were recorded in the warrant liabilities line item in the accompanying condensed consolidated balance sheets upon issuance. The fair value change during the three and nine months ended September 30, 2025 was an expense of $0.5 million and $0.3 million, respectively. The fair value of these instruments were based on a Monte Carlo simulation incorporating a volatility rate of 72.5% and 80.0% as of September 30, 2025 and March 24, 2025, respectively, a risk free rate of 3.6% and 4.0% as of September 30, 2025 and March 24, 2025, respectively, the market price of the Company's common stock at $1.65 and $1.15 per share as of September 30, 2025 and March 24, 2025, respectively, and other factors over a simulated term of 4.5 years and 5 years as of September 30, 2025 and March 24, 2025, respectively. As of September 30, 2025 transaction costs attributed to the March 2025 Private Placement Warrants were de minimis and were recorded in the accompanying condensed consolidated statements of comprehensive loss under financing costs.

Pre-Funded Warrants

The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and are immediately exercisable and are exercisable at any time until exercised in full. The exercise prices and numbers of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the common stock. A holder may not exercise the Pre-Funded Warrant if, after giving effect to such exercise, the holder (together with its affiliates) would beneficially own (as determined in accordance with the terms of the Pre-Funded Warrants) more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after giving effect to the exercise. In the event of a fundamental transaction, as defined in the Form of Pre-Funded Warrant, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

The Pre-Funded Warrants were recorded in the accompanying condensed consolidated balance sheets as Additional paid-in capital.

At-The-Market Program

On January 13, 2025, the Company filed a prospectus supplement with the SEC in connection with the establishment of an at-the-market equity offering program (the "ATM Program") for the offer and sale, from time to time, of shares of its common stock having an aggregate offering price of up to $40.0 million. On the same date, the Company entered into a Sales Agreement (the "Sales Agreement") with Leerink Partners LLC ("Leerink"), pursuant to which the Company may offer and sell shares of its common stock through or to Leerink, acting as sales agent, under the ATM Program. In connection with the entry into the Sales Agreement, the Company terminated its prior ATM program established under the Capital on DemandTM Sales Agreement dated March 11, 2021, between the Company and JonesTrading Institutional Services LLC.

During the three and nine months ended September 30, 2025, the Company sold 1,472,703 and 1,825,656 shares of common stock, respectively, under the Leerink ATM program for gross proceeds of $1.7 million and $2.1 million, respectively, before deducting issuance expenses. Total issuance expenses, including sales agent fees and legal and accounting expenses, were $0.1 million and $0.3 million for the three- and nine-month periods ended September 30, 2025, respectively. During the three and nine months ended September 30, 2024, the Company sold 219,406 and 1,608,522 shares of common stock under the JonesTrading ATM program, respectively, for aggregate gross proceeds of $0.5 million and $3.8 million, respectively, before deducting issuance expenses. Total issuance expenses, including sales agent fees and legal and accounting expenses, were $0.1 million and $0.2 million, for the three- and nine-month periods ended September 30, 2024, respectively. As of September 30, 2025, the Company had sold an aggregate of 9,479,494 shares of common stock under the ATM programs since their inception, resulting in gross proceeds of $28.5 million and total issuance costs of $1.4 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, 2025, 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 $0.3 million 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.

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, 2025. The Series A Warrants were accounted for and classified as equity on the accompanying condensed consolidated balance sheets.

Warrant Activity and Summary

	Warrants	Exercise Price Per Warrant	Weighted Average Exercise Price	Weighted Average Term (Years)
Outstanding and exercisable at December 31, 2024	7,204,299	$ 4.48-6.09	$ 4.82	1.00
Issued	22,229,102	$ 0.95-1.15	$ 0.96	5.00
Exercised	—	$ —	$ —	—
Expired	—	$ —	$ —	—
Outstanding and exercisable at September 30, 2025	29,433,401	$ 0.95-6.09	$ 1.91	3.45

The following table summarizes information about warrants outstanding at September 30, 2025:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual life (Years)	Number Exercisable at September 30, 2025
$ 0.95	21,052,631	4.48	21,052,631*
$ 1.15	1,176,471	4.48	1,176,471*
$ 4.48	5,665,838	0.13	5,665,838
$ 6.09	1,538,461	0.68	1,538,461
Total	29,433,401		29,433,401

*Liability classified warrants in connection with March 2025 Financings

The above tables exclude the 8,832,895 Pre-Funded Warrants issued in connection with the March 2025 Offering. The Pre-Funded Warrants were deemed outstanding common stock for net loss per share purposes (See Note 12 – Net Loss per Share).

9. 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 for the three- and nine-month periods indicated below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
General and administrative	$ 567	$ 549	$ 1,810	$ 1,850
Research and development	249	227	815	717
Total stock-based compensation	$ 816	$ 776	$ 2,625	$ 2,567

Inducement Plan

On August 8, 2025, the Company amended the Opus Genetics, Inc. 2021 Inducement Plan (the "Inducement Plan") to adjust the reserve by 800,000 shares to a total of 4,125,258 shares of its common stock. The Inducement Plan is 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 Nasdaq's continued listing requirements.

2020 Equity Incentive Plan

In November 2020, the stockholders of the Company approved the 2020 Equity Incentive Plan (the "2020 Plan") for stock-based awards. 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. 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. The 2020 Plan permits the grant of incentive and nonstatutory stock options, appreciation rights, restricted stock, restricted stock units, performance stock and cash awards, and other stock-based awards. On January 1, 2025, 1,578,733 shares were added to the 2020 Plan as a result of its annual increase provision.

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, 2025, 733,448 and 2,793,277 stock options were granted, respectively, to directors, officers, employees and consultants, 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, 2024, zero and 1,021,166 stock options were granted, respectively, to directors, officers, employees and consultants, generally vesting over a one- to four-year period with monthly, quarterly and annual vesting tranches.

The Company recognized $0.5 million and $0.5 million in stock-based compensation expense related to stock options during the three months ended September 30, 2025 and 2024, respectively, and $1.5 million and $1.4 million during the nine months ended September 30, 2025 and 2024, respectively. There were 25,000 and 30,000 stock options exercised during the three and nine months ended September 30, 2025, respectively with an intrinsic value of less than $0.1 million for each period. There were no stock option exercises during the nine months ended September 30, 2024. As of September 30, 2025 and December 31, 2024, 7,218,064 and 5,073,736 stock options were outstanding, respectively. The following table provides a summary of stock option activity under the Company's equity award plans:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value[(1)] (in thousands)
Outstanding at December 31, 2024	5,073,736	$ 2.68	7.37	$ 124
Granted	2,793,277	$ 1.00		
Exercised	(30,000)	$ 0.90		
Forfeited/Cancelled	(618,949)	$ 2.07		
Outstanding at September 30, 2025	7,218,064	$ 2.09	7.64	$ 2,256
Vested and expected to vest at September 30, 2025	7,218,064	$ 2.09	7.64	$ 2,256
Vested and exercisable at September 30, 2025	3,491,162	$ 2.75	5.84	$ 506

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of our common stock as of September 30, 2025 and December 31, 2024 of $1.65 and $1.19 per share, respectively.

The weighted average fair value per share of options granted during the three and nine months ended September 30, 2025 was $0.79 and $0.68, respectively, during each of these periods. The weighted average fair value per share of options granted during the three and nine months ended September 30, 2024 was nil and $1.95, 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 trading history of its common stock 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.

Notes to Condensed Consolidated Financial Statements

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

The weighted average assumptions used in the Black-Scholes option pricing model are as follows during the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Expected stock price volatility	75.6%	—%	75.7%	97.7%
Expected life of options (years)	6.1	—	5.9	5.9
Expected dividend yield	—%	—%	—%	—%
Risk free interest rate	3.9%	—%	4.0%	4.2%

During the three and nine months ended September 30, 2025, 118,728 and 781,125 stock options vested, respectively. During the three and nine months ended September 30, 2024, 79,225 and 386,097 stock options vested, respectively.

During the three and nine months ended September 30, 2025, 145,319 and 618,949 options were forfeited, respectively. During the three and nine months ended September 30, 2024, 114,425 and 583,360 options were forfeited, respectively.

Restricted Stock Units

During the three and nine months ended September 30, 2025, the Company granted an aggregate of 200,000 and 1,655,361 restricted stock units ("RSUs"), respectively, to members of the Board and certain officers, employees and consultants under the 2020 Plan. The weighted average grant date per unit fair value of the RSUs granted during the three and nine months ended September 30, 2025 was $1.33 and $0.99, respectively, during each of these periods. The vesting period of the RSUs range from a one-year period to a four-year period during which 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, the Company granted an aggregate of zero and 592,222 RSUs, respectively, to the members of the Board and certain 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, 2024 was $2.24. The vesting period of the RSUs range from a one-year period to a four-year period during which 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, 2025, zero and 381,534 RSUs vested, respectively, and 26,038 and 257,826 were forfeited during the three and nine months ended September 30, 2025, respectively.

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, 2025 related to RSUs was $0.3 million and $1.1 million, respectively. The total expense for the three and nine months ended September 30, 2024 related to these RSUs was $0.3 million and $0.9 million, respectively. As of September 30, 2025 and December 31, 2024, there were 2,409,231 and 1,393,230 RSUs were outstanding, respectively. The following table summarized the Company's RSU activity under the Company's equity award plans:

	Number of Shares
Non-vested at December 31, 2024	1,393,230
Granted	1,655,361
Forfeited	(257,826)
Vested	(381,534)
Non-vested at September 30, 2025	2,409,231

Common Stock Issued for Services

The Company granted stock for services in the amount of nil and 84,243 common shares during the three and nine month periods ended September 30, 2025, respectively, and nil and 81,234 common shares during the three and nine month periods ended September 30, 2024, respectively. The awards were granted to members of the Board who elected to receive their Board compensation in the form of stock for services. The weighted average fair value of the shares granted was nil and $1.26 per share during the three and nine month periods ended September 30, 2025, respectively, and nil and $3.01 per share during the three and nine month periods ended September 30, 2024, respectively, and were 100% vested upon issuance. The stock-based compensation related to these services amounted to nil and $0.1 million during the three and nine month periods ended September 30, 2025, respectively, and nil and $0.2 million during the three and nine month periods ended September 30, 2024, respectively.

General

As of September 30, 2025, 874,829 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 $6.0 million as of September 30, 2025. The unrecognized stock-based expense is expected to be recognized over a weighted average period of 1.7 years.

10. Apexian Sublicense Agreement

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

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

None of the milestone or royalty payments were triggered or deemed probable as of September 30, 2025.

Notes to Condensed Consolidated Financial Statements

11. License and Collaboration Revenue and Other Funding Agreements

Viatris License Agreement

On November 6, 2022, the Company entered into the Viatris License Agreement, pursuant to which it granted Viatris 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. In addition, in August 2025, Opus and Viatris entered into a side letter to the Viatris License Agreement providing for the sharing of expenses arising in connection with a patent dispute.

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.

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 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 initial research and development services that were constrained to the 120-day non-cancellation period were to be recognized over time as the services were rendered based on an estimated percentage of completion input model. The initial research and development services were completed in the first quarter of 2023. Revenue related to the on-going research and development services are based on activities completed during the period.

Recognition of Revenue

Revenue recognized under the Viatris License Agreement during the three and nine months ended September 30, 2025 was $3.1 million and $10.3 million, respectively. 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 ongoing research and development services and to a much lesser extent royalty payments. The Company records a provision for credit losses, when appropriate, based on historical experience, current conditions and reasonable supportable forecasts. The Company has not incurred any bad debt expense to date and no allowance for credit losses has been recorded during the periods presented.

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.

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, 2025 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, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Contract assets and unbilled receivables		
Balance as of beginning of nine-month period	$ 2,209	$ 1,407
Revenue recognized	10,331	6,690
Reclassification to Accounts receivable related to costs billed under the Viatris License Agreement	(11,176)	(6,629)
Balance as of end of nine-month period	$ 1,364	$ 1,468

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 $84.5 million 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, 2025, 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, if any, will be recognized in the period the underlying sales transaction occurs.

Payments received under the BioSense License and Assignment Agreement will be subject to the CVR Agreement described in Note 2 – Mergers.

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.

Pursuant to the agreement, Processa is obligated to make future payments to the Company upon the achievement of certain development, regulatory and commercial milestones. In addition, Processa is obligated to pay the Company mid-single-digit percentage royalties based on annual sales.

On June 27, 2025, Processa notified the Company that it would not be developing RX-3117 and terminated the Processa License Agreement, effective October 25, 2025 (the "Termination Date"). No future payments will be received under the Processa License Agreement after the Termination Date and if any future payments are received prior to the Termination Date, they will be subject to the CVR Agreement described in Note 2 – Mergers.

The Company determined that none of the milestone payments under the Processa License Agreement were probable of payment as of September 30, 2025, and as a result, no revenue related to the milestones was recognized.

SBIR Grant Agreement

In September 2024, Private Opus received a Small Business Innovation Research ("SBIR") grant through the Department of Health and Human Services in the amount of $0.9 million to be used on the development of the RHO product. Direct and allocated indirect costs for development activities are reimbursed on a draw-down basis as development activities are completed. For the three and nine months ended September 30, 2025, the Company recognized $0.1 million and $0.3 million of revenue related to the SBIR grant, respectively, and was recorded as other income, net in the accompanying condensed consolidated statements of comprehensive loss. There was no revenue recognized related to the SBIR grant during the prior periods presented.

RDH12 Agreement

On July 22, 2025, the Company, together with its wholly owned subsidiary, OpusTX, LLC (collectively, "Opus"), entered into a funding and license agreement (the "RDH12 Agreement") with Eyes on the Future ("EOTF"), and RDH12 Fund for Sight (the "Fund," and together with EOTF, the "Funding Parties"), charitable organizations, relating to Opus' program to develop gene therapies that treat patients with inherited retinal degeneration associated with mutations in the RDH12 gene (the "RDH12 Program").The RDH12 Agreement provides for funding by the Funding Parties of up to $1.6 million to support the development of the RDH12 Program. Opus is required to use the funding to conduct development activities in accordance with a mutually agreed development plan.

Under the RDH12 Agreement, Opus is subject to certain diligence obligations to develop a product under the RDH12 Program. If Opus is unable to achieve certain milestones by the specified dates, or if certain other events occur (a "License Trigger Event"), then the Funding Parties may exercise their rights under a non-exclusive, global, royalty-free and fully paid-up license granted by Opus to the Funding Parties to develop products under the RDH12 Program. If the Funding Parties exercise such license rights, then Opus will receive a non-exclusive license under the data and other intellectual property generated by the Funding Parties to develop products under the RDH12 Program, and the right to negotiate an exclusive license to such data and intellectual property to commercialize products under the RDH12 Program. The RDH12 Agreement includes certain restrictions on Opus' ability to out-license rights to the RDH12 Program, and during the term of the RDH12 Agreement, Opus may not grant a third party an exclusive license to develop or commercialize products under the RDH12 Program in the United States without the prior written consent of the Funding Parties.

The term of the RDH12 Agreement continues until the earlier of (a) dosing by Opus of three patients in a Phase 1a/2b clinical trial prior to a License Trigger Event, and (b) the first commercial sale of a product under the RDH12 Program following receipt of regulatory approval in the United States or certain other European countries. The RDH12 Agreement will also terminate if an exclusive, global licensee of Opus for the RDH12 Program assumes Opus' obligations under the RDH12 Agreement. The RDH12 Agreement may be terminated by either party for cause, including material breach or bankruptcy, subject to a cure period, or by the Funding Parties for convenience following a License Trigger Event.

Eligible research and development costs under the RDH12 Agreement, as approved by the Funding Parties, are reimbursed on a draw-down basis as development activities are completed by the Company. For the three and nine months ended September 30, 2025, the Company recognized $0.1 million of income related to the RDH12 Agreement, which was recorded in the accompanying condensed consolidated statements of comprehensive loss under the other income, net line item.

Notes to Condensed Consolidated Financial Statements

12. Net Loss per Share

Basic loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted earnings or loss per share of common stock is computed similarly to basic loss or earnings 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 Series A preferred stock, warrants, stock options and RSUs, while outstanding, are considered common stock equivalents for this purpose. Diluted earnings is computed utilizing the treasury method for the warrants, stock options and RSUs. Diluted earnings with respect to the Series A preferred stock utilizing the if-converted method was not applicable during the periods presented as no conditions required for conversion had occurred. 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 periods presented.

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

	September 30,	
	2025	2024
Warrants	29,433,401	7,204,299
Stock options	7,218,064	4,848,064
RSUs	2,409,231	1,130,430
Total	39,060,696	13,182,793

13. Income Taxes

The effective tax rate for the three and nine months ended September 30, 2025 and 2024 was zero percent. As of September 30, 2025, 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. On July 4, 2025, the One Big, Beautiful Bill ("OBBB") was signed into law and included certain provision that may impact the Company such as the capitalization of research and development expenses under Section 174 of the Internal Revenue Code. The Company is currently assessing the provisions of the OBBB but expects minimal impacts. 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.

14. 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, 2025 and 2024, the Company contributed less than $0.1 million and less than $0.1 million to the 401K Plan, respectively. During the nine months ended September 30, 2025 and 2024, the Company contributed $0.1 million and $0.1 million to the 401K Plan, respectively.

15. Subsequent Events

November 2025 Registered Direct Offering

On November 5, 2025, the Company entered into a securities purchase agreement to sell securities in a registered direct offering for gross proceeds of approximately $23.0 million, before deducting offering expenses.

In the offering, the Company sold an aggregate of 3,827,751 shares of its common stock at a price of $2.09 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 7,177,033 shares of common stock at a purchase price of $2.0899 per pre-funded warrant. Each pre-funded warrant has an exercise price of $0.0001 per share of common stock, will be immediately exercisable subject to certain conditions set forth in each pre-funded warrant, and will not expire. The offering closed on November 7, 2025.

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 I "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, 2024.

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:

- Our clinical data related to gene therapies for the treatment of inherited retinal diseases ("IRDs") is preliminary and related to a relatively small group of patients, and, as a result, data that initially appears promising may be revised, updated, or invalidated at a later data readout and/or may ultimately not be capable of duplication in additional patients;
- Failure to successfully integrate our businesses following our acquisition of former Opus Genetics Inc. (the "Opus Acquisition") could have a material adverse effect on our business, financial condition and results of operations;
- The Opus Acquisition significantly expanded our product pipeline and business operations and shifted our business strategies, which may not improve the value of our common stock;
- Our gene therapy product candidates are based on a novel technology that is difficult to develop and manufacture, which may result in delays and difficulties in obtaining regulatory approval;
- Our planned clinical trials may face substantial delays, result in failure, or provide inconclusive or adverse results that may not satisfy FDA requirements to further develop our therapeutic products;
- Delays or difficulties associated with patient enrollment in clinical trials may affect our ability to conduct and complete those clinical trials and obtain necessary regulatory approvals;
- Changes in regulatory requirements could result in increased costs or delays in development timelines;
- We depend heavily on the success of our product pipeline; if we fail to find strategic partners or fail to adequately develop or commercialize our pipeline products, our business will be materially harmed;
- Others may discover, develop, or commercialize products similar to those in our pipeline before or more successfully than we do or develop generic variants of our products even while our product patents remain active, thereby reducing our market share and potential revenue from product sales;
- We do not currently have any sales or marketing infrastructure in place and we have limited drug research and discovery resources;

- The future commercial success of our products could significantly depend upon several uncertain factors, including third-party reimbursement practices and the existence of competitors with similar products;
- Product liability lawsuits against us or our suppliers or manufacturers could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop;
- Failure to comply with health and safety laws and regulations could lead to material fines;
- We have not generated significant revenue from sales of any products and expect to incur losses for the foreseeable future;
- Our future viability is difficult to assess due to our short operating history and our future need for substantial additional capital, access to which could be limited by any adverse developments that affect the financial services markets;
- Raising additional capital may cause our stockholders to be diluted, among other adverse effects;
- We operate in a highly regulated industry and face many challenges adapting to sudden changes in legislative reform or the regulatory environment, which affects our pipeline stability and could impair our ability to compete in international markets;
- We may not receive regulatory approval to market our developed product candidates within or outside of the U.S.;
- With respect to any of our product candidates that receive marketing approval, we may be subject to substantial penalties if we fail to comply with applicable regulatory requirements;
- Our potential relationships with healthcare providers and third-party payors will be subject to certain healthcare laws and regulations, which could expose us to extensive potential liabilities;
- We rely on third parties for material aspects of our business, such as conducting our nonclinical and clinical trials and supplying and manufacturing bulk drug substances, which exposes us to certain risks;
- We may be unsuccessful in entering into or maintaining licensing arrangements (such as the Viatris License Agreement (as defined below)) or establishing strategic alliances on favorable terms, which could harm our business;
- Our current focus on the cash-pay utilization for future sales of RYZUMVI may limit our ability to increase sales or achieve profitability with this product;
- Inadequate patent protection for our product candidates may result in our competitors developing similar or identical products or technology, which would adversely affect our ability to successfully commercialize;
- We may be unable to obtain full protection for our intellectual property rights under U.S. or foreign laws;
- We may become involved in lawsuits for a variety of reasons associated with our intellectual property rights, including alleged infringement suits initiated by third parties;
- 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;
- As we grow, we may not be able to operate internationally or adequately develop and expand our sales, marketing, distribution, and other corporate functions, which could disrupt our operations;
- The market price of our common stock is expected to be volatile;
- Our common stock may be subject to delisting from the Nasdaq Capital Market (“Nasdaq”) and delisting could adversely affect our ability to access capital markets;
- Factors out of our control related to our securities, such as securities litigation or actions of activist stockholders, could adversely affect our business and stock price and cause us to incur significant expenses;

- Instability and operational disruptions at government agencies, such as the FDA, may adversely impact our development and commercialization plans by causing delays and requiring the use of additional, unforeseen resources to obtain regulatory approval for trials and products in our pipeline; and

- Impact from current or proposed tariffs on imported goods we purchase.

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, 2024 and below under the heading "Risk Factors," and in 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

Opus Genetics, Inc. (the "Company," "Opus," "we," "us," or "our") is a clinical-stage biopharmaceutical company developing gene therapies for the treatment of IRDs and small molecule therapies for other ophthalmic disorders.

On October 22, 2024, Opus Genetics, Inc., a Delaware corporation formerly known as Ocuphire Pharma, Inc. (the "Company," "Opus," "we," "us" or "our"), acquired a private corporation then operating under the name of "Opus Genetics Inc." ("Private 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, Private 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.

Gene Therapy Programs

Our pipeline features a portfolio of seven adeno-associated virus ("AAV") based gene therapies that address mutations in genes that cause different forms of Leber congenital amaurosis ("LCA"), bestrophinopathy, and retinitis pigmentosa.

OPGx-LCA5

OPGx-LCA5 is designed to address a form of LCA due to biallelic mutations in the LCA5 gene, which encodes the lebercilin protein. LCA5-associated IRD is an early-onset severe inherited retinal dystrophy. Studies in patients with this mutation have reported evidence for the dissociation of retinal architecture and visual function in this disease, suggesting an opportunity for therapeutic intervention through gene augmentation. OPGx-LCA5 uses an adeno-associated virus 8 (AAV8) vector to precisely deliver a functional LCA5 gene to the outer retina via a single subretinal injection. The program has been granted Rare Pediatric Disease, Regenerative Medicine Advanced Therapy (RMAT), and Orphan Drug designations from the FDA.

OPGx-LCA5 is currently being evaluated in an open-label, Phase 1/2 clinical trial. To date, six late-stage participants have been treated with OPGx-LCA5, all of whom have experienced improvements in vision, providing evidence of biological activity with the potential for functional restoration of vision in individuals with advanced disease. In September 2025, we reported positive data from the six participants. The three pediatric participants treated over three months demonstrated large gains in cone-mediated vision with improvements across multiple measures of visual function. In the three adult participants, responses have been observed out to 18 months, underscoring the potential durability of the treatment response. OPGx-LCA5 has been well tolerated with no ocular serious adverse events or dose-limiting toxicities.

On November 6, 2025 the Company announced the successful completion of a Type B RMAT meeting with the FDA regarding OPGx-LCA5. The meeting provided constructive feedback from the FDA on key elements of the Company's registration strategy, including Chemistry, Manufacturing and Controls ("CMC"), and the pivotal trial design. The FDA acknowledged the significant unmet medical need for individuals with LCA5-related blindness and reaffirmed its commitment to regulatory flexibility for rare genetic diseases.

The Company will incorporate the FDA's feedback into its updated clinical development and CMC plans for the Phase 3 portion of the study to include enrolling as few as 8 participants in a single arm, 12-month study utilizing an adaptive design, which provides flexibility on endpoints and number of participants, reflective of LCA5 as a rare condition with an urgent medical need.

The Company expects the Phase 3 portion of the trial will include a run-in period prior to dosing to evaluate the natural history of each participant to serve as their own control in the study. The Company is actively identifying patients for this segment and has enrolled the first participant for ongoing disease monitoring. Following availability of validated clinical drug supply manufactured with the intended commercial processes, dosing with OPGx-LCA5 is anticipated in the second half of 2026 with topline clinical data expected approximately one year later.

In September 2025, the FDA introduced the Rare Disease Evidence Principles ("RDEP") review process to provide greater speed and predictability in the review of therapies intended to treat rare diseases with very small patient populations with significant unmet medical need and that are driven by a known genetic defect that is the major driver of the pathophysiology. With a patient population of fewer than 1,000 individuals, the Company believes that its LCA5 program meets the eligibility criteria for the RDEP process and plans to submit an application.

OPGx-BEST1

OPGx-BEST1 is being developed for the treatment of IRDs associated with mutations in the BEST1 gene. BEST1 disease, or vitelliform macular dystrophy, is a rare, inherited retinal condition causing macular degeneration by mutations in the BEST1 gene, leading to progressive vision loss and, in some cases, blindness. In preclinical studies conducted in a naturally occurring canine model of BEST1 disease, OPGx-BEST1 demonstrated restoration of the retinal pigment epithelium-photoreceptor interface using AAV-mediated gene delivery, providing evidence in support of a first-in-man clinical trial. In August 2025, we announced FDA clearance of an Investigational New Drug ("IND") application to initiate a clinical trial. An adaptive, open-label, dose-exploring Phase 1/2 trial, known as BIRD1, is currently recruiting participants to study the safety and tolerability of subretinally injected OPGx-BEST1 in participants with Best Vitelliform Macular Dystrophy (BVMD) or Autosomal-Recessive Bestrophinopathy (ARB). Initial data is expected in the first quarter of 2026.

Earlier Stage Programs

We also have five programs in pre-clinical development. Three programs are currently in IND-enabling studies and received grant/partner funding to support their development: OPGx-RHO is being co-funded by the Foundation Fighting Blindness ("FFB") and the National Institutes of Health ("NIH"); OPGx-RDH12 is being co-funded by the Global RDH12 Alliance; and OPGx-MERTK is being co-funded by the Retinal Degeneration Fund ("RDF") of the FFB. Our pre-IND programs include OPGx-NMNAT1 and OPGxCNGB1.

Phentolamine Ophthalmic Solution 0.75% (PS)

Our pipeline also includes Phentolamine Ophthalmic Solution 0.75% (PS), a relatively non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size, administered as an eye drop. It aims to work by uniquely blocking the alpha-1 receptors found on the radial iris dilator muscles, which are activated by the alpha-1 adrenergic receptors. PS is designed to reduce pupil diameter through a sympatholytic mechanism of action that avoids engaging the ciliary muscle, potentially reducing risks such as retinal tears or detachment associated with older parasympathomimetic agents. PS is targeting three different indications.

In November 2022, we entered into a license and collaboration agreement (as amended, the "Viatris License Agreement") with Viatris, Inc. ("Viatris"), pursuant to which we granted Viatris an exclusive license to develop, manufacture, import, export and commercialize 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. For more information on the Viatris License Agreement, please refer to Note 11 – License and Collaboration Agreements and Other Funding Agreements included in Part I, Item 1– Financial Statements and Supplementary Data of this Report.

RYZUMVI® (phentolamine ophthalmic solution) 0.75%: 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.

Presbyopia: In June 2025, we announced positive results from VEGA-3, our second pivotal Phase 3 trial evaluating PS for the treatment of presbyopia, an ophthalmic disorder that involves the progressive loss of ability to focus on close objects that results in blurred near vision, difficulty seeing in dim light, and eye strain. VEGA-3 met its primary endpoint, with a statistically significant 27.2% of participants treated with PS achieving a ≥15-letter improvement in binocular distance-corrected near visual acuity (DCNVA), with less than a 5-letter loss in binocular best-corrected distance visual acuity (BCDVA) at 12 hours post-dose on Day 8, compared to 11.5% of patients on placebo ($p<0.0001$). The trial also met key secondary efficacy endpoints, reinforcing the benefit observed. We intend to file a Supplemental New Drug Application ("sNDA") for the treatment of presbyopia with PS in the fourth quarter of 2025.

Mesopic, Low-Contrast Conditions: We are conducting our second Phase 3 trial, known as LYNX-3, to treat significant, chronic night driving impairment in keratorefractive patients with reduced mesopic vision. The program is being conducted under a Special Protocol Assessment ("SPA") and has received Fast Track Designation from the FDA. The first Phase 3 trial, LYNX-2, met its primary endpoint of a gain of three lines (or 15 letters) or more of distance vision improvement on a low contrast chart in low light conditions after 15 days of dosing. In the study, 17.3% of participants treated with PS achieved a ≥15-letter Early Treatment Diabetic Retinopathy Study (ETDRS) (≥ 3-line) improvement in Mesopic Low Contrast Distance Visual Acuity (mLCVA) at Day 15, compared to 9.2% in the placebo group ($p<0.05$). We are currently enrolling participants in LYNX-3, with results expected in 2026.

APX3330

APX3330 is a selective small molecule that is designed to act on the dual-functioning Apurinic/Apyrimidinic Endonuclease 1/Redox Effector Factor-1 (APE1/Ref-1) protein, referred to as Ref-1. We completed a Phase 2 clinical study of APX3330 in diabetic retinopathy and reached FDA agreement under a SPA for a Phase 3 program. We are currently seeking a strategic partner to advance the clinical development of this diabetic retinopathy program and redirecting existing resources toward the acquired gene therapy programs.

Recent Developments

November 2025 Registered Direct Offering

On November 5, 2025, we entered into a securities purchase agreement to sell securities in a registered direct offering for gross proceeds of approximately $23.0 million, before deducting offering expenses (the "November 2025 Registered Direct Offering"). The offering closed on November 7, 2025. See *Historical Capital Resources* section below for further detail.

August 2025 Private Placement

On August 25, 2025, we entered into subscription agreements pursuant to which we agreed to issue and sell in a private placement (the "August 2025 Private Placement") to certain investors an aggregate of 3,138,338 shares of our common stock. The aggregate gross proceeds from the August 2025 Private Placement were $3.5 million. The August 2025 Private Placement closed on August 25, 2025. See *Historical Capital Resources* section below for further detail.

Global RDH12 Alliance Agreement

On July 22, 2025, the Company, together with its wholly owned subsidiary, OpusTX, LLC (collectively, "Opus"), entered into a funding and license agreement (the "RDH12 Agreement") with Eyes on the Future ("EOTF"), and RDH12 Fund for Sight (the "Fund," and together with EOTF, the "Funding Parties"), relating to Opus' program to develop gene therapies that treat patients with inherited retinal degeneration associated with mutations in the RDH12 gene (the "RDH12 Program"). The RDH12 Agreement provides for funding by the Funding Parties of up to $1.6 million to support the development of the RDH12 Program. For more information on the terms of the RDH12 Agreement, see Note 11 — License and Collaboration Revenue and Other Funding Agreements in Part I, Item 1 – Financial Statements and Supplementary Data of this Report.

RDF Agreement

On June 13, 2025, we entered into a funding agreement (the "RDF Agreement") with the RDF, whose sole member is the FFB, a significant stockholder of the Company, relating to our program to develop gene therapies to treat patients impacted by retinitis pigmentosa caused by pathogenic variants in the Mer proto-oncogene tyrosine kinase (MERTK) gene (the "MERTK Program"). The RDF Agreement provides for nondilutive funding by RDF of up to $2.0 million to support the development of the MERTK Program, $1.0 million of which was disbursed to us in June 2025 and up to $1.0 million of which may be disbursed to us upon achievement of a specified development milestone subject to RDF's receipt of eligible funds. For more information on the terms and related obligations under the RDF Agreement, see Note 6 — Related Party Transactions in Part I, Item 1 – Financial Statements and Supplementary Data of this Report.

Letter Agreement and Strategic Partnership—FFB

On May 27, 2025 a binding letter of agreement ("2025 Letter Agreement") between the Company and FFB was executed that superseded and canceled the previous binding letter agreement between the parties, executed on August 22, 2022.

Under the 2025 Letter Agreement, we will collaborate with FFB and the Jaeb Center for Health Research on portions of a study involving individuals with retinal dystrophies associated with mutations in the RDH12 or BEST1 genes. For more information on the terms of the 2025 Letter Agreement and related payments thereunder, see Note 6 — Related Party Transactions in Part I, Item 1 – Financial Statements and Supplementary Data of this Report.

Regenerative Medicine Advanced Therapy (RMAT) designation to OPGx-LCA5

On May 6, 2025, we announced that the FDA has granted RMAT designation to OPGx-LCA5, our investigational gene therapy for the treatment of LCA due to genetic variations in the LCA5 gene. The RMAT designation for OPGx-LCA5 is based on early clinical evidence from our ongoing Phase 1/2 open-label, which is evaluating the safety and potential efficacy of OPGx-LCA5 in patients with severe vision loss due to confirmed mutations in the LCA5 gene. The RMAT designation program offers the potential for expedited development and review of regenerative medicine therapies that demonstrate the potential to address serious or life-threatening diseases based on preliminary clinical evidence. The designation provides sponsors with early interactions with the FDA, guidance on efficient development and manufacturing, and the opportunity to discuss surrogate endpoints to support accelerated approval.

Conversion of Series A preferred stock to Common Stock

During the 2025 Annual Meeting, our stockholders voted to approve the conversion of each share of Series A preferred stock into 1,000 shares of common stock. Subsequently, on May 5, 2025, all shares of Series A preferred stock were converted into 14,145,374 shares of common stock.

March 2025 Offering and Private Placement

On March 21, 2025, we entered into an underwriting agreement with Craig-Hallum Capital Group, LLC, as the sole underwriter (the "March 2025 Offering"). Under the March 2025 Offering and the March 2025 Private Placement (as defined below), we agreed to issue and sell common stock and warrants to purchase up to 13,396,207 shares of common stock, 8,832,895 pre-funded warrants to purchase common stock and 22,239,102 warrants to purchase common stock. The aggregate proceeds received from the March 2025 Offering and March 2025 Private Placement was 21.5 million. See *Historical Capital Resources* section below for further detail.

Strategic Outlook

We intend to advance our current active pipeline and may explore opportunities to out-license from our portfolio or in-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 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, debt and alternative financings as well as through collaborations, strategic alliances and licensing arrangements.

Through September 30, 2025, we have funded our operations primarily through equity financings, the issuance of convertible notes in private placements, and license fee and milestone payments in connection with the Viatris License Agreement.

Our net loss was $17.5 million and $33.1 million for the three and nine months ended September 30, 2025, respectively, as compared to a net loss of $7.5 million and $22.4 million for the three and nine months ended September 30, 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $172.1 million. We anticipate that our expenses will continue to increase as we:

- continue clinical trials for LCA5, BEST1, PS and for any other product candidate in our future pipeline;
- continue nonclinical studies for our pipeline of gene therapies;
- 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, 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.

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”). 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 or from other license agreements entered into the future; however, the attainment of milestones or level of sales required to earn significant royalty payments is highly uncertain for the reasons explained below. Until further notice, we will report earned RYZUMVI royalties as a component of license and collaboration revenue listed in the condensed consolidated statements of comprehensive loss.

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 additional indications. If we fail to complete the development of LCA5, BEST1, PS, or any other product candidate we may pursue or fail to obtain regulatory approval, our ability to generate significant revenue will 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 our IRD programs, including LCA5 and BEST1, PS, and APX3330. 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. We do not expect to incur meaningful research and development expenses in the future for APX3330, and we announced plans to seek a partner for the program to advance development.

Pursuant to the Viatris License Agreement, our research and development expenses related to the development of PS to date have been fully reimbursed by Viatris.

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.

Fair value change in warrant and other derivative liabilities

The fair value change in warrant and other derivative liabilities consists of the fair value changes associated with the March 2025 Warrants and March 2025 Private Placement Warrants are described further, below.

Financing costs

Financing costs consist of issuance costs attributed to our March 2025 Warrants and March 2025 Private Placement Warrants described below. There were no issuance costs attributed to the equity line financing with Lincoln Park during the periods presented.

Interest Expense

Interest expenses consists of interest cost during the period ended September 30, 2025 incurred under the RDF Agreement, which is accounted for as debt under ASC 470, *Debt*. ASC 470

Other Income, net

Other income, net includes interest earned from cash and cash equivalent investments, realized and unrealized gains (losses) from equity investments, 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.

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, 2025 and December 31, 2024 given the uncertainty of future taxable income and other related factors impacting the realizability or our remaining net deferred tax assets.

Results of Operations

Comparison of Three Months Ended September 30, 2025 and 2024

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

	For the Three Months Ended September 30,		
	2025	**2024**	**Change**
License and collaborations revenue	$ 3,079	$ 3,867	$ (788)
Operating expenses:			
General and administrative	4,981	2,894	2,087
Research and development	6,409	8,982	(2,573)
Total operating expenses	11,390	11,876	(486)
Loss from operations	(8,311)	(8,009)	(302)
Fair value change in warrant and other derivative liabilities	(9,525)	—	(9,525)
Interest expense	(68)	—	(68)
Other income, net	450	483	(33)
Loss before income taxes	(17,454)	(7,526)	(9,928)
Provision for income taxes	—	—	—
Net loss	$ (17,454)	$ (7,526)	$ (9,928)

License and Collaborations Revenue

License and collaborations revenue was $3.1 million and $3.9 million for the three months ended September 30, 2025 and 2024, respectively. Revenue during both quarterly periods was derived from the Viatris License Agreement, largely for the reimbursement of research and development services. To a much lesser extent, revenue includes an earned royalty payment 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 $0.8 million decrease in license and collaborations revenue during the current three month period ended September 30, 2025 compared to the corresponding prior year period was due to a decrease in PS research and development services.

General and Administrative

General and administrative expenses for the three months ended September 30, 2025 were $5.0 million compared to $2.9 million for the three months ended September 30, 2024. The increase of $2.1 million was primarily attributable to public company related costs of $0.4 million, general legal costs of $0.5 million, patent costs of $0.1 million, payroll related costs of $0.6 million, professional service fees of $0.2 million and other operating expenses of $0.3 million on a net basis when compared to the corresponding prior year period. General and administrative expenses included $0.6 million and $0.5 million in stock-based compensation expense during the three months ended September 30, 2025 and 2024, 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,		
	2025	2024	Change
External costs:			
IRD programs	$ 2,575	$ —	$ 2,575
Phentolamine Ophthalmic Solution 0.75% ("PS")	2,421	3,561	(1,140)
APX 3330	203	4,272	(4,069)
Unallocated	102	90	12
Total external cost	5,301	7,923	(2,622)
Internal costs:			
Employee related expenses	1,016	993	23
Facilities, supplies and other	92	66	26
Total internal costs	1,108	1,059	49
Total research and development expenses	$ 6,409	$ 8,982	$ (2,573)

A greater percentage of research and development expense incurred has been allocated to IRD programs for the three months ended September 30, 2025 as compared to the three months ended September 30, 2024 as the Company continues to focus on developing the IRD gene therapy programs acquired in connection with the Opus Acquisition. Conversely, a lesser percentage of research and development expense incurred has been allocated to APX 3330 for the three months ended September 30, 2025 as compared to the three months ended September 30, 2024, as we do not expect to incur meaningful research and development expenses in the future for APX3330, and we are currently seeking a strategic partner to advance the clinical development of this program.

Research and development expenses for the three months ended September 30, 2025 were $6.4 million compared to $9.0 million for the three months ended September 30, 2024. The $2.6 million decrease was primarily attributable to lower APX 3330 expense of $4.1 million, including lower manufacturing costs of $1.9 million, lower toxicology costs of $1.5 million, and lower regulatory costs of $0.2 million; and by lower PS expense of $1.1 million, driven by lower clinical research costs of $0.8 million. These decreases are partially offset by increased IRD program expense of $2.6 million, including higher toxicology costs of $1.4 million and higher IRD clinical research costs of $0.8 million when compared to the corresponding prior year period. Pursuant to the Viatris License Agreement, our research and development expenses related to the development of the PS Products have been fully reimbursed by Viatris to date. Research and development expenses included $0.2 million in stock-based compensation expense during each of the three months ended September 30, 2025 and 2024.

Fair value change in warrant and other derivative liabilities

The fair value change in warrant and other derivative liabilities was attributed to the March 2025 Warrants and March 2025 Private Placement Warrants, as described further below, and was $9.5 million for the three months ended September 30, 2025. The fair value changes are attributed to the fluctuations in our common stock fair value and underlying changes in volatility, expected term and interest rates.

Interest expense

During the three months ended September 30, 2025, Opus had interest expense in connection with the RDF Agreement in the amount of $0.1 million. There was no interest expense during the comparable prior year period.

Other Income, net

During the three months ended September 30, 2025, Opus had other income, net of $0.4 million which primarily consisted of interest income in the amount of $0.3 million in connection with our cash and cash equivalents on-hand and to a lesser extent grant revenue in the amount of $0.1 million.

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

Comparison of Nine Months Ended September 30, 2025 and 2024

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

	For the Nine Months Ended September 30,		
	2025	**2024**	**Change**
License and collaborations revenue	$ 10,331	$ 6,690	$ 3,641
Operating expenses:			
General and administrative	17,093	10,918	6,175
Research and development	20,384	19,817	567
Total operating expenses	37,477	30,735	6,742
Loss from operations	(27,146)	(24,045)	(3,101)
Fair value change in warrant and other derivative liabilities	(5,803)	—	(5,803)
Financing costs	(1,337)	—	(1,337)
Interest expense	(68)	—	(68)
Other income, net	1,286	1,648	(362)
Loss before income taxes	(33,068)	(22,397)	(10,671)
Provision for income taxes	—	—	—
Net loss	$ (33,068)	$ (22,397)	$ (10,671)

License and Collaborations Revenue

License and collaborations revenue was $10.3 million and $6.7 million for the nine months ended September 30, 2025 and 2024, respectively. Revenue during the nine month periods was derived primarily from the reimbursement of research and development services under the Viatris License Agreement. The $3.6 million increase in license and collaborations revenue during the current nine month period ended September 30, 2025 when compared to the corresponding prior year period was due to an increase in PS research and development services.

General and Administrative

General and administrative expenses for the nine months ended September 30, 2025 were $17.1 million compared to $10.9 million for the nine months ended September 30, 2024. The increase of $6.2 million was primarily attributable to public company related costs of $2.0 million, legal fees of $1.7 million, patent fees of $0.7 million, professional service costs of $0.5 million, payroll related costs of $0.9 million and business development activity and other operating costs on a net basis of $0.4 million when compared to the corresponding prior year period. General and administrative expenses totaled $1.8 million and $1.9 million in stock-based compensation expense during the nine months ended September 30, 2025 and 2024, 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,		
	2025	**2024**	**Change**
External costs:			
IRD programs	$ 6,624	$ —	$ 6,624
Phentolamine Ophthalmic Solution 0.75% ("PS")	8,914	5,678	3,236
APX3330	325	10,959	(10,634)
Unallocated	340	238	102
Total external cost	16,203	16,875	(672)
Internal costs:			
Employee related expenses	3,880	2,776	1,104
Facilities, supplies and other	301	166	135
Total internal costs	4,181	2,942	1,239
Total research and development expenses	$ 20,384	$ 19,817	$ 567

A greater percentage of research and development expense incurred has been allocated to IRD programs for the nine months ended September 30, 2025 as compared to the nine months ended September 30, 2024 as the Company continues to focus on developing the IRD gene therapy programs acquired in connection with the Opus Acquisition. Conversely, a lesser percentage of research and development expense incurred has been allocated to APX 3330 for the nine months ended September 30, 2025 as compared to the nine months ended September 30, 2024, as we do not expect to incur meaningful research and development expenses in the future for APX3330, and we are currently seeking a strategic partner to advance the clinical development of this program.

Research and development expenses for the nine months ended September 30, 2025 were $20.4 million compared to $19.8 million for the nine months ended September 30, 2024. The $0.6 million increase was primarily attributable to increased IRD program expense of $6.6 million, including higher toxicology costs of $4.2 million, higher IRD clinical research costs of $1.7 million, and higher CMC costs of $0.4 million; higher PS expense of $3.2 million, driven by clinical research costs related to the PS Vega-3 and PS Lynx-2 trials; and higher research and development employee related compensation expense of $1.1 million. These increases are partially offset by decreased APX3330 expense of $10.6 million, including lower manufacturing costs of $4.6 million, lower toxicology costs of $3.6 million, lower clinical costs of $1.5 million, and lower regulatory costs of $0.8 million when compared to the corresponding prior year period. Pursuant to the Viatris License Agreement, our research and development expenses related to the development of PS are fully reimbursed by Viatris. Research and development expenses also included $0.8 million and $0.7 million in stock-based compensation expense during the nine months ended September 30, 2025 and 2024, respectively.

Fair value change in warrant and other derivative liabilities

The fair value change in warrant and other derivative liabilities was attributed largely to the March 2025 Warrants and March 2025 Private Placement Warrants, as described further below. The fair value change in the March 2025 Warrants and March 2025 Private Placement Warrants was $5.8 million for the nine months ended September 30, 2025. The fair value changes are attributed to the fluctuations in our common stock fair value and underlying changes in volatility, expected term and interest rates. During the comparable prior year period, the fair value change in our other derivative liabilities was de minimis.

Financing costs

Financing costs for the nine months ended September 30, 2025 of $1.3 million was comprised of issuance costs attributed to the March 2025 Warrants and March 2025 Private Placement Warrants. We did not have any financing costs during the nine months ended September 30, 2024.

Interest expense

During the nine months ended September 30, 2025, Opus had interest expense in connection with the RDF Agreement in the amount of $0.1 million. There was no interest expense during the comparable prior year period.

Other Income, net

During the nine months ended September 30, 2025, Opus had other income, net of $1.3 million which primarily consisted of interest income in the amount of $1.0 million in connection with our cash and cash equivalents on-hand and to a lesser extent grant revenue in the amount of $0.3 million.

During the nine months ended September 30, 2024, Opus had other income, net of $1.6 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, 2025, our principal sources of liquidity consisted of cash and cash equivalents of $30.8 million. We believe that our cash on hand as of September 30, 2025 will be sufficient to fund our operations for at least twelve months beyond the date of this filing. As of September 30, 2025, our cash and cash equivalents were invested primarily in cash deposits and cash equivalent investments at four large financial institutions.

Historical Capital Resources

Our primary source of cash to fund our operations has been various equity offerings in the amount of $94.9 million and the issuance of convertible notes in the amount of $8.5 million, inclusive of the promissory notes exchanged for Opus convertible notes. In addition, we received a one-time non-refundable cash payment of $35.0 million during the fourth quarter of 2023, 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. Lastly, we received funding in the amount of $1.3 million from the RDF Agreement and various research and development grants.

November 2025 Registered Direct Offering

On November 5, 2025, we entered into a securities purchase agreement to sell securities in the November 2025 Registered Direct Offering for gross proceeds of approximately $23.0 million, before deducting offering expenses. The financing was led by Perceptive Advisors and Balyasny Asset Management, with participation by new and existing institutional investors, including Nantahala Capital. We intend to use the net proceeds to advance our LCA5 and BEST-1 gene therapy programs, as well as for working capital and general corporate purposes.

In the November 2025 Registered Direct Offering, we sold an aggregate of 3,827,751 shares of common stock at a price of $2.09 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 7,177,033 shares of common stock at a purchase price of $2.0899 per pre-funded warrant. Each pre-funded warrant has an exercise price of $0.0001 per share of common stock, will be immediately exercisable subject to certain conditions set forth in each pre-funded warrant, and will not expire. The offering closed on November 7, 2025.

August 2025 Private Placement

On August 25, 2025, we entered into subscription agreements pursuant to which we agreed to issue and sell in the August 2025 Private Placement to certain investors an aggregate of 3,138,338 shares of our common stock. The aggregate gross proceeds from the August 2025 Private Placement were approximately $3.5 million. The August 2025 Private Placement closed on August 25, 2025.

We intend to use the net proceeds of the August 2025 Private Placement to expedite manufacturing process development, including scale-up of clinical and commercial production and testing, to ensure sufficient supply of cGMP material for its gene therapy candidates, OPGx-LCA5 and OPGx-BEST1. No underwriting discounts or commissions were paid with respect to the August 2025 Private Placement.

The August 2025 Private Placement was led by Cam Gallagher, Chair of our board of directors (the "Board"), with an investment of $1.0 million, along with participation by Sean Ainsworth, the lead independent director of the Board, and other investors.

March 2025 Financings

On March 21, 2025, we entered into an underwriting agreement with Craig-Hallum Capital Group, LLC, as the sole underwriter. Pursuant to the underwriting agreement, we agreed to issue and sell, in an underwritten public offering, 12,219,736 shares of common stock and warrants to purchase up to 21,052,631 shares of common stock (the "March 2025 Warrants"). Each share of common stock was sold together with one March 2025 Warrant to purchase one share of common stock, at a price to the public of $0.95 per share and related March 2025 Warrant. We also agreed to issue 8,832,895 pre-funded warrants ("Pre-Funded Warrants") at a price to the public of $0.9499 per Pre-Funded Warrant.

Also on March 21, 2025, we entered into a subscription agreement (the "Subscription Agreement") with each of Dr. George Magrath, the Company's Chief Executive Officer, and Cam Gallagher, the chairman our Board. Pursuant to the Subscription Agreement, the Company agreed to issue and sell, in a private offering (the "March 2025 Private Placement"), a total of 392,157 shares of common stock to Mr. Magrath and 784,314 shares of common stock to Mr. Gallagher, as well as 392,157 warrants to purchase shares of common stock to Mr. Magrath and 784,314 warrants to purchase shares of common stock to Mr. Gallagher ("March 2025 Private Placement Warrants"). Each March 2025 Private Placement Warrant has an initial exercise price of $1.15, expires on the five-year anniversary of the original issuance date and may be called by the Company 30 days following the release of the Company's OPGx-BEST1 DUO-1001 Cohort 1 data upon achievement of a volume weighted average price of our common stock for 30 consecutive trading days of over $1.725 per share and the trading average daily volume for such 30 day period exceeds $150,000 per trading day.

The combined gross proceeds from the March 2025 Offering and the March 2025 Private Placement, which closed on March 24, 2025, were approximately $21.5 million, before deducting underwriting discounts and commissions and offering expenses payable by us.

The March 2025 Offering (including the shares of common stock issuable from time to time upon exercise of the March 2025 Warrants and the Pre-Funded Warrants) was made pursuant to our Registration Statement on Form S-3 (File No. 333-276462) filed with the SEC on January 10, 2024, including the prospectus dated January 23, 2024 contained therein, as the same has been supplemented.

March 2025 Warrants

The March 2025 Warrants have an initial exercise price equal to $0.95 per share of common stock and are exercisable for five years from the date of issuance. The exercise prices and numbers of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. A holder may not exercise the March 2025 Warrant if, after giving effect to such exercise, the holder (together with its affiliates) would beneficially own (as determined in accordance with the terms of the March 2025 Warrants) more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after giving effect to the exercise.

The March 2025 Warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the March 2025 Warrants are outstanding, if, after the closing date, March 24, 2025 (the "Closing Date"), (i) we have announced OPGx-BEST1 DUO-1001 Cohort 1 data, (ii) the volume weighted average price of the common stock for 30 consecutive trading days ("Warrant Measurement Period"), which 30 consecutive trading day period shall not have commenced until after the initial exercise date) exceeds $1.425 (subject to adjustment), (iii) the trading average daily volume for such Warrant Measurement Period exceeds $150,000 per trading day and (iv) the March 2025 Warrant holder is not in possession of any information that constitutes or might constitute material non-public information which was provided by the Company, its subsidiaries or any of its officers, directors, employees, agents or affiliates, then the Company may, within one trading day of the end of such Warrant Measurement Period, upon notice, call for cancellation of all or any portion of the March 2025 Warrants for which a notice of exercise has not yet been delivered for consideration equal to $0.001 per March 2025 Warrant share.

In the event of a fundamental transaction, as defined in the Form of Warrant, the holders of the March 2025 Warrants will be entitled to receive upon exercise the kind and amount of securities, cash or other property that the holders would have received had they exercised immediately prior to such fundamental transaction. Additionally, as more fully described in the Form of Warrant, in the event of certain fundamental transactions, the holders of the March 2025 Warrants will be entitled to receive consideration in an amount equal to the Black Scholes Value of the remaining unexercised portion of the March 2025 Warrants on the date of consummation of such fundamental transaction.

March 2025 Private Placement Warrants

The March 2025 Private Placement Warrants have an initial exercise price equal to $1.15 per share of common stock and are exercisable for five years from the date of issuance. The March 2025 Private Placement Warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the March 2025 Private Placement Warrants are outstanding, if, after the Closing Date, (i) the Company announces OPGx-BEST1 DUO-1001 Cohort 1 data, (ii) the volume weighted average price of the common stock for 30 consecutive trading days ("Private Placement Measurement Period"), which 30 consecutive trading day period shall not have commenced until after the initial exercise date) exceeds $1.725 (subject to adjustment), (iii) the trading average daily volume for such Private Placement Measurement Period exceeds $150,000 per trading day and (iv) the March 2025 Private Placement Warrant holder is not in possession of any information that constitutes or might constitute material non-public information which was provided by the Company, its subsidiaries or any of its officers, directors, employees, agents or affiliates, then the Company may, within one trading day of the end of such Private Placement Measurement Period, upon notice, call for cancellation of all or any portion of the March 2025 Private Placement Warrants for which a notice of exercise has not yet been delivered for consideration equal to $0.001 per March 2025 Private Placement Warrant share. All other terms under the March 2025 Private Placement Warrants are identical to the terms of the March 2025 Warrants discussed above.

Pre-Funded Warrants

The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and are immediately exercisable and are exercisable at any time until exercised in full. The exercise prices and numbers of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the common stock. A holder may not exercise the Pre-Funded Warrant if, after giving effect to such exercise, the holder (together with its affiliates) would beneficially own (as determined in accordance with the terms of the Pre-Funded Warrants) more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after giving effect to the exercise. In the event of a fundamental transaction, as defined in the Form of Pre-Funded Warrant, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

At-The-Market Program

On January 13, 2025, the Company filed a prospectus supplement with the SEC in connection with the establishment of an at-the-market equity offering program (the "ATM program") for the offer and sale, from time to time, of shares of its common stock, having an aggregate offering price of up to $40.0 million. On the same date, the Company also entered into a sales agreement (the "Sales Agreement") with Leerink Partners LLC ("Leerink"), pursuant to which the Company may offer and sell shares of its common stock through or to Leerink, acting as sales agent, under the ATM program. In connection with the entry into the Sales Agreement, the Company terminated its prior ATM program established under the Capital on Demand™ Sales Agreement, dated March 11, 2021, between the Company and JonesTrading Institutional Services LLC.

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 ("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 $0.3 million invested by directors of the Company, 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.

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, 2025, 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.

Cash Flows

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

	For the Nine Months Ended September 30,	
	2025	**2024**
Net cash used in operating activities	$ (25,420)	$ (18,138)
Net cash provided by (used in) investing activities	—	—
Net cash provided by financing activities	25,914	4,269
Net increase (decrease) in cash and cash equivalents	$ 494	$ (13,869)

Cash Flow from Operating Activities

For the nine months ended September 30, 2025, cash used in operating activities of $25.4 million was attributable to a net loss of $33.1 million, adjusted by a reclassification to financing activities related to the March 2025 financings and by non-cash net operating income of approximately $9.9 million in the aggregate, and attributed to a net change cash use of approximately $2.2 million in Opus's net operating assets and liabilities. The non-cash expenses consisted principally of a fair value change in warrant and other derivative liabilities benefit of $5.8 million, stock-based compensation of $2.6 million, non-cash interest expense of $0.1 million, and depreciation of less than $0.1 million. The reclassification to financing activities for issuance costs attributed to our liability classified warrants was $1.3 million. The change in operating assets and liabilities was primarily attributable to a net decrease in our accounts payable and accrued expenses and by an increase in our prepaid expenses and other current assets, offset in part by a decrease in our accounts receivable, contract assets. All of the changes were attributed to fluctuations in Opus's operating expenses and collections under the normal course of business.

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.

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, 2025 was $25.9 million that consisted principally of gross proceeds received from the March 2025 Offering and March 2025 Private Placement of $21.5 million in the aggregate, August 2025 Private Placement in the amount of $3.5 million and from the ATM in the amount of $2.1 million. Both financings were offset by issuance costs of $2.2 million in the aggregate. Lastly, we received funding of $1.0 million in connection with the RDF Agreement.

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.

Liquidity and Capital Resource Requirements

As of September 30, 2025 we had cash and cash equivalents of $30.8 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 and Processa in connection with the Rexahn RX-3117 drug compound, and other reimbursement from grants. 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 agreement with Viatris, 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 additional indications. 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 program with Leerink, we may offer and sell, from time to time at our sole discretion, to or through Leerink, acting as agent and/or principal, shares of our common stock having an aggregate offering price of up to $40 million. As of September 30, 2025, the Company had sold an aggregate of 9,479,494 shares of common stock under the ATM programs since their inception, resulting in gross proceeds of $28.5 million and total issuance costs of $1.4 million.

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

Our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 31, 2025, have not materially changed since we filed that report, except as discussed below.

Facility Lease

On January 1, 2025, the Company relocated its headquarters to Durham, North Carolina. On July 1st, 2025, the Company amended the lease for its headquarters in Durham, North Carolina for three months through September 30, 2025, and the lease is currently in place on a month-to-month basis.

The Company also leases additional laboratory space in Durham, North Carolina on a month-to-month basis. Upon the Opus Acquisition, the Company assumed a number of equipment leases which expired in July 2025 and are now on a month-to-month basis.

Letter Agreement and Strategic Partnership—FFB

Under the 2025 Letter Agreement, we are required to make the remaining $0.3 million payment installment on or before January 31, 2027 upon receipt of semi-annual reports from the FFB outlining the progress being made in the Study, including visit completion status and publication plans. For more information on the terms of the 2025 Letter Agreement and related payments thereunder, see Note 6 — Related Party Transactions in Part I, Item 1 – Financial Statements and Supplementary Data" of this Report.

RDF Agreement

On June 13, 2025, we entered into the RDF Agreement with the RDF, whose sole member is FFB, a significant stockholder of the Company, relating to our program to develop gene therapies to treat patients impacted by retinitis pigmentosa caused by pathogenic variants in the MERTK gene.

Under the RDF Agreement, we will pay a milestone payment equal to the total amounts funded by RDF under the RDF Agreement upon the achievement of a regulatory milestone. We will also make tiered royalty payments to RDF in low-to-mid single percentages until RDF has received aggregate royalty payments equal to 300% of the amounts funded by RDF under the Agreement. In the event of a change of control of the Company or a sale or exclusive license of the MERTK Program, RDF will have the option to require us to buy out RDF's interest under the Agreement for an amount equal to 100% of the funds disbursed to us under the Agreement. For more information on the terms and related obligations under the RDF Agreement, see Note 6 — Related Party Transactions in "Part I, Item 1 – Financial Statements and Supplementary Data" of this Report.

As of the date of this Report, we determined that none of the future obligations under the agreement were probable.

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 our gene therapy product candidates, inclusive of any potential milestone and royalty obligations under our intellectual property licenses. See "Part I, Item 1— Business— Pipeline— Sales and Marketing—Manufacturing— Apexian Sublicense Agreement— Review and Approval of Drugs and Biologics in the United States" in our Annual Report on Form 10-K for the year ended December 31, 2024 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 2026. Refer to Note 4 – 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. generally accepted accounting principles (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 Accounting Standards Codification 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 11 — License and Collaboration Revenue and Other Funding Agreements 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 13 — 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, 2024, and see Note 13 — Income Taxes 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 consolidated 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, 2025. 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, 2025.

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, 2025, 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

Other than as set forth below, there have been no material changes in our risk factors previously disclosed in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024. You should carefully consider the risks and uncertainties described below and therein.

Our ability to utilize our common stock to finance future capital needs, or for other purposes, is limited by our authorized shares available for issuance.

Following the November 2025 Registered Direct Offering, we had authority to issue a total of 125.0 million shares of common stock, of which approximately 69.0 million shares had been issued and 54.4 million shares were reserved for issuance pursuant to outstanding stock options, restricted stock units, and warrants.

With the limited shares of common stock presently available for issuance, our ability to secure additional funding through the sale of common stock is very limited. Absent an increase in the shares of common stock authorized to be issued, we will be limited to other financing structures in the event additional financing is required. Such alternative structures may be less favorable or unavailable in which case we may be forced to forego opportunities. We may also be limited in our ability to offer equity awards to incentive our employees if we do not have adequate shares available for issuance.

Instability and operational disruptions at government agencies, such as the FDA, may adversely impact our development and commercialization plans by causing delays and requiring the use of additional, unforeseen resources to obtain regulatory approval for trials or products in our pipeline.

Our business depends largely on the successful clinical development, regulatory approval and commercialization of our product candidates. To advance our candidates, we, along with many of the third-parties we currently and may in the future work with, must work closely with the FDA and comparable regulatory agencies in foreign jurisdictions. Such authorities play a vital role in the development of our product candidates by providing guidance on our clinical programs and reviewing and approving our regulatory submissions, including IND applications, requests for special designations, such as Orphan Drug Designation and Rare Pediatric Disease Designation, and marketing applications.

If these agencies experience unexpected funding losses or mass layoffs or are otherwise affected by the current or any future shutdown of the U.S. federal government, their oversight and review activities of existing and new submissions, such as IND applications, may be significantly disrupted or delayed. Such disruptions or delays could adversely impact our ability to develop and secure timely approval of our product candidates.

There are also ongoing deliberations within the current presidential administration and Congress over potentially substantial proposed cuts to the overall budget for the U.S. Department of Health and Human Services and funding of the FDA for the 2026 federal fiscal year. These budgetary decisions are unpredictable and remain subject to change. Such decisions could make it more difficult to secure grant funding from government agencies and nongovernmental foundations. Further, there is also instability and uncertainty surrounding how the current U.S. administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. We may have to expend additional resources to comply with any new policies and to engage with the appropriate agencies.

Government shutdowns and funding cuts may also negatively affect the SEC. In the event of an extended shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

If we fail to comply with the continued listing standards of Nasdaq, our common stock may be delisted, and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on the Nasdaq Capital Market ("Nasdaq"). In order to maintain our listing, we must satisfy Nasdaq's continued listing requirements (the "Nasdaq Listing Rules"). The Nasdaq Listing Rules require that the closing price of our common stock generally remains at or above $1.00 per share (the "Minimum Bid Price Requirement"). The closing price of our common stock has recently traded below $1.00, and may fall below $1.00 per share in the future. If our common stock closes at a price below $1.00 per share for 30 consecutive business days, we could be delisted from Nasdaq. In the event we do receive notice of deficiency from Nasdaq, we expect that applicable Nasdaq Listing Rules would provide us with an initial period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement, which may be extended by Nasdaq in its discretion.

There are no assurances that we will be able to continue to comply with the Minimum Bid Price Requirement. We intend to monitor the closing price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement, which could include seeking to effect a reverse stock split. There are many factors outside of our control that may adversely affect our minimum bid price, including those described in the "Risk Factors" section of our most recent Annual Report on Form 10-K for the year ended December 31, 2024 and in our other filings with the SEC.

Any potential delisting of our common stock from Nasdaq would likely result in decreased liquidity and increased volatility for our common stock and may damage our reputation, adversely affecting our ability to raise additional capital or to pursue our strategic business plans. Additionally, delisting would make it more difficult for our stockholders to sell our common stock in the public market. Further, if the Company seeks to implement a reverse stock split in order to remain listed, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock.

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

During the quarter ended September 30, 2025, 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
4.1	Fourth Amendment to Ocuphire Pharma, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 4.8 to Registrant's Registration Statement on Form S-8, filed on September 10, 2025).
10.1+	Funding and License Agreement, dated as of July 22, 2025, by and among the Company, OpusTX, LLC, Eyes on the Future and RDH12 Fund for Sight (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q, filed on August 13, 2025).
10.2	Employment Agreement, dated as of August 29, 2025, by and between the Company and Robert Gagnon (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed on September 2, 2025).
10.3**+	Side Letter to the License and Collaboration Agreement, dated as of August 13, 2025, by and between the Company and FamilyGen Life Sciences, Inc.
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.

\+ Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

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, 2025

Opus Genetics, Inc.

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

By: /s/ Robert Gagnon
Robert Gagnon
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 10.3

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. OMITTED INFORMATION HAS BEEN REPLACED WITH ASTERISKS [***].

Side Letter to the License and Collaboration Agreement

FamyGen Life Sciences, Inc. ("***FamyGen***") and Opus Genetics, Inc. f/k/a Ocuphire Pharma Inc., ("***Opus***") (each a "Party" and collectively, the "***Parties***") have entered into a License and Collaboration Agreement dated November 6, 2022 (the "***License Agreement***"), defining certain rights and obligations between the parties regarding Third Party Infringement actions concerning the Licensed Intellectual Property Rights. In accordance with Section 8.5 of the License Agreement, FamyGen and Opus have instituted Civil Action No. 25-1895 (D.N.J) against a Third Party asserting one or more patents listed in the Orange Book in connection with NDA No. 217064 for RYZUMVI® (the "***Action***"). This letter sets forth the terms and conditions upon which FamyGen and Opus shall share the expenses associated with the Action only.

The Parties hereby agree that Opus shall pay Expenses[1] up to a cap of $[***] in the Action as follows:

1. Opus shall pay the first $[***] in Expenses as they are billed.

2. Any Expenses in excess of the first $[***] incurred as of October 15, 2026, will be paid initially by FamyGen. The accrued balance of those Expenses, up to the cap of $[***], will then be paid by Opus to FamyGen in full by no later than November 15, 2026.

3. After October 15, 2026, any Expenses up to the cap of $[***] will be paid by Opus as they are billed.

4. To the extent there are any outstanding Expenses (up to the cap of $[***] less Expenses already paid by Opus) owed to FamyGen by Opus upon achieving FDA Approval for Product 1B or Product 1C (as defined in the License Agreement), FamyGen shall have the right to offset such amount of outstanding Expenses by withholding the equivalent amount from any Regulatory Milestone payment related to FDA Approval for either Product 1B or Product 1C under Schedule 3, Section 1. (b) of the License Agreement.

5. To the extent FDA Approval for Product 1B or Product 1C has not occurred, or occurred at a point in time where no Expenses were owed, FamyGen shall have the right to offset any outstanding Expenses (up to the cap of $[***] less Expenses already paid by Opus) by withholding the equivalent amount from any royalties owed pursuant to the Royalty Payments owed under Schedule 3, Section 1.(c) of the License Agreement.

[1] The term "Expenses" means all reasonable and necessary costs and expenses related to the Action, exclusive of attorneys' fees of Katten and Dechert and any other outside counsel retained by Opus and FamyGen, and includes without limitation court filing fees, third party document review, process server fees, expert witness fees and expenses, local counsel fees, deposition costs, including court reporter fees and transcription costs, document and electronic data hosting and duplication costs, travel expenses, demonstrative exhibits costs, translation services and any other out-of-pocket expenses directly related to the Action.

6. Opus agrees to pay any and all attorneys' fees and costs of any law firm retained solely by Opus in connection with the Action.

Except as expressly provided in this letter, all terms and provisions of the License Agreement are and will remain in full force and effect.

[SIGNATURE PAGE FOLLOWS]

The foregoing accurately reflects the Parties' understanding of the terms and conditions for the sharing of expenses for the Action brought pursuant to the License Agreement.

FAMYGEN LIFE SCIENCES, INC.

By: /s/ Kevin Macikowski

Name: Kevin Macikowski

Title: Assistant Secretary

OPUS GENETICS, INC.

By: /s/ Bernhard Hoffmann

Name: Bernhard Hoffmann

Title: SVP – Corporate Development

Exhibit 31.1

CERTIFICATION 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 quarter ended September 30, 2025 of Opus Genetics, 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 consolidated 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(s) 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 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(s) 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, 2025

/s/ George Magrath

Name: George Magrath
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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, Robert Gagnon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 of Opus Genetics, 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 consolidated 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(s) 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 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(s) 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, 2025

/s/ Robert Gagnon

Name: Robert Gagnon
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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, 2025 (the "Report") of Opus Genetics, Inc., a Delaware corporation (the "Company") as filed with the Securities and Exchange Commission, George Magrath, as Chief Executive Officer of the Company, and Robert Gagnon, 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.

Date: November 12, 2025

/s/ George Magrath
George Magrath
Chief Executive Officer
(*Principal Executive Officer*)

/s/ Robert Gagnon
Robert Gagnon
Chief Financial Officer
(*Principal Financial Officer and Principal Accounting Officer*)