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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 June 30, 2025

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-37759

**OUTLOOK THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

38-3982704  
(I.R.S. Employer  
Identification No.)

111 S. Wood Avenue, Unit #100  
Iselin, New Jersey  
(Address of principal executive offices)

08830  
(Zip Code)

(609) 619-3990

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock	OTLK	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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any 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 shares of the registrant's common stock, \$0.01 par value per share, outstanding as of August 11, 2025 was 44,419,529.

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In this report, unless otherwise stated or as the context otherwise requires, references to “Outlook Therapeutics,” “Outlook,” “the Company,” “we,” “us,” “our” and similar references refer to Outlook Therapeutics, Inc. and its consolidated subsidiaries. The Outlook logo, LYTENAVA and other trademarks or service marks of Outlook Therapeutics, Inc. appearing in this report are the property of Outlook Therapeutics, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

References to ONS-5010 and/or LYTENAVA refer to an ophthalmic formulation of bevacizumab for use in retinal indications which, as the context requires: (i) is currently commercially available in Germany and in the United Kingdom as LYTENAVA™ (bevacizumab gamma) for the treatment of wet age-related macular degeneration (wet AMD) and (ii) is currently the subject of a Biologics Licensing Application under review by the U.S. Food and Drug Administration.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this report, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “seek,” “should,” “will,” “would,” or the negative of these terms or similar expressions in this report.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended September 30, 2024, filed with the Securities and Exchange Commission (“SEC”) on December 27, 2024, and in Part II, Item 1A. “Risk Factors” of this Quarterly Report, including, among other things, risks associated with:

- our ability to obtain and maintain regulatory approval for ONS-5010/LYTENAVA in the United States and other markets;
- our ability to successfully commercialize and generate revenues from the sale of LYTENAVA™ (bevacizumab gamma) in the United Kingdom and European Union;
- the rate and degree of market acceptance of our current and future product candidates, including our commercialization strategy and manufacturing capabilities for ONS-5010/LYTENAVA;
- our ability to fund our working capital requirements, the sufficiency of our current cash resources and our need for additional funding;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved, for commercial use;
- whether the results of our clinical trials will be sufficient to support domestic or global regulatory approvals;
- the initiation, timing, progress and results of our clinical trials of our lead product candidate, ONS-5010/LYTENAVA;
- our reliance on our contract manufacturing organizations and other vendors;
- the implementation of our business model and strategic plans for our business and product candidates;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our ability to maintain and establish collaborations or obtain additional funding;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve; and
- the factors that may impact our financial results.

These risks are not exhaustive. Additional factors could harm our business and financial performance, such as risks associated with the current macroeconomic environment, including as a result of the impacts of fluctuations in inflation, and interest rates, tariffs and trade tensions, current or potential future bank failures or ongoing overseas conflict. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, 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, or implied by, any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. We qualify all of the forward-looking statements in this report by these cautionary statements.

**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Outlook Therapeutics, Inc.  
Consolidated Balance Sheets  
(unaudited)**

	<u>June 30, 2025</u>	<u>September 30, 2024</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,900,814	\$ 14,927,538
Accounts receivable	1,751,422	—
Inventory	4,126,716	—
Prepaid expenses and other current assets	6,317,332	12,488,498
Total current assets	<u>21,096,284</u>	<u>27,416,036</u>
Operating lease right-of-use assets, net	238,266	274,645
Equity method investment	592,602	693,190
Other assets	464,388	439,283
Total assets	<u>\$ 22,391,540</u>	<u>\$ 28,823,154</u>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Current portion of unsecured convertible promissory note	\$ 14,000,000	\$ 29,440,000
Current portion of operating lease liabilities	56,560	50,907
Accounts payable	10,262,137	7,968,725
Accrued expenses	5,313,670	3,237,468
Income taxes payable	1,856,629	1,856,629
Total current liabilities	<u>31,488,996</u>	<u>42,553,729</u>
Unsecured convertible promissory note	20,437,000	—
Operating lease liabilities	204,145	246,922
Warrant liability	7,451,124	59,099,013
Total liabilities	<u>59,581,265</u>	<u>101,899,664</u>
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Preferred stock, par value \$0.01 per share: 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, par value \$0.01 per share; 260,000,000 shares authorized; 43,479,051 and 23,905,635 shares issued and outstanding at June 30, 2025 and September 30, 2024, respectively	434,791	239,057
Additional paid-in capital	554,792,478	469,969,333
Accumulated deficit	(592,416,994)	(543,284,900)
Total stockholders' deficit	<u>(37,189,725)</u>	<u>(73,076,510)</u>
Total liabilities and stockholders' deficit	<u>\$ 22,391,540</u>	<u>\$ 28,823,154</u>

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

**Outlook Therapeutics, Inc.**  
**Consolidated Statements of Operations**  
**(unaudited)**

	Three months ended June 30,		Nine months ended June 30,	
	2025	2024	2025	2024
Revenues, net	\$ 1,505,322	\$ —	\$ 1,505,322	\$ —
Cost of revenues	439,815	—	439,815	—
Gross profit	1,065,507	—	1,065,507	—
Operating expenses:				
Research and development	7,134,706	11,201,754	21,201,875	29,240,046
Selling, general and administrative	9,679,481	8,360,933	29,610,692	19,585,738
Loss from operations	(15,748,680)	(19,562,687)	(49,747,060)	(48,825,784)
Loss on equity method investment	30,884	57,497	100,588	85,544
Interest expense (income), net	49,351	(404,593)	18,972	2,490,765
Loss (gain) from change in fair value of promissory notes	2,323,977	(7,563,000)	5,739,005	1,949,153
Warrant related expenses (Note 9)	—	3,392,444	—	37,490,012
Warrant inducement expenses (Note 9)	—	—	33,856,814	—
Loss (gain) from change in fair value of warrant liability	1,999,610	(59,454,222)	(40,333,145)	(9,786,063)
(Loss) income before income taxes	(20,152,502)	44,409,187	(49,129,294)	(81,055,195)
Income tax expense	—	—	2,800	2,800
Net (loss) income	<u>\$ (20,152,502)</u>	<u>\$ 44,409,187</u>	<u>\$ (49,132,094)</u>	<u>\$ (81,057,995)</u>
Per share information:				
Net (loss) income per share of common stock, basic	<u>\$ (0.55)</u>	<u>\$ 1.91</u>	<u>\$ (1.60)</u>	<u>\$ (4.82)</u>
Net loss per share of common stock, diluted	<u>\$ (0.55)</u>	<u>\$ (0.89)</u>	<u>\$ (1.60)</u>	<u>\$ (4.82)</u>
Weighted average shares outstanding, basic	<u>36,956,582</u>	<u>23,227,069</u>	<u>30,663,988</u>	<u>16,822,774</u>
Weighted average shares outstanding, diluted	<u>36,956,582</u>	<u>25,476,438</u>	<u>30,663,988</u>	<u>16,822,774</u>

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

**Outlook Therapeutics, Inc.**  
**Consolidated Statements of Stockholders' Deficit**  
**(unaudited)**

	<b>Stockholders' Deficit</b>				
	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Deficit</b>
	<b>Shares</b>	<b>Amount</b>			
Balance at October 1, 2024	23,905,635	\$ 239,057	\$ 469,969,333	\$ (543,284,900)	\$ (73,076,510)
Sale of common stock, net of issuance costs	1,000,000	10,000	1,726,042	—	1,736,042
Stock-based compensation expense	—	—	3,672,420	—	3,672,420
Net income	—	—	—	17,377,614	17,377,614
Balance at December 31, 2024	24,905,635	249,057	475,367,795	(525,907,286)	(50,290,434)
Sale of common stock, net of issuance costs	926,742	9,268	1,401,947	—	1,411,215
Issuance of common stock and common stock warrants in connection with exercise of common stock warrants	7,074,637	70,746	60,980,296	—	61,051,042
Stock-based compensation expense	—	—	1,722,778	—	1,722,778
Net loss	—	—	—	(46,357,206)	(46,357,206)
Balance at March 31, 2025	32,907,014	329,071	539,472,816	(572,264,492)	(32,462,605)
Sale of common stock, net of issuance costs	10,560,976	105,609	13,612,639	—	13,718,248
Issuance of common stock in connection with conversion of convertible promissory note	11,061	111	24,889	—	25,000
Stock-based compensation expense	—	—	1,682,134	—	1,682,134
Net loss	—	—	—	(20,152,502)	(20,152,502)
Balance at June 30, 2025	<u>43,479,051</u>	<u>\$ 434,791</u>	<u>\$ 554,792,478</u>	<u>\$ (592,416,994)</u>	<u>\$ (37,189,725)</u>

	<b>Stockholders' Equity Deficit</b>				
	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Deficit</b>
	<b>Shares</b>	<b>Amount</b>			
Balance at October 1, 2023	13,012,833	\$ 130,128	\$ 453,350,281	\$ (467,918,186)	\$ (14,437,777)
Stock-based compensation expense	—	—	1,272,611	—	1,272,611
Net loss	—	—	—	(11,178,239)	(11,178,239)
Balance at December 31, 2023	13,012,833	130,128	454,622,892	(479,096,425)	(24,343,405)
Sale of common stock, net of issuance costs	8,571,423	85,714	—	—	85,714
Issuance of common stock in connection with conversion of convertible promissory note	428,571	4,286	2,995,714	—	3,000,000
Stock-based compensation expense	—	—	1,310,507	—	1,310,507
Net loss	—	—	—	(114,288,943)	(114,288,943)
Balance at March 31, 2024	22,012,827	\$ 220,128	\$ 458,929,113	\$ (593,385,368)	\$ (134,236,127)
Sale of common stock, net of issuance costs	714,286	7,143	—	—	7,143
Issuance of common stock in connection with conversion of convertible promissory note	678,524	6,786	4,743,214	—	4,750,000
Stock-based compensation expense	—	—	1,396,309	—	1,396,309
Net income	—	—	—	44,409,187	44,409,187
Balance at June 30, 2024	<u>23,405,637</u>	<u>\$ 234,057</u>	<u>\$ 465,068,636</u>	<u>\$ (548,976,181)</u>	<u>\$ (83,673,488)</u>

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

**Outlook Therapeutics, Inc.**  
**Consolidated Statements of Cash Flows**  
**(unaudited)**

	<b>Nine months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (49,132,094)	\$ (81,057,995)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization	87,315	85,062
Non-cash interest expense	—	2,681,847
Stock-based compensation	7,077,332	3,979,427
Loss from change in fair value of promissory notes	5,739,005	1,949,153
Warrant related expenses (Note 9)	—	37,490,012
Warrant inducement expenses (Note 9)	33,856,814	—
Gain from change in fair value of warrant liability	(40,333,145)	(9,786,063)
Loss on equity method investment	100,588	85,544
Changes in operating assets and liabilities:		
Accounts receivable	(1,751,422)	—
Inventory	(4,126,716)	—
Prepaid expenses and other current assets	6,171,166	(6,006,045)
Other assets	(95,246)	(28,866)
Operating lease liabilities	(37,124)	(2,220)
Accounts payable	1,635,794	(1,136,993)
Accrued expenses	1,355,493	(64,826)
Net cash used in operating activities	<u>(39,452,240)</u>	<u>(51,811,963)</u>
<b>FINANCING ACTIVITIES</b>		
Proceeds from the sale of common stock and warrants to purchase common stock, net of issuance costs	17,311,389	60,448,635
Proceeds from exercise of common stock warrants	16,831,132	—
Proceeds from debt	33,100,000	—
Payments of finance lease obligations	—	(4,267)
Repayment of debt	(33,817,005)	—
Net cash provided by financing activities	<u>33,425,516</u>	<u>60,444,368</u>
Net (decrease) increase in cash and cash equivalents	<u>(6,026,724)</u>	<u>8,632,405</u>
Cash and cash equivalents at beginning of period	14,927,538	23,391,982
Cash and cash equivalents at end of period	<u>\$ 8,900,814</u>	<u>\$ 32,024,387</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ —	\$ 475,000
Supplemental schedule of non-cash financing activities:		
Convertible promissory note converted into common stock	\$ 25,000	\$ 7,750,000
Recognition of warrant liability	\$ —	\$ 97,730,836
Fair value of common stock warrants exercised reclassified from warrant liability to equity	\$ 13,262,801	\$ —
Common stock and warrant issuance costs in accounts payable and accrued expenses	\$ 1,378,327	\$ 114,954
Reclassification of deferred offering costs against ATM proceeds	\$ 19,205	\$ —
Right-of-use asset and lease liability recognized for new operating lease liabilities	\$ —	\$ 294,416

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

**Outlook Therapeutics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**1. Organization and Description of Business**

Outlook Therapeutics, Inc. (“Outlook” or the “Company”) was incorporated in New Jersey on January 5, 2010, started operations in July 2011, reincorporated in Delaware by merging with and into a Delaware corporation in October 2015 and changed its name to “Outlook Therapeutics, Inc.” in November 2018. The Company is a biopharmaceutical company focused on developing and commercializing ONS-5010/LYTENAVA™, an ophthalmic formulation of bevacizumab for use in retinal indications. The Company is based in Iselin, New Jersey.

In May 2024 the Company received Marketing Authorization from the European Commission for LYTENAVA (bevacizumab gamma), an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (“AMD”) in the European Union (“EU”). Additionally, in July 2024 the Company also received marketing authorization for LYTENAVA (bevacizumab gamma) in the United Kingdom (“UK”) from the UK Medicines and Healthcare products Regulatory Agency (“MHRA”). LYTENAVA (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK. In June 2025, the Company launched LYTENAVA commercially in both Germany and the UK, and commenced commercial sales in those countries.

In the fourth quarter of calendar 2023, the Company agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the U.S. Food and Drug Administration (“FDA”) in support of the Company’s Biologics License Application (“BLA”) for ONS-5010/LYTENAVA. In December 2023, the Company submitted a Special Protocol Assessment (“SPA”) to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA’s requirement for a second adequate and well-controlled clinical trial to support its planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, the Company received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA and that, if the NORSE EIGHT trial is successful, it would satisfy the FDA’s requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (“CRL”). In addition, through a Type A meeting and additional interactions, the Company has identified the approaches needed to resolve the chemistry, manufacturing and controls (“CMC”) comments in the CRL. In November 2024, the Company reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. In January 2025, the Company reported the complete data and safety results from NORSE EIGHT which demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. The Company resubmitted the BLA application for ONS-5010/LYTENAVA in February 2025. In April 2025, the Company received notification from the FDA that the Prescription Drug User Fee Act (“PDUFA”) goal date for a decision on the BLA is August 27, 2025.

**2. Liquidity**

The Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of \$592,416,994 as of June 30, 2025. As of June 30, 2025, the Company had a working capital deficit. Additionally, the Company has \$35,718,663 of principal, accrued interest and exit fees due under an unsecured convertible promissory note issued in March 2025 (the “March 2025 Note”), maturing on July 1, 2026. Refer to Note 7 for further details on the March 2025 Note. As a result, there is substantial doubt about the Company’s ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Subsequent to June 30, 2025, the Company sold 940,478 shares of common stock under the ATM Agreement (refer to Note 9 for further details) and generated \$1,875,835 in net proceeds after paying fees to BTIG and other issuance costs of \$58,016.

**Outlook Therapeutics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

On July 31, 2025, the Company paid \$1,000,000 on the March 2025 Note. This payment constituted a partial fulfillment of the debt reduction obligations for the quarter ended June 30, 2025. Refer to Note 7 for further details.

Management does not believe that the existing cash and cash equivalents as of June 30, 2025, together with \$1,875,835 in net proceeds from the sale of shares of common stock under the ATM Agreement since June 30, 2025, are sufficient to fund the Company's operations through one year from the date of this Quarterly Report on Form 10-Q. As a result, additional financing will be needed by the Company to fund its operations in the future, fully commercialize ONS-5010/LYTENAVA and to develop any other product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations, including but not limited to, proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, sale of the development and commercial rights to the Company's drug product candidates in regions outside of the U.S., the issuance of additional debt, the issuance of equity securities, including accessing capital through at-the-market offerings (refer to Note 9 for further details), and revenues from product sales. There can be no assurance that any of these future funding efforts will be successful.

The Company's future operations are highly dependent on a combination of factors, including: (i) the timely and successful completion of additional financing discussed above; (ii) the Company's ability to successfully commercialize ONS-5010/LYTENAVA, including executing marketing arrangements or completing revenue-generating partnerships with other companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products.

### **3. Basis of Presentation and Summary of Significant Accounting Policies**

#### **Basis of presentation**

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2025 and its results of operations for the three and nine months ended June 30, 2025 and 2024, cash flows for the nine months ended June 30, 2025 and 2024, and stockholders' deficit for the three and nine months ended June 30, 2025 and 2024. Operating results for the nine months ended June 30, 2025 are not necessarily indicative of the results that may be expected for the full year ending September 30, 2025. The unaudited interim consolidated financial statements presented herein do not contain all of the required disclosures under GAAP for annual consolidated financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended September 30, 2024 included in the Company's Annual Report on Form 10-K filed with the SEC on December 27, 2024.

#### **Reverse stock split**

Effective on March 14, 2024, the Company amended its amended and restated certificate of incorporation to implement a 1-for-20 reverse stock split of its common stock. As a result of the reverse stock split, the Company made corresponding adjustments to the share amounts under its employee incentive plans, outstanding options, and common stock warrant agreements with third parties. The disclosure of common shares and per common share data in the accompanying unaudited interim consolidated financial statements and related notes reflect the reverse stock split for all periods presented.

**Outlook Therapeutics, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**

**Accounts Receivable**

As of June 30, 2025, the Company had no allowance for credit losses. An allowance for credit losses is determined based on the Company's assessment of the creditworthiness and financial condition of its customers, aging of receivables, as well as the general economic environment. Any allowance would reduce the net receivables to the amount that is expected to be collected.

**Inventory**

The Company values inventory at the lower of cost or net realizable value, computed on a weighted average basis. The Company regularly reviews its inventory quantities and, when appropriate, records a provision for obsolete and excess inventory to derive the new cost basis, which takes into account the Company's sales forecast and corresponding expiry dates. The Company has not recognized a provision for obsolete and excess inventory as of June 30, 2025.

Upon the initiation of production for the first commercial batches of drug product in October 2024, the Company began capitalizing the purchases of saleable inventory of the product from suppliers. The Company expenses prelaunch inventory as research and development expense in the period incurred unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and where the Company also expects the future economic benefit from the sales of the product candidate to be realized. There were no costs related to prelaunch inventory included in inventory as of June 30, 2025, and September 30, 2024. As of June 30, 2025, the inventory consisted of the following:

	June 30, 2025	September 30, 2024
Work-in-process	\$ 3,749,493	\$ —
Finished goods	377,223	—
Total inventory	<u>\$ 4,126,716</u>	<u>\$ —</u>

**Use of estimates**

The preparation of the unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim consolidated financial statements, such as the current macroeconomic environment, including as a result of fluctuations in inflation and interest rates, tariffs and trade tensions, and ongoing overseas conflict, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

**Revenue recognition**

The Company recognizes revenue from sales of a single product, LYTENAVA (bevacizumab gamma) (the "Product") in accordance with ASC Topic 606 – *Revenue from Contracts with Customers*. LYTENAVA (bevacizumab gamma) became available for commercial sale and shipment to patients in Europe in fiscal year 2025. The Company sells the Product to several customers who are pharmaceutical wholesalers/distributors (the "Customers") who in turn sell the Product directly to clinics, hospitals, and pharmacies. Revenue is recognized as the Product is physically delivered to the customers.

Gross product sales are reduced by corresponding Gross-to-Net ("GTN") estimates using the expected value method, resulting in the Company's reported "Revenues, net" in the accompanying consolidated statements of operations. Revenues, net reflects the amount the Company ultimately expects to realize in net cash proceeds, taking into account the current period gross sales and related cash receipts and the subsequent cash disbursements on these sales that the Company estimates for the various GTN categories discussed below. The GTN estimates are based upon information received from

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external sources, such as written or oral information obtained from customers with respect to their period-end inventory levels and sales to end-users during the period, in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount of product returns, rebates and administrative fees may be materially above or below the amount estimated. The variance between actual amounts and estimated amounts may result in prospective adjustments to the reported net product revenue.

Each of the GTN estimate categories are discussed below:

- Sales returns are estimated by the Company based on the relative risk of return based on expiration date, and other qualitative factors that can impact the volume of future returns, including competitive developments, product discontinuation, or new product introductions. The Company will consider the level of inventory in the distribution channel by monitoring inventories held at the distributor and wholesalers to assess whether historical rates of returns continue to be appropriate.
- Administrative fees are contractually charged by the wholesalers and are typically credited directly against amounts due to the Company.
- Rebates are contractually charged to the Company by customers, including a Voluntary Scheme for Branded Medicines Pricing, Access and Growth rebate with the National Health System in the UK.

**Cost of revenues**

Cost of revenues consists primarily of the cost of inventory sold, which includes direct manufacturing, production and packaging materials for LYTENAVA (bevacizumab gamma) sales. Prior to receiving authorization to sell LYTENAVA (bevacizumab gamma) in Europe, the Company expensed costs associated with manufacturing of LYTENAVA (bevacizumab gamma) as a component of research and development expense that would have been included in cost of revenues for the three and nine months ended June 30, 2025 in the amount of \$261,450 in both periods. Therefore, these costs are not included in cost of revenues.

**Net (loss) income per share**

Basic net income (loss) per share of common stock is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, warrants, performance-based stock options and units, and stock options using the treasury stock method, which would result in the issuance of incremental shares of common stock. For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

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The following table sets forth the computation of basic (loss) income per share and diluted loss per share:

	<u>Three months ended June 30,</u>		<u>Nine months ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Numerator:				
Net (loss) income attributable to common stockholders	\$ (20,152,502)	\$ 44,409,187	\$ (49,132,094)	\$ (81,057,995)
Effect of dilutive securities:				
Gain from change in fair value of warrant liability	—	(59,393,374)	—	—
Gain from change in fair value of promissory notes	—	(7,563,000)	—	—
Adjusted net loss attributable to common stockholders	<u>\$ (20,152,502)</u>	<u>\$ (22,547,187)</u>	<u>\$ (49,132,094)</u>	<u>\$ (81,057,995)</u>
Denominator:				
Weighted average shares outstanding, basic	36,956,582	23,227,069	30,663,988	16,822,774
Effect of dilutive securities:				
Common stock warrants	—	562,685	—	—
Convertible promissory notes	—	1,686,684	—	—
Common stock shares outstanding (weighted average)	<u>36,956,582</u>	<u>25,476,438</u>	<u>30,663,988</u>	<u>16,822,774</u>
Basic net (loss) income per share	<u>\$ (0.55)</u>	<u>\$ 1.91</u>	<u>\$ (1.60)</u>	<u>\$ (4.82)</u>
Diluted net loss per share	<u>\$ (0.55)</u>	<u>\$ (0.89)</u>	<u>\$ (1.60)</u>	<u>\$ (4.82)</u>

During the three and nine months ended June 30, 2025, and the nine months ended June 30, 2024, the Company incurred a net loss. As a result, all potentially dilutive securities were considered anti-dilutive and were excluded from the calculation of diluted EPS. Therefore, basic and diluted EPS are the same for such periods. The following potentially dilutive securities (in common stock equivalents) have been excluded from the computation of diluted weighted-average shares outstanding for the three and nine months ended June 30, 2025 and 2024, as they would be antidilutive:

	<u>Three months ended June 30,</u>		<u>Nine months ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Performance-based stock options	190,000	666,500	190,000	666,500
Stock options	2,822,893	1,928,646	2,822,893	1,928,646
Common stock warrants	39,811,227	279,060	39,811,227	14,207,622
Convertible debt	14,702,063 (i)	—	14,702,063 (i)	1,648,884

- (i) The potentially dilutive securities related to convertible debt are calculated based on a fixed conversion price of \$2.26, which is subject to change as described in Note 7.

**Recently issued accounting pronouncements**

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07, which is applicable to entities with a single reportable segment and will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The ASU requires greater disaggregation of income tax disclosures primarily on the income tax rate

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reconciliation and income taxes paid. This authoritative guidance will be effective for fiscal years beginning after December 15, 2024, and for interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the effect of this new standard on the Company's disclosures.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*. ASU 2024-03 requires additional disclosure of specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its consolidated financial statements and disclosures.

#### 4. Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

The following table presents the Company's liabilities that are measured at fair value on a recurring basis:

	June 30, 2025		
	(Level 1)	(Level 2)	(Level 3)
<b>Liabilities</b>			
Unsecured convertible promissory note	\$ —	\$ —	\$ 34,437,000
Warrant liability	—	—	7,451,124
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 41,888,124</u>
	September 30, 2024		
	(Level 1)	(Level 2)	(Level 3)
<b>Liabilities</b>			
Unsecured convertible promissory note	\$ —	\$ —	\$ 29,440,000
Warrant liability	—	—	59,099,013
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 88,539,013</u>

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The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the warrant liability and unsecured convertible promissory notes for the nine months ended June 30, 2025:

	Unsecured Convertible Promissory Notes	Warrants
Balance at October 1, 2024	\$ 29,440,000	\$ 59,099,013
Fair value of unsecured convertible promissory note issued	33,100,000	—
Loss (gain) from change in fair value	5,739,005	(40,333,145)
Loss from change in fair value from warrant inducement	—	1,948,057
Fair value of common stock warrants exercised reclassified to equity	—	(13,262,801)
Accrued interest converted to common stock	(25,000)	—
Repayment	(33,817,005)	—
Balance at June 30, 2025	<u>\$ 34,437,000</u>	<u>\$ 7,451,124</u>

*Unsecured convertible promissory notes*

As further described in Note 7, the Company elected the fair value option to account for the unsecured convertible promissory notes. The fair value is estimated using a binomial lattice model, which evaluates the payouts under hold, convert or call decisions. Significant estimates in the binomial lattice model include the Company's stock price, volatility, risk-free rate of return, and credit-adjusted discount rate.

The fair values of the unsecured convertible promissory notes were estimated using a binomial lattice model with the following assumptions:

	June 30, 2025	September 30, 2024
Term (years)	1.0	0.8
Volatility	137.0 %	91.0 %
Risk-free rate	4.0 %	4.2 %
Dividend yield	— %	— %
Credit-adjusted discount rate	18.7 %	20.4 %
Stock price	\$ 1.60	\$ 5.34

*Common stock warrants*

The warrants issued (i) in connection with the convertible senior secured notes originally issued pursuant to that certain Note and Warrant Purchase Agreement dated December 22, 2017, of which the remaining warrants expired on May 31, 2025 (the "2017 Warrants"), and (ii) in connection with private placements that closed on March 18, 2024 and April 15, 2024 (the "Private Placement Warrants") were classified as liabilities on the accompanying unaudited interim consolidated balance sheets. The 2017 warrants were classified as liabilities as the warrants include cash settlement features at the option of the holders under certain circumstances. The Private Placement Warrants are classified as liabilities as the Company assessed that they are not indexed to the Company's own stock.

During the nine months ended June 30, 2025, the Company reclassified the warrant liability balance of \$13,262,801 into additional paid in capital upon the exercise of certain of the Private Placement Warrants. Refer to Note 9 for further details on warrants exercised pursuant to the Warrant Inducement Transaction.

The above warrant liabilities are revalued each reporting period with the change in fair values recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair values of the

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warrant liabilities are estimated using the Black-Scholes option pricing model using the following weighted average assumptions:

	<u>June 30, 2025</u>	<u>September 30, 2024</u>
Risk-free interest rate	3.72 %	3.58 %
Remaining contractual term of warrants (years)	3.7	4.5
Expected volatility	138.2 %	125.0 %
Annual dividend yield	— %	— %
Stock price	\$ 1.60	\$ 5.34

## 5. Equity Method Investment

In connection with the execution of a stock purchase agreement with Syntone Ventures, LLC (“Syntone”), the United States-based affiliate of Syntone Technologies Group Co. Ltd. (“Syntone PRC”) on May 22, 2020, the Company and Syntone PRC entered into a joint venture agreement pursuant to which they agreed to form a People’s Republic of China (“PRC”) joint venture, Beijing Syntone Biopharma Ltd (“Syntone JV”), that is 80% owned by Syntone PRC and 20% owned by the Company. As the Company can exert significant influence over, but does not control, Syntone JV’s operations through voting rights or representation on Syntone JV’s board of directors, the Company accounts for this investment using the equity method of accounting. Upon formation of Syntone JV in April 2021, the Company entered into a royalty-free license with Syntone JV for the development, commercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.

The Company made the initial investment of \$900,000 in June 2020 and is committed to making capital contributions to Syntone JV of approximately \$2,100,000, based upon the development plan contemplated in the license agreement. The maximum exposure to a loss as a result of the Company’s involvement in Syntone JV is limited to the initial investment and the future capital contributions totaling approximately \$3,000,000.

## 6. Accrued Expenses

Accrued expenses consist of:

	<u>June 30, 2025</u>	<u>September 30, 2024</u>
Compensation	\$ 1,930,744	\$ 1,012,962
Severance and related costs	300,055 (i)	—
Professional fees	717,324	1,798,767
Research and development	1,310,055	41,373
Accrued rebates	172,558	—
Other accrued expenses	882,934	384,366
	<u>\$ 5,313,670</u>	<u>\$ 3,237,468</u>

- (i) In December 2024, the Chief Executive Officer of the Company stepped down, and the Company implemented a workforce reduction to conserve capital. The Chief Executive Officer’s departure constituted a termination without cause, and accordingly he was entitled to 12 months of base salary, a lump sum of 100% of his target bonus for the year, employee benefits for up to 12 months, full vesting of 50% of his unvested equity awards, and reimbursement of expenses owed up to his termination date. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against the Company.

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In connection with the departure of the Chief Executive Officer and the reduction in the workforce, during the nine months ended June 30, 2025, the Company recognized \$1,428,455 in severance related charges consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs. In addition, during the nine months ended June 30, 2025, the Company recorded a non-cash expense totaling \$2,079,083 related to stock-based compensation in connection with the acceleration of equity awards for the former Chief Executive Officer. There were no severance related charges recognized during the three months ended June 30, 2025. The Company made total cash payments related to severance and related charges of \$1,114,183 during the nine months ended June 30, 2025.

## 7. Debt

Debt consists of:

	June 30, 2025	September 30, 2024
Unsecured convertible promissory note (measured at fair value)	\$ 34,437,000	\$ 29,440,000
Less: current portion	(14,000,000)	(29,440,000)
Long-term debt	<u>\$ 20,437,000</u>	<u>\$ —</u>

### *December 2022 Note*

On December 22, 2022, the Company entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note (the “December 2022 Note”) with a face amount of \$31,820,000 to Streeterville Capital, LLC (the “Lender”), the holder of the Company’s unsecured promissory note issued in November 2021 (the “November 2021 Note”). The December 2022 Note had an original issue discount of \$1,820,000. The Company received net proceeds of \$18,052,461 upon the closing on December 28, 2022 after deducting the Lender’s transaction costs in connection with the issuance and payment of the remaining outstanding principal and accrued interest on the November 2021 Note.

In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a \$475,000 extension fee, which was expensed and included in interest expense in the unaudited interim consolidated statement of operations.

On January 22, 2024, the Company entered into an amendment to the December 2022 Note (the “Note Amendment”) with the Lender, which became effective on April 1, 2024 after satisfaction of certain conditions, including various required stockholder approvals and the closing of the private placement on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of \$2,681,847 (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. The extension fee was expensed in the quarter ended March 31, 2024 and included in interest expense in the unaudited interim consolidated statement of operations.

On March 13, 2025, the Company used the proceeds from the March 2025 Note to pay off the December 2022 Note.

The Company elected to account for the December 2022 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the original issue discount and debt issuance costs were written off upon election to fair value and accounted for as interest. During the three and nine months ended June 30, 2025, no interest expense was recognized. During the nine months ended June 30, 2024, the Company recorded \$3,156,964 of interest expense associated with the fees incurred for extending the debt. During the three months ended June 30, 2024, no interest expense was recognized.

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*March 2025 Note*

On March 13, 2025, the Company issued the March 2025 Note for \$33,100,000 to Avondale Capital, LLC (“Avondale”) pursuant to a Securities Purchase Agreement (“SPA”) dated January 31, 2025. Certain terms of the March 2025 Note were approved at the Company’s annual meeting of stockholders on March 11, 2025, and the Company used the proceeds from the March 2025 Note to pay off the December 2022 Note.

The March 2025 Note bears interest at the prime rate plus 3% (subject to a floor of 9.5%), is scheduled to mature on July 1, 2026, and is convertible into common stock. The Company must repay at least \$3,000,000 (by cash or conversions into common stock) of the outstanding balance on the March 2025 Note each quarter starting in the second calendar quarter of 2025 (subject to adjustments for conversions and to payment of a 7.5% exit fee) (the “Quarterly Debt Reduction Obligations”). Any amount converted by Avondale during a given calendar quarter in excess of the Quarterly Debt Reduction Obligations will be credited toward meeting the Quarterly Debt Reduction Obligations for the next quarter or quarters. During the nine months ended June 30, 2025, Avondale converted \$25,000 of accrued interest on the March 2025 Note into shares of common stock and the Company made cash payments totaling \$975,000. These transactions constituted a \$1,000,000 payment toward the Quarterly Debt Reduction Obligations for the calendar quarter ended June 30, 2025.

On June 26, 2025, the Company and Avondale entered into an agreement to temporarily amend the payment schedule for the Quarterly Debt Reduction Obligations for the calendar quarter ended June 30, 2025, which permits staged monthly payments of \$1,000,000, to be made on June 30, July 31, and August 31, 2025. Refer to Note 2 for details on debt payments made after June 30, 2025. As of June 30, 2025, the Company classified a total of \$14,000,000 as a current liability, which consisted of four minimum Quarterly Debt Reduction Obligations and the two remaining monthly payments related to the Quarterly Debt Reduction Obligations for the calendar quarter ended June 30, 2025.

Avondale has the right to convert all or any portion of the outstanding balance under the March 2025 Note into shares of common stock, calculated by dividing the amount of the March 2025 Note being converted by the Conversion Price (as defined below). Furthermore, the Company retains the right to convert any portion of the outstanding balance under the March 2025 Note into shares of common stock at the Conversion Price, provided certain conditions are met at the time of conversion, including, but not limited to, the condition that the daily volume-weighted average price of the Company’s common stock on Nasdaq equals or exceeds \$3.00 per share (subject to adjustments for stock splits and combinations) for a continuous period of 30 trading days, and that the median daily dollar trading volume during the preceding 30 consecutive trading day period meets or exceeds \$1,000,000. The Company reserves the right to make payments (i) in cash, (ii) in shares of common stock, calculated as the applicable payment amount divided by the Conversion Price, or (iii) a combination of both cash and shares of common stock. Any cash payments made by the Company, including prepayments or payments made at maturity, will incur an additional fee of 7.5%.

The March 2025 Note stipulates that the Company shall not permit any conversion of the March 2025 Note if, following such conversion, Avondale and its affiliates would beneficially own shares of common stock exceeding 4.99% of the total number of outstanding shares as of that date (the “Beneficial Ownership Limitation”). However, this limitation shall increase to 9.99% when the Company’s market capitalization falls below \$25,000,000. Avondale may, by written notice to the Company, adjust the Beneficial Ownership Limitation for itself, though any such adjustment will not take effect until the 61st day after such notice is received.

In the event that specific occurrences outlined in the March 2025 Note transpire—such as the Company’s failure to fulfill payment obligations, non-compliance with the Quarterly Debt Reduction Obligations, insolvency or bankruptcy events, breaches of covenants in the SPA and the March 2025 Note, and unauthorized transactions without Avondale’s consent (collectively referred to as “Trigger Events”)—Avondale reserves the right to increase the balance of the March 2025 Note by 10% in the case of a Major Trigger Event (as defined in the March 2025 Note) and by 5% for a Minor Trigger Event (as defined in the March 2025 Note). Should any Trigger Event persist without resolution for ten trading days following written notification from Avondale, this will constitute an event of default (such event, an “Event of Default”). Upon an event of default, Avondale may accelerate the March 2025 Note, resulting in all amounts becoming immediately due and payable, with interest accruing at a rate of 22% per annum until full payment is made.

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Under the terms of the March 2025 Note, the “Conversion Price” is defined as \$2.26 per share prior to a Major Trigger Event (subject to adjustments for stock splits and combinations). Following a Major Trigger Event, the Conversion Price will be the lesser of (i) \$2.26 per share (subject to adjustments) or (ii) 90% of the lowest closing bid price over the three trading days preceding the conversion notice. Furthermore, if the Conversion Price falls below \$0.404 per share (subject to adjustments), the Company will be required to fulfill a conversion notice from Avondale in cash.

The Company elected to account for the March 2025 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the debt issuance costs were written off upon election to fair value and accounted for as interest. During the nine months ended June 30, 2025, the Company recorded \$40,686 of interest expense associated with the debt issuance costs for the March 2025 Note. During the three and nine months ended June 30, 2025, the Company recognized \$68,023 of interest expense associated with the exit fees on debt repayments for the March 2025 Note.

## **8. Commitments and Contingencies**

### **Litigation**

On November 3, 2023, a securities class action lawsuit was filed against the Company and certain of its officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by the Company related to the Company’s BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that the Company violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that the Company and/or their manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time the Company’s BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve the Company’s BLA, and that the Company’s stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys’ fees. On June 25, 2024, the defendants filed a motion to dismiss the amended class action complaint in its entirety. On February 6, 2025, the court entered an order granting the motion to dismiss and dismissing the complaint without prejudice and with leave to amend. On March 14, 2025, the plaintiffs filed their second amended class action complaint. On April 23, 2025, the defendants filed a motion to dismiss the plaintiffs’ second amended class action complaint in its entirety. Defendants’ motion to dismiss is currently pending before the court.

On October 10, 2024, certain of the Company’s officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the Company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys’ fees, and other costs. The derivative action is currently stayed, pending the final resolution of the November 3, 2023 securities class action pending in the United States District Court for the District of New Jersey.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. The Company could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and the Company may not prevail. In addition, the Company may incur substantial legal fees and costs in connection with such lawsuits. The Company currently is not able to estimate the possible cost to it from these matters, as the pending lawsuits are currently at an early stage, and the Company cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that the Company may be required to pay. Such amounts could be material to the Company’s financial statements if it does not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if it does prevail. The Company has not established any

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reserve for any potential liability relating to the pending lawsuits and any other related lawsuits as there is still uncertainty as to whether the litigation will result in any liability. It is possible that the Company could, in the future, incur judgments or enter into settlements of claims for monetary damages.

**Leases**

*Corporate office*

In March 2021, the Company entered into a three-year term corporate office lease for its former corporate headquarters in Iselin, New Jersey that ended on April 30, 2024.

In March 2024, the Company entered into a five-year term corporate office lease for its new corporate headquarters in Iselin, New Jersey that commenced on May 1, 2024.

The components of lease cost for the three and nine months ended June 30, 2025 and 2024 are as follows:

	Three months ended June 30,		Nine months ended June 30,	
	2025	2024	2025	2024
<b>Lease cost:</b>				
Interest on lease liabilities	—	—	\$ —	\$ 116
Total finance lease cost	—	—	—	116
Operating lease cost	19,080	16,459	57,241	38,892
Total lease cost	<u>\$ 19,080</u>	<u>\$ 16,459</u>	<u>\$ 57,241</u>	<u>\$ 39,008</u>

Amounts reported in the unaudited interim consolidated balance sheets for leases where the Company is the lessee are as follows:

	June 30, 2025	September 30, 2024
<b>Operating leases:</b>		
Right-of-use asset	\$ 238,266	\$ 274,645
Operating lease liabilities	260,705	297,829
<b>Weighted-average remaining lease term (years):</b>		
Operating leases	3.8	4.6
<b>Weighted-average discount rate:</b>		
Operating leases	9.9%	9.9%

Other information related to leases for the nine months ended June 30, 2025 and 2024 are as follows:

	Nine months ended June 30,	
	2025	2024
<b>Cash paid for amounts included in the measurement of lease obligations:</b>		
Operating cash flows from finance leases	\$ —	\$ 116
Operating cash flows from operating leases	57,986	11,799
Financing cash flows from finance leases	—	4,267
<b>Right-of-use assets obtained in exchange for lease obligations:</b>		
Operating leases	\$ —	\$ 294,416

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Future minimum lease payments under non-cancelable leases at June 30, 2025 are as follows for the years ending September 30:

	Operating leases
2025 (remaining three months)	\$ 20,104
2026	79,954
2027	81,817
2028	83,680
2029	49,447
Total undiscounted lease payments	315,002
Less: Imputed interest	54,297
Total lease obligations	\$ 260,705

## 9. Common Stock and Stockholders' Equity

### Preferred Stock

On May 13, 2024, the Company filed a Certificate of Elimination to its Certificate of Incorporation, as then amended, with the Secretary of State of the State of Delaware to eliminate from the Certificate of Incorporation all matters set forth in the Certificates of Designation filed with the Secretary of State of the State of Delaware on September 8, 2017 (with respect to its Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock) and July 18, 2018, as amended on March 19, 2020 (with respect to its Series A-1 Convertible Preferred Stock) and returning each of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series. There were no outstanding shares of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock or Series A-1 Convertible Preferred Stock as of May 13, 2024. Immediately following the filing of the Certificate of Elimination, the Company filed a Restated Certificate of Incorporation of the Company with the Secretary of State of the State of Delaware, which restates and integrates but does not further amend the Company's Certificate of Incorporation, as then amended. The number of authorized shares of preferred stock under the Company's Certificate of Incorporation is 10,000,000 shares.

### Common stock

On March 11, 2025, following receipt of stockholder approval at the Company's 2025 annual meeting of stockholders, the number of authorized shares of common stock under the Company's Certificate of Incorporation was increased from 60,000,000 shares to 260,000,000 shares.

### Private Placements

On March 18, 2024, in a private placement (the "Private Placement") pursuant to a securities purchase agreement entered in January 2024 with certain institutional and accredited investors, including GMS Ventures and Investments ("GMS Ventures"), the Company's largest stockholder, the Company issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of \$7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for \$55,498,311 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the Private Placement. The Warrants have an exercise price of \$7.70 per share of common stock and will expire on March 18, 2029.

On April 15, 2024, in a private placement with Syntone (the "Syntone Private Placement", and together with the Private Placement, the "Private Placements"), the Company issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for \$5.0 million in gross proceeds pursuant to a securities purchase

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agreement entered in January 2024. The warrants have an exercise price of \$7.70 per share of common stock and will expire on April 15, 2029.

On January 16, 2025, the Company executed warrant inducement agreements with GMS Ventures and certain other holders of Private Placement Warrants to exercise warrants for 7,074,637 shares of common stock. Concurrently, the Company entered into a warrant inducement transaction with Syntone to exercise warrants for 1,071,429 shares of common stock issued under the Syntone Warrant Inducement Transaction. For further details on the warrant inducement agreements, refer to the sections on the Warrant Inducement Transaction and the Syntone Warrant Inducement Transaction below.

The Company evaluated the equity classification for the common stock warrants and considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity* ("ASC 815-40"). The Company determined that the warrants did not meet the "fixed for fixed" settlement provision set forth in Step 2 of the indexation guidance and as a result they are not indexed to the Company's own stock and must be classified as liabilities. The warrants were measured at fair value at issuance and recorded as a liability and will be remeasured to fair value at each subsequent reporting date, with changes in fair value recorded in current earnings. The net proceeds from the Private Placement were allocated first to the warrants at fair value, with the residual amount recorded as common stock at par value. The Company will continue to classify such warrants as liabilities until they are exercised, expire, or are no longer required to be classified as liabilities.

As the fair value of the warrants upon issuance was more than the proceeds of the Private Placement and Syntone Private Placement, there are no proceeds allocated to additional paid in capital. The excess fair value of the Private Placement Warrants over the net proceeds was \$3,392,444 and \$37,490,012 in the aggregate during the three and nine months ended June 30, 2024, respectively, and was recorded as warrant related expenses in the unaudited interim consolidated statement of operations.

**BTIG, LLC At-the-Market Offering Agreement**

On May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") as sales agent (as amended, the "ATM Agreement" or the "ATM Offering"), under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$100,000,000 from time to time through BTIG. The Company incurred financing costs of \$353,688 in connection with the execution of the ATM Agreement, which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when the Company sells common stock under the ATM Offering. As of June 30, 2025, the remaining balance under the ATM Agreement was \$88,301,796 and \$312,306 of unamortized deferred costs are included in other assets on the unaudited interim consolidated balance sheets.

Under the ATM Agreement, the Company pays BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the ATM Agreement. The offering of common stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the ATM Agreement or (ii) termination of the ATM Agreement in accordance with its terms.

During the three months ended June 30, 2025, the Company sold 1,275,262 shares of common stock under the ATM Offering and generated \$2,108,418 in net proceeds after payment of fees to BTIG and other issuance costs of \$65,209. During the nine months ended June 30, 2025, the Company sold 3,202,004 shares of common stock under the ATM Offering and generated \$5,267,169 in net proceeds after payment of fees to BTIG and other issuance costs of \$162,903. No shares of common stock were sold under the ATM Offering during the three and nine months ended June 30, 2024.

**Warrant Inducement Transaction**

On January 16, 2025, the Company entered into warrant exercise inducement offer letter agreements with GMS Ventures and certain other holders of Private Placement Warrants, pursuant to which the holders agreed to exercise their existing warrants ("Existing Warrants") for an aggregate of 7,074,637 shares of common stock at a reduced exercise price of \$2.51 per share. In exchange, the Company issued two new inducement warrants for each Existing Warrant exercised

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(“Inducement Warrants”), which are exercisable for an aggregate of up to 14,149,274 additional shares of common stock (the “Inducement Warrant Shares”) at an exercise price of \$2.26 per share (collectively, the “Warrant Inducement Transaction”). The Company received net proceeds of \$15,879,484 after capital markets advisory fees and offering costs, from the Warrant Inducement Transaction. Prior to the modification to reduce the warrant exercise price, the Company remeasured the warrants and recognized a \$2,009,886 mark to market adjustment in the unaudited interim consolidated statements of operations for the nine months ended June 30, 2025. On the modification date, the Company remeasured the warrants at the reduced exercise price and recognized a \$1,692,779 inducement charge in the unaudited interim consolidated statements of operations for the nine months ended June 30, 2025. Upon the exercise of these liability classified warrants, the Company reclassified the warrant liability balance of \$13,262,801 into additional paid in capital.

In connection with the Warrant Inducement Transaction, half of the Inducement Warrants (the “Tranche A Inducement Warrants”), representing warrants to purchase up to 7,074,637 shares of common stock were exercisable immediately and expire on January 17, 2030. The remaining Inducement Warrants (the “Tranche B Inducement Warrants”) became exercisable upon the effective date of an amendment to the Company’s Certificate of Incorporation to increase the number of authorized shares of common stock. The Tranche A and B Inducement Warrants are considered equity-classified warrants. Given that the Tranche A and Tranche B Inducement Warrants were issued concurrently with the exercise of the Existing Warrants, the Company recorded an inducement charge in the unaudited interim consolidated statements of operations in the amount of \$27,711,889 for the nine months ended June 30, 2025.

**Syntone Warrant Inducement Transaction**

Concurrently with the Warrant Inducement Transaction, the Company entered into a warrant exercise inducement offer letter agreement with Syntone, pursuant to which Syntone agreed to exercise existing warrants (“Existing Syntone Warrants”) for an aggregate of 1,071,429 shares of common stock at a reduced exercise price of \$2.51 per share. In exchange, the Company agreed to issue two new inducement warrants for each Existing Syntone Warrant exercised (the “Syntone Inducement Warrants”), which will be exercisable for up to 2,142,858 shares of common stock (the “Syntone Inducement Warrant Shares”) at an exercise price of \$2.26 per share (the “Syntone Warrant Inducement Transaction”). The closing of the Syntone Warrant Inducement Transaction is subject to receipt of certain regulatory approvals. Prior to the modification to reduce the warrant exercise price, the Company remeasured the warrants and recognized a \$303,328 mark to market adjustment in the unaudited interim consolidated statements of operations for the nine months ended June 30, 2025. On the modification date, the Company remeasured the warrants at the reduced exercise price and recognized a \$255,278 inducement charge in the unaudited interim consolidated statements of operations for the nine months ended June 30, 2025. As of the date of this filing, Syntone has not received regulatory approval and, thus, the Company has not yet received the proceeds from the exercise of the Existing Syntone Warrants. There can be no assurance that Syntone will receive the requisite regulatory approval in the near term or at all, and the Company may never receive the proceeds from the exercise of the Existing Syntone Warrants, or issue, or receive proceeds from the exercise of, the Syntone Inducement Warrants. In connection with the Syntone Warrant Inducement Transaction, half of the Syntone Inducement Warrants (the “Syntone Tranche A Inducement Warrants”) will be immediately exercisable upon receipt of certain regulatory approvals and will expire on the five-year anniversary of the date of issuance. The remaining Syntone Inducement Warrants (the “Syntone Tranche B Inducement Warrants”) will be exercisable upon receipt of certain regulatory approvals. As of the date of this filing, the Syntone Tranche A and Tranche B Inducement Warrants have not been issued. Given that the Company agreed to issue Syntone Tranche A and Tranche B Inducement Warrants in exchange for Syntone’s agreement to exercise existing warrants at a reduced exercise price, the Company recorded an inducement charge in the unaudited interim consolidated statements of operations in the amount of \$4,196,868 for the nine months ended June 30, 2025.

The fair value per share of the Tranche A Inducement Warrants, Tranche B Inducement Warrants, Syntone Tranche A and B Inducement Warrants of \$1.96 was estimated using the Black-Scholes option pricing model using the following weighted average assumptions: a risk-free interest rate of 4.39%, a contractual term of 5 years, an expected volatility of 133.6%, an anticipated annual dividend yield of 0%, and a stock price of \$2.23.

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**Underwritten Public Offering**

On May 27, 2025, the Company completed an underwritten public offering (the “Public Offering”) of 9,285,714 shares of common stock and warrants to purchase an aggregate of 18,571,428 shares of common stock pursuant to an underwriting agreement dated May 22, 2025, between the Company and BTIG. The combined price for each share of common stock and accompanying warrant to purchase two shares of common stock was \$1.40. The Company received aggregate net proceeds of \$11,625,229, after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 4,285,714 shares of common stock and warrants to purchase an aggregate of 8,571,428 shares of common stock in the Public Offering. The warrants have an exercise price of \$1.40 per share of common stock and will expire on May 27, 2030.

**Common stock warrants**

As of June 30, 2025, shares of common stock issuable upon the exercise of outstanding warrants were as follows:

Expiration Date	Shares of common stock issuable upon exercise of warrants	Exercise Price Per Share
December 28, 2025	25,787	\$ 21.00
January 28, 2026	12,576	\$ 25.00
February 2, 2026	93,238	\$ 25.00
November 23, 2026	104,999	\$ 31.25
March 18, 2029	(i) 5,782,496	\$ 7.70
April 15, 2029	(i) (ii) 1,071,429	\$ 7.70
January 17, 2030	(iii) 14,149,274	\$ 2.26
May 27, 2030	18,571,428	\$ 1.40
	<u>39,811,227</u>	

- (i) The Private Placement Warrants were issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 and are exercisable only for cash, except in limited circumstances, at any time after the date of issuance. The Company evaluated the warrants under ASC 815, *Derivatives and Hedging*, guidance and determined that the warrants did not meet Step 2 of the indexation, as a result they are not indexed to the Company’s own stock and must be classified as liabilities. Refer to the disclosure in Note 4 for further details on classification and fair value measurements.

A holder of warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than a specified percentage of the outstanding common stock (4.99%, 9.99% or 19.99%, as applicable), immediately after giving effect to such exercise, which may be increased or decreased at the holders’ option (not to exceed 19.99%), effective 61 days after written notice to the Company. In addition, the Company may require the holders to cash exercise the warrants under certain circumstances as follows: (i) if the VWAP of the common stock equals or exceeds \$20.00 per share (subject to adjustment in the event of stock splits, combinations or similar events, such as the reverse stock split implemented prior to Closing as discussed below) for 30 consecutive days (the “Stock Price Condition”) at any time after the Company publicly announces topline data from its NORSE EIGHT clinical trial evidencing satisfaction of the trial’s primary endpoints (the “NORSE EIGHT Announcement”), upon the consent of a majority of the members of the Company’s board of directors, the Company may require the holders to exercise up to 20% of the aggregate number of warrants issued to such holder on the issue date; and (ii) the Company may require up to the remainder of the warrants be exercised (A) if the Stock Price Condition is satisfied at any time after the Company publicly announces approval from the FDA of its BLA for ONS-5010/LYTENAVA, upon the consent of a majority of the members of the board of directors or (B) if the Stock Price Condition is satisfied

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at any time after the NORSE EIGHT Announcement, upon the unanimous consent of the members of the Company’s Board of Directors present at duly called meeting.

- (ii) Refer above for disclosures on the Syntone Warrant Inducement Transaction for details on these warrants.
- (iii) These are Inducement Warrants. Refer above for disclosures on the Inducement Warrants.

**10. Stock-Based Compensation**

**2024 Equity Incentive Plan**

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the “2015 Plan”). The 2015 Plan provided for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units (“RSUs”) awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. In August 2024, the Company’s stockholders approved the amendment and restatement of the 2015 Plan, at which time, the name of the 2015 Plan was updated to the Outlook Therapeutics, Inc. 2024 Equity Incentive Plan (the “2024 Plan”). The 2024 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The aggregate number of shares of common stock authorized for issuance pursuant to the Company’s 2024 Plan is 7,293,901. As of June 30, 2025, there were 4,281,053 shares available for grant under the 2024 Plan.

Stock options and RSUs are granted under the Company’s 2024 Plan and generally vest over a period of one to four years from the date of grant and, in the case of stock options, have a term of 10 years. The Company recognizes the grant date fair value of each option and RSU over its vesting period.

The Company recorded stock-based compensation expense in the following expense categories of its unaudited interim consolidated statements of operations for the three and nine months ended June 30, 2025 and 2024:

	<u>Three months ended June 30,</u>		<u>Nine months ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Research and development	\$ 91,636	\$ 147,359	\$ 289,889	\$ 615,735
General and administrative	1,579,176	1,248,950	6,757,008	3,363,692
<b>Total</b>	<b>\$ 1,670,812</b>	<b>\$ 1,396,309</b>	<b>\$ 7,046,897</b>	<b>\$ 3,979,427</b>

During the three and nine months ended June 30, 2025, the Company capitalized stock-based compensation expense in inventory totaling \$11,322 and \$30,435, respectively. No stock-based compensation expense was capitalized in inventory during the three and nine months ended June 30, 2024.

**Stock options**

As of June 30, 2025, options to purchase common stock of the Company outstanding under the 2024 Plan were as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value</u>
Balance at October 1, 2024	1,946,646	\$ 19.51	7.3	\$ 53,985
Granted	1,206,599	5.14		
Forfeited	(304,636)	10.25		
Expired	(25,716)	30.48		
Balance at June 30, 2025	<u>2,822,893</u>	\$ 14.27	7.8	\$ 1,200
Vested and exercisable at June 30, 2025	<u>1,520,249</u>	\$ 21.29	6.6	\$ —

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The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options.

The weighted average grant date fair value of the options awarded to employees for the nine months ended June 30, 2025 and 2024 was \$4.60 and \$6.01 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine months ended June 30,	
	2025	2024
Risk-free interest rate	3.6 %	4.3 %
Expected term (years)	5.5	6.0
Expected volatility	134.1 %	131.3 %
Expected dividend yield	—	—

As of June 30, 2025, there was \$3,134,083 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 0.4 years.

**Performance-based stock options**

The Company granted certain officers of the Company option awards whose vesting is contingent upon meeting company-wide performance goals. The performance stock options were granted “at-the-money” and have a term of 10 years.

The fair value of each option grant under the performance share option plan was estimated on the date of grant using the same option valuation model used for non-statutory options above. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest.

A summary of the activity under the performance share option plan as of June 30, 2025 and changes during the nine months then ended are presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at October 1, 2024	666,500	\$ 7.94	9.0	\$ —
Granted	—	—		
Forfeited	(476,500)	6.78		
Balance at June 30, 2025	190,000	\$ 10.85	8.1	\$ —
Vested and exercisable at June 30, 2025	35,000	\$ 28.80	5.6	\$ —

The vesting of the performance-based stock options is conditional upon FDA approval of ONS-5010/LYTENAVA. The expense for the performance-based stock options is not recognized until the performance conditions are deemed probable of achievement. The Company did not record any expense related to the performance-based stock options during the three and nine months ended June 30, 2025 as the performance conditions were not deemed probable of being met. The Company did not record any expense related to the performance-based stock options during the three and nine months ended June 30, 2024. As of June 30, 2025, the Company assessed that the performance conditions related to the performance options granted were not probable of achievement. The assessment was based on the relevant facts and circumstances and therefore no compensation costs were recognized.

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**11. Subsequent Events**

*Appointment of Chief Executive Officer*

On June 28, 2025, the Board of Directors of Outlook Therapeutics, Inc. appointed Robert Charles Jahr as President, Chief Executive Officer, and director, effective July 1, 2025. The Board also expanded its size to ten members, electing Mr. Jahr as a Class III director for a term ending at the 2028 annual meeting. Mr. Jahr succeeds Lawrence Kenyon, who resigned as Interim CEO and will continue as Chief Financial Officer and director.

In connection with his appointment, Mr. Jahr entered into an employment agreement providing for an initial annual base salary of \$600,000, a discretionary annual bonus targeted at 70% of base salary, and participation in employee benefits plans. Mr. Jahr was granted a stock option to purchase 800,000 shares of common stock outside the 2024 Equity Incentive Plan, with a ten-year term and standard vesting conditions.

*One Big Beautiful Bill Act*

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted in the United States. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented in subsequent years. The Company is currently assessing its impact on its consolidated financial statements.

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

*You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I, Item 1 of this report and our audited consolidated financial statements and related notes thereto and management’s discussion and analysis of financial condition and results of operations for the years ended September 30, 2024 and 2023 included in our Annual Report on Form 10-K for the year ended September 30, 2024, filed with the Securities and Exchange Commission, or SEC, on December 27, 2024.*

### **Forward-Looking Statements**

*This discussion contains 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, or the Exchange Act. Forward-looking statements are identified by words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “seek,” “should,” “will,” “would,” or the negative of these terms or similar expressions in this report. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other forward-looking information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause a material difference including, but not limited to, those discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended September 30, 2024, filed with the SEC on December 27, 2024, and elsewhere in this report. See “Special Note Regarding Forward-Looking Statements.” Forward-looking statements are based on our management’s current beliefs and assumptions and based on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.*

### **Overview**

We are a biopharmaceutical company that has developed ONS-5010/LYTENAVA™ as the first ophthalmic formulation of bevacizumab approved by the European Commission in the European Union, or EU, and the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, or UK, for use in adults for the treatment of wet age-related macular degeneration, or wet AMD. In June 2025, we launched directly into the initial markets of Germany and the UK. Additionally, our Biologics License Application, or BLA, is currently under review at the U.S. Food and Drug Administration, or FDA, for the use of ONS-5010/LYTENAVA as a treatment for wet AMD in the United States. If approved in the US., our goal is to also launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of wet AMD. In addition to Europe and the U.S., our plans also include potentially seeking approval and launching the product in other markets.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. Prior to the approval of ONS-5010/LYTENAVA in the EU and UK, bevacizumab had only been approved for use in the treatment of various forms of cancer and had not been optimized for use in the treatment of retina diseases. Because there previously were no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted standard biologic therapeutic applications and are not using the biosimilar drug regulatory pathway that would be required if bevacizumab were an approved drug for the targeted disease. Off-label repackaged bevacizumab is a frequently used first-line anti-VEGF treatment in Europe (approximately 2.8 million injections annually) and the United States (approximately 2.7 million injections annually) based on data compiled from various sources (Citeline (2023), Global Data (2023) and Market Scope (2022); ASRS 2024 Membership Survey; Market Scope 2024 US Retina Quarterly Updates; GlobalData: Age-Related Macular Degeneration: Global Drug Forecast and Market Analysis to 2028 (April 2020)). We believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of unapproved bevacizumab. We believe there is significant opportunity in Europe with a total anti-VEGF retina market estimated to be approximately \$3.6 billion, including approximately 1.52 million treated patients and approximately 8.3 million total anti-VEGF units (Global Data (2023); Market Scope (2022); IQVIA MIDAS data Q3 2023; Graefe’s Archive for Clinical and Experimental Ophthalmology (2020) 258:503–511). We similarly see significant opportunity in the United States, with an estimated \$8.5 billion total anti-VEGF retina market, where 55% of physician state off-label repackaged bevacizumab is the preferred first-line product. It is estimated that 34% of the total anti-VEGF market is off-label bevacuzimab (new and maintenance

therapy) (Citeline (2023); Global Data (2023); Market Scope (2022); ASRS 2024 Membership Survey; Market Scope 2024 US Retina Quarterly Updates; GlobalData: Age-Related Macular Degeneration: Global Drug Forecast and Market Analysis to 2028 (April 2020)). We estimate the global market for anti-VEGF retina to be approximately \$16 billion (Citeline (2023), Global Data (2023) and Market Scope (2022)).

In May 2024, the European Commission granted the Marketing Authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU. The decision applied automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein. In July 2024, the MHRA granted marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK under the new International Recognition Procedure, or IRP, which allows the MHRA to rely on an authorization received for the same product from one of MHRA's specified Reference Regulators, or RRs, when considering an application for marketing authorization in the UK. ONS-5010/LYTENAVA is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.

Separately, in March 2022, we submitted a BLA with the FDA for ONS-5010/LYTENAVA for the treatment of wet AMD. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD.

We agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010/LYTENAVA. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDA's requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, we received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the CRL. In addition, through a Type A meeting and additional interactions with the FDA, including Type C and Type D meetings, we identified the approaches needed to resolve the CMC comments in the CRL. We believe that we have addressed the open CMC items to help resolve these comments. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the complete week 12 data set for NORSE EIGHT provided additional evidence of improvement in vision and biological activity. We resubmitted the BLA application for ONS-5010/LYTENAVA in February 2025. In April 2025, we received notification from the FDA that the Prescription Drug User Fee Act, or PDUFA, goal date for a decision on the BLA is August 27, 2025. If approved, we expect to receive 12 years of regulatory exclusivity in the United States.

Our initial BLA submission for ONS-5010/LYTENAVA in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010/LYTENAVA as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. In August 2020, we reported achieving the anticipated safety and efficacy proof-of-concept results from NORSE ONE, a clinical experience study. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010/LYTENAVA.

As agreed to with the FDA in the SPA, NORSE EIGHT was a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits, with a final follow-up visit at Week 12. The primary endpoint was the mean change in best corrected visual acuity (BCVA) from baseline to week 8. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. The difference in the means between the ONS-5010/LYTENAVA and ranibizumab arms in the NORSE EIGHT trial was -2.257 BCVA letters with a 95% confidence interval of (-4.044, -0.470) while the lower bound of the pre-specified non-inferiority margin in the SPA was -3.5 at a 95% confidence interval; the hypothesis of noninferiority was not met ( $p > 0.025$ ). In the intent-to-treat, or ITT, primary dataset, NORSE EIGHT demonstrated a mean +4.2 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and +6.3 letter improvement in BCVA in the ranibizumab arm. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. In January 2025, we reported the complete week 12 data and safety results from NORSE EIGHT, which continued to demonstrate an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile. At week 12, the difference in the mean between ONS-5010/LYTENAVA and ranibizumab was -1.009 BCVA letters with a 95% confidence interval of (-2.865, 0.848) in the NORSE EIGHT trial. Applying the statistical parameters from the week 8 primary endpoint with the lower bound of the non-inferiority margin at -3.5 with a 95% confidence interval, the noninferiority margin was met at week 12, indicating that the two study arms are not different at this timepoint. In the ITT population, NORSE EIGHT demonstrated a mean 5.5 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and 6.5 letter improvement in BCVA in the ranibizumab arm. Additionally, the change in central retinal thickness, a measure of anatomical response, was similar in both study arms at all three study timepoints. The safety results demonstrated across the full duration of NORSE EIGHT are consistent with previously reported safety results from the NORSE ONE, NORSE TWO, and NORSE THREE clinical trials, with no cases of retinal vasculitis reported in either study arm.

Previously, in November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative age-related macular degeneration, DME, or BRVO. Subjects will be treated for three months, and the enrollment of subjects in the arm of the study receiving ONS-5010/LYTENAVA in vials has been completed.

We have also received agreement from the FDA on three Special Protocol Assessments, or SPAs, for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. The timing for initiating these studies has not been determined pending initial FDA approval for wet AMD.

### ***Macroeconomic and Geopolitical Factors***

Global uncertainty due to tariffs and global macroeconomic conditions may have a material adverse effect on our commercialization efforts for LYTENAVA in various markets. The global financial markets recently have experienced significant disruptions due to various macroeconomic factors, including, among other things, the impacts of fluctuations in inflation and interest rates, tariffs and trade tensions, and ongoing overseas conflict, resulting in a general global economic slowdown. If these disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our ability to pursue our business strategy. Finally, there is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with raw materials, laboratory equipment and research materials and

components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we continue to expand our commercialization efforts, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects. Currently, we manufacture ONS-5010/LYTENAVA in the US.

### ***Going Concern***

Through June 30, 2025, we have funded substantially all of our operations with \$598.1 million in net proceeds from the sale and issuance of our equity and debt securities. We have also received \$29.0 million pursuant to our collaboration and licensing agreements through such date. Our net loss for the nine months ended June 30, 2025 was \$49.1 million. We also had a net loss of \$81.1 million for the nine months ended June 30, 2024. We have not generated any significant revenue from product sales. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop.

Subsequent to June 30, 2025, we sold 940,478 shares of common stock under the ATM Agreement (as defined below), generating \$1.9 million in net proceeds after deducting fees paid to BTIG and other issuance costs, which were assessed as immaterial. For additional information regarding the ATM Agreement with BTIG, refer to Note 9 to the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

On July 31, 2025, we paid \$1,000,000 on the March 2025 Note. This payment covered part of the required debt reduction for the quarter ending June 30, 2025. For further information regarding the March 2025 Note, refer to Note 7 of the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We evaluated whether there are conditions or events considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We do not believe that the existing cash and cash equivalents as of June 30, 2025, together with \$1.9 million in net proceeds from the sale of shares of common stock under the ATM Agreement since June 30, 2025, are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. As a result, there is substantial doubt about our ability to continue as a going concern. Our unaudited interim consolidated financial statements do not include any adjustments that might be necessary if it is unable to continue as a going concern.

### **Components of our Results of Operations**

#### ***Revenues, net***

We recognize revenue from sales of a single product, LYTENAVA (bevacizumab gamma), which became available for commercial sale and shipment to patients in the UK and Germany in June 2025.

#### ***Cost of revenues***

Cost of revenues consists primarily of the cost of inventory sold, which includes direct manufacturing, production and packaging materials for LYTENAVA sales. Prior to receiving authorization to sell LYTENAVA in Europe, we expensed costs associated with manufacturing of LYTENAVA as a component of research and development expense that would have been included in cost of goods.

#### ***Research and development expenses***

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;

- expenses incurred by us directly, as well as under agreements with contract manufacturing organizations, or CMOs, for manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments made under a third-party assignment agreement, under which we acquired intellectual property;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses, utilities and other facility-related costs.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our other product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of our clinical trials;
- the establishment of commercial manufacturing capabilities;
- the receipt of marketing approvals; and
- the commercialization of product candidates.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our biosimilar product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Full product commercialization will take several years and millions of dollars in additional costs.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, complexity and duration of later-stage clinical trials.

#### ***Selling, general and administrative expenses***

Selling, general and administrative expenses consist principally of distribution expenses, salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for business development, legal, auditing and tax services and insurance costs.

We anticipate that our general and administrative expenses will increase if and when we believe a regulatory approval of a product candidate appears likely, and we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our product.

***Loss on equity method investment***

Loss on equity method investment represents our proportionate share for the period of the net loss of our investee to which the equity method of accounting is applied. We account for equity investments where we own a non-controlling interest, but have the ability to exercise significant influence, under the equity method of accounting.

***Interest expense (income), net***

Interest expense (income), net consists of original issue discount and debt issuance costs that were written off, net of interest income. We elected to account for the unsecured convertible promissory notes at fair value and were not required to bifurcate the conversion option as a derivative and as a result the original issue discount and debt issuance costs were written off upon election to fair value and accounted for as interest. Interest income is earned from short term investments primarily money market investments.

***Loss (gain) from change in fair value of promissory notes***

The change in fair value relates to convertible promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our convertible promissory notes. We recorded the convertible promissory note at fair value with changes in fair value recorded in the unaudited interim consolidated statements of operations. The changes in fair value are primarily driven by variations in risk yield, stock price, and the remaining term of the notes.

***Warrant related expenses***

The warrant related expense relates to the excess of the fair value of the warrants upon issuance over the proceeds of the private placement that closed on March 18, 2024. The excess fair value of the warrants over the net proceeds was recorded in the unaudited interim consolidated statement of operations.

***Warrant inducement expenses***

The warrant inducement expenses are composed of the remeasurement charges for existing warrants that were exercised in a warrant inducement transaction, which were exercised at a modified, reduced exercise price. Additionally, this expense includes the fair value of the inducement warrants that were issued concurrently with the exercise of the existing warrants. For further details on warrant inducement transaction, refer to Note 9 of the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

***Loss (gain) from change in fair value of warrant liability***

We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017. Additionally, we issued warrants in connection with private placements that closed on March 18, 2024 and April 15, 2024. These warrants are categorized as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date, and we recognize any change in fair value in our statements of operations.

**Income taxes**

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted in the United States. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented in subsequent years. We are currently assessing its impact on our consolidated financial statements.

Since inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research and development, or R&D, tax credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2024, we had federal and state NOL carryforwards of \$406.7 million and \$242.5 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2024, we had federal foreign tax credit carryforwards of \$0.3 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2024, we also had federal and state R&D tax credit carryforwards of \$13.0 million and \$0.8 million, respectively, that will begin to expire in 2032 and 2033, respectively.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after our Initial Public Offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

**Results of Operations**

**Comparison of Three Months Ended June 30, 2025 and 2024**

	<u>Three months ended June 30,</u>		
	<u>2025</u>	<u>2024</u>	<u>Change</u>
Revenues, net	\$ 1,505,322	\$ —	\$ 1,505,322
Cost of revenues	439,815	—	439,815
Gross profit	1,065,507	—	1,065,507
Operating expenses:			
Research and development	\$ 7,134,706	\$ 11,201,754	\$ (4,067,048)
Selling, general and administrative	9,679,481	8,360,933	1,318,548
Loss from operations	(15,748,680)	(19,562,687)	3,814,007
Loss on equity method investment	30,884	57,497	(26,613)
Interest expense (income), net	49,351	(404,593)	453,944
Loss (gain) from change in fair value of promissory notes	2,323,977	(7,563,000)	9,886,977
Warrant related expenses	—	3,392,444	(3,392,444)
Loss (gain) from change in fair value of warrant liability	1,999,610	(59,454,222)	61,453,832
Net (loss) income	<u>\$ (20,152,502)</u>	<u>\$ 44,409,187</u>	<u>\$ (64,561,689)</u>

*Revenues, net*

During the three months ended June 30, 2025, we recognized revenues of \$1.5 million from sales of LYTENAVA in Germany and the UK. This revenue represents the initial shipments of product into Germany and the UK in June 2025.

*Cost of revenues*

Cost of revenues for the three months ended June 30, 2025, were \$0.4 million, consists primarily of the cost of inventory sold, which includes direct manufacturing, production and packaging materials for LYTENAVA sales. Prior to receiving regulatory approval for LYTENAVA for the treatment of wet AMD by the European Commission in the EU and the MHRA in the UK, inventory and related manufacturing costs were recognized as research and development expenses. The research and development expenses that would have been classified as cost of revenues for the three and nine months ended June 30, 2025, was \$0.3 million in both periods. Accordingly, these amounts are not included in cost of revenues.

*Research and development expenses*

The following table summarizes our research and development expenses by functional area for the three months ended June 30, 2025 and 2024:

	<b>Three months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
ONS-5010/LYTENAVA development	\$ 5,847,020	\$ 10,074,668
Compensation and related benefits	906,195	613,382
Stock-based compensation	91,636	147,359
Other research and development	289,855	366,345
<b>Total research and development expenses</b>	<b>\$ 7,134,706</b>	<b>\$ 11,201,754</b>

Research and development expenses for the three months ended June 30, 2025 decreased by \$4.1 million compared to the three months ended June 30, 2024. The decrease was primarily due to a decrease of \$4.2 million in ONS-5010/LYTENAVA development expenses related to conducting the NORSE EIGHT clinical trial, which was initiated and began enrolling patients in January 2024 and completed enrollment in September 2024.

*Selling, general and administrative expenses*

The following table summarizes our selling, general and administrative expenses by type for the three months ended June 30, 2025 and 2024:

	<b>Three months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
Professional fees	\$ 1,315,395	\$ 2,710,432
Compensation and related benefits	1,943,321	1,432,343
Stock-based compensation	1,579,176	1,248,950
Europe launch expenses	3,867,013	1,528,955
Facilities, fees and other related costs	974,576	1,440,253
<b>Total general and administrative expenses</b>	<b>\$ 9,679,481</b>	<b>\$ 8,360,933</b>

Selling, general and administrative expenses for the three months ended June 30, 2025 increased by \$1.3 million when compared to the three months ended June 30, 2024. The increase was primarily driven by \$2.3 million in launch expenses related to ONS-5010/LYTENAVA in Europe and a \$0.8 million increase in compensation and related benefits related to accruals for incentive compensation in 2025. These increases were partially offset by a \$1.4 million reduction in professional fees driven by ongoing efforts to reduce expenditures unrelated to launch costs.

*Interest expense (income), net*

During the three months ended June 30, 2025, the Company recognized minimal interest expense related to exit fees on cash debt payments made during the period partially offset by interest income from money market instruments. During the three months ended June 30, 2024, the Company recorded interest income of \$0.4 million, primarily earned from money market instruments.

*Loss (gain) from change in fair value of promissory notes*

The change in fair value relates to the promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our promissory note. We record the promissory note at fair value with changes in fair value recorded in the unaudited interim consolidated statements of operations. The changes in fair value are primarily driven by variations in risk yield, stock price, and the remaining term of the notes.

*Warrant related expenses*

During the three months ended June 30, 2024, we recognized charges associated with warrants issued during the quarter, which were categorized as liabilities. These expenses amounted to the difference between the fair value of the warrants and the net proceeds received from a private placement that closed on March 18, 2024. For further details on warrants to purchase shares of common stock, refer to Note 9 of the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

*Loss (gain) from change in fair value of warrant liability*

The loss recognized during the three months ended June 30, 2025 resulted from an increase in the price per share of common stock from March 31, 2025 to June 30, 2025. The gain recognized during the three months ended June 30, 2024 was primarily attributable to a decrease in the price per share of common stock from March 31, 2024 to June 30, 2024.

**Comparison of Nine Months Ended June 30, 2025 and 2024**

	Nine months ended June 30,		Change
	2025	2024	
Revenues, net	\$ 1,505,322	\$ —	\$ 1,505,322
Cost of revenues	439,815	—	439,815
Gross profit	1,065,507	—	1,065,507
Operating expenses:			
Research and development	21,201,875	29,240,046	(8,038,171)
Selling, general and administrative	29,610,692	19,585,738	10,024,954
Loss from operations	(49,747,060)	(48,825,784)	(921,276)
Loss on equity method investment	100,588	85,544	15,044
Interest expense, net	18,972	2,490,765	(2,471,793)
Loss from change in fair value of promissory notes	5,739,005	1,949,153	3,789,852
Warrant related expenses	—	37,490,012	(37,490,012)
Warrant inducement expenses	33,856,814	—	33,856,814
Gain from change in fair value of warrant liability	(40,333,145)	(9,786,063)	(30,547,082)
Loss before income taxes	(49,129,294)	(81,055,195)	31,925,901
Income tax expense	2,800	2,800	—
Net loss	\$ (49,132,094)	\$ (81,057,995)	\$ 31,925,901

**Revenues, net**

During the nine months ended June 30, 2025, we recognized revenues of \$1.5 million from sales of LYTENAVA in Germany and the UK. This revenue represents the initial shipments of product into Germany and the UK in June 2025.

**Cost of revenues**

Cost of revenues for the nine months ended June 30, 2025, were \$0.4 million, consists primarily of the cost of inventory sold, which includes direct manufacturing, production and packaging materials for LYTENAVA sales. Prior to receiving regulatory approval for LYTENAVA for the treatment of wet AMD by the European Commission in the EU and the MHRA in the UK, inventory and related manufacturing costs were recognized as research and development expenses. The research and development expenses that would have been classified as cost of revenues for the three and nine months ended June 30, 2025, was \$0.3 million in both periods. Accordingly, these amounts are not included in cost of revenues.

**Research and development expenses**

The following table summarizes our research and development expenses by functional area for the nine months ended June 30, 2025 and 2024:

	Nine months ended June 30,	
	2025	2024
ONS-5010/LYTENAVA development	\$ 18,282,667	\$ 25,859,092
Compensation and related benefits	1,831,860	1,942,010
Stock-based compensation	289,889	615,735
Other research and development	797,459	823,209
Total research and development expenses	\$ 21,201,875	\$ 29,240,046

Research and development expenses for the nine months ended June 30, 2025 decreased by \$8.0 million compared to the nine months ended June 30, 2024. This reduction was primarily attributable to a \$7.6 million decrease in ONS-5010/LYTENAVA development expenses associated with the NORSE EIGHT clinical trial, which commenced patient enrollment in January 2024 and completed enrollment in September 2024.

*Selling, general and administrative expenses*

The following table summarizes our selling, general and administrative expenses by type for the nine months ended June 30, 2025 and 2024:

	Nine months ended June 30,	
	2025	2024
Professional fees	\$ 5,120,664	\$ 6,164,989
Compensation and related benefits	5,806,232	4,833,221
Stock-based compensation	6,757,008	3,363,692
Europe launch expenses	9,177,513	2,006,402
Facilities, fees and other related costs	2,749,275	3,217,434
Total general and administrative expenses	<u>\$ 29,610,692</u>	<u>\$ 19,585,738</u>

Selling, general and administrative expenses for the nine months ended June 30, 2025 increased by \$10.0 million when compared to the nine months ended June 30, 2024. This increase was due to \$7.2 million in launch expenses for ONS-5010/LYTENAVA in Europe, an increase of \$4.4 million in combined cash and stock-based compensation, which was primarily related to severance costs from the departure of our former Chief Executive Officer and our December 2024 reduction in headcount. These increases were partially offset by a \$1.0 million reduction in professional fees and \$0.5 million decrease in other general and administration expenses driven by ongoing efforts to reduce expenditures unrelated to launch costs.

*Interest expense, net*

Interest expense, net decreased by \$2.5 million primarily due to convertible promissory note maturity extension fees of \$3.1 million recognized during the nine months ended June 30, 2024, partially offset by interest income earned of \$0.7 million from money market investments.

*Loss from change in fair value of promissory notes*

The change in fair value relates to the promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our promissory note. We record the promissory note at fair value with changes in fair value recorded in the unaudited interim consolidated statements of operations. The changes in fair value are primarily driven by variations in risk yield, stock price, and the remaining term of the notes.

*Warrant related expenses*

During the nine months ended June 30, 2024, we recognized charges associated with warrants issued during the quarter, which were categorized as liabilities. These expenses amounted to the difference between the fair value of the warrants and the net proceeds received from a private placement that closed on March 18, 2024. For further details on warrants to purchase shares of common stock, refer to Note 9 of the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

*Warrant inducement expenses*

During the nine months ended June 30, 2025, we recognized inducement charges associated with warrants exercised in the period. For further details on warrant inducement transaction refer to Note 9 of the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

*Gain from change in fair value of warrant liability*

The gain recorded during the nine months ended June 30, 2025 and 2024 was primarily due to the reduction in the price per share of common stock.

## Liquidity and Capital Resources

We have not generated any significant revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through June 30, 2025, we have funded substantially all of our operations with \$598.1 million in net proceeds from the sale and issuance of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of \$29.0 million pursuant to emerging markets collaboration and licensing agreements for our inactive biosimilar development programs.

We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop. We will need additional financing to fund our operations in the future, fully commercialize ONS-5010/LYTENAVA, to develop any other product candidates and to continue as a going concern. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, the issuance of equity securities, including through an at-the-market offering program, the issuance of additional debt, and revenues from potential future product sales, if any. Alternatively, we may be required to, among other things, modify our clinical trial plans for ONS-5010/LYTENAVA in additional indications, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

On May 16, 2023, we entered into an At-the-Market Sales Agreement with BTIG, LLC, or BTIG, as sales agent, as amended, the ATM Agreement or the ATM Offering, under which we may issue and sell shares of our common stock having an aggregate offering price of up to \$100.0 million from time to time through BTIG. Under the ATM Agreement, we pay BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the ATM Agreement. The offering of common stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the ATM Agreement or (ii) termination of the ATM Agreement in accordance with its terms.

During the nine months ended June 30, 2025, we sold 3,202,004 shares of common stock under the ATM Offering and generated approximately \$5.3 million in net proceeds after paying fees to BTIG and other issuance costs of \$0.2 million.

Subsequent to June 30, 2025, we sold 940,478 shares of common stock under the ATM Agreement and generated \$1.9 million in net proceeds after paying fees to BTIG and other issuance costs assessed as immaterial.

On December 22, 2022, we entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of \$31.8 million, or the December 2022 Note, to Streeterville Capital, LLC, or the Lender, who was the holder of our November 2021 Note. The December 2022 Note had an original issue discount of \$1.8 million. A portion of the proceeds from the December 2022 Note was used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. We received net proceeds of \$18.1 million upon the closing on December 28, 2022, after deducting the Lender's transaction costs in connection with the issuance and November 2021 Note repayment. In December 2023, we extended the maturity of the December 2022 Note from January 1, 2024, to April 1, 2024. We incurred a \$475 thousand extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. On January 22, 2024, we entered into an amendment to the December 2022 Note, or the Note Amendment, with the Lender, which became effective on April 1, 2024, after the satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of \$2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the Note Amendment, the initial conversion price with respect to \$15.0 million in aggregate principal amount of the December 2022 Note was changed to \$7.00, the price per share in the private placement that closed on March 18, 2024, and the remaining aggregate principal amount was converted at a price of \$40.00 per share. Effective April 1, 2024, the December 2022 Note bore interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%), and we had an obligation to repay at least \$3.0 million (by either cash or conversion into common stock) of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in

the December 2022 Note) and continuing until the December 2022 Note was repaid in full. On March 13, 2025, we used the proceeds from the March 2025 Note (as defined below) to pay off the December 2022 Note.

On March 13, 2025, we issued an unsecured convertible promissory note for \$33.1 million, or the March 2025 Note, to Avondale Capital, LLC, or Avondale, pursuant to a Securities Purchase Agreement, or the SPA, dated January 31, 2025. Certain terms of the March 2025 Note were approved at our annual meeting of stockholders on March 11, 2025, and we used the proceeds from the March 2025 Note to pay off the December 2022 Note. For a description of the SPA and the March 2025 Note, see “Description of Indebtedness” below for additional detail.

During the nine months ended June 30, 2025, Avondale converted \$25,000 of accrued interest on the March 2025 Note into shares of common stock and we made cash payments totaling \$975,000. These transactions constituted a \$1,000,000 payment toward the Quarterly Debt Reduction Obligations for the calendar quarter ending June 30, 2025.

On June 26, 2025, we and Avondale entered into an agreement to temporarily amend the payment schedule for the Quarterly Debt Reduction Obligations for the calendar quarter ended June 30, 2025, which permits staged monthly payments of \$1,000,000, to be made on June 30, July 31, and August 31, 2025.

On January 16, 2025, we entered into warrant inducement offer letter agreements, or the Warrant Inducement Transaction, with GMS Ventures and Investments, or GMS, and certain other holders of existing warrants to purchase our common stock, or Existing Warrants, pursuant to which the holders agreed to exercise their Existing Warrants for an aggregate of 7,074,637 shares of common stock at a reduced exercise price of \$2.51 per share. In exchange, we issued two new inducement warrants for each Existing Warrant exercised, which are exercisable for an aggregate of up to 14,149,274 shares of common stock at an exercise price of \$2.26 per share. We received net proceeds of \$15.9 million, after capital markets advisory fees and offering costs, from the Warrant Inducement Transaction.

Concurrently with the Warrant Inducement Transaction, we entered into the Syntone Warrant Inducement Transaction, pursuant to which Syntone agreed to exercise the Existing Syntone Warrants for an aggregate of 1,071,429 shares of common stock at a reduced exercise price of \$2.51 per share. In exchange, we agreed to issue two new Syntone Inducement Warrants for each existing warrant exercised, which will be exercisable for up to 2,142,858 Syntone Inducement Warrant Shares at an exercise price of \$2.26 per share. The closing of the Syntone Warrant Inducement Transaction is subject to receipt of regulatory approval. We expect to generate net proceeds of approximately \$2.4 million after capital markets advisory fees and estimated offering costs. As of the date of this filing, Syntone has not received regulatory approval and, thus, we have not yet received the proceeds from the exercise of the Existing Syntone Warrants, and the Syntone Inducement Warrants have not been issued. There can be no assurance that Syntone will receive the requisite regulatory approval in the near term or at all, and we may never receive the proceeds from the exercise of the Existing Syntone Warrants, or issue, or receive proceeds from the exercise of, the Syntone Inducement Warrants. For further details on the Warrant Inducement Transaction and Syntone Warrant Inducement Transaction, refer to Note 9 to the unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

On May 27, 2025, we completed an underwritten public offering (the “Public Offering”) of 9,285,714 shares of common stock and warrants to purchase an aggregate of 18,571,428 shares of common stock pursuant to an underwriting agreement, dated May 22, 2025, between us and BTIG, LLC. The combined price for each share of common stock and accompanying warrant to purchase two shares of common stock was \$1.40. We received aggregate net proceeds of \$11.6 million after payment of placement agent fees and other offering costs. GMS purchased an aggregate of 4,285,714 shares of common stock and warrants to purchase an aggregate of 8,571,428 shares of common stock in the Public Offering. The warrants have an exercise price of \$1.40 per share of common stock and will expire on May 27, 2030. Holders of the warrants may not exercise the warrants if it would result in such holder owning more than 4.99%, 9.99%, or 19.99%, as applicable, of our outstanding common stock.

We evaluated whether there are conditions or events considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We do not believe that the existing cash and cash equivalents as of June 30, 2025, together with \$1.9 million in net proceeds from the sale of shares of common stock under the ATM Agreement since June 30, 2025, are sufficient to fund the Company’s operations through one year from the date of this Quarterly Report on Form 10-Q. As a result, there is substantial doubt about the Company’s ability to continue as a going concern. Our unaudited

interim consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our future operations are highly dependent on a combination of factors, including: (i) the timely and successful completion of additional financing discussed above; (ii) our ability to successfully commercialize ONS-5010/LYTENAVA, including executing marketing arrangements, or complete revenue-generating partnerships with other companies; (iii) the success of our research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately; (v) regulatory approval and market acceptance of our proposed future products. See “Overview—Macroeconomic and Geopolitical Factors” for additional information regarding the macroeconomic and geopolitical factors that could have a material adverse effect on our business and results of operations.

#### *Funding Requirements*

We plan to focus in the near term on supporting the review of our BLA submission for ONS-5010/LYTENAVA with the FDA and to prepare for the potential launch of ONS-5010/LYTENAVA, if approved, to support the generation of commercial revenues, in the U.S. We anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able to successfully commercialize ONS-5010/LYTENAVA if, among other things, the FDA does not approve our BLA when we expect, or at all, or if we are not able to secure sufficient funding of our expected post-launch commercial costs.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, manufacturing and facility costs, external research and development services, legal and other regulatory expenses and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the development of our lead product candidate and any other product candidates we may choose to pursue.

We do not believe that the existing cash and cash equivalents as of June 30, 2025, together with \$1.9 million in net proceeds from the sale of shares of common stock under the ATM Agreement since June 30, 2025, are sufficient to fund our operations through one year from the date of this Quarterly Report on Form 10-Q. Our unaudited interim consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

We plan to finance our future operations with a combination of proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, sale of the development and commercial rights to our drug product candidates in regions outside of the U.S., the issuance of additional debt, the issuance of equity securities, including accessing capital through at-the-market offering agreements, and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Further, due to current market volatility, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. There are no assurances that we will be successful in obtaining an adequate level of financing for the commercialization of ONS-5010/LYTENAVA or the development of any other current or future product candidates. Alternatively, we will be required to, among other things, modify our clinical trial plans for ONS-5010/LYTENAVA in additional indications, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

#### *Cash Flows*

The following table summarizes our cash flows for each of the periods presented:

	<b>Nine months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
Net cash used in operating activities	\$ (39,452,240)	\$ (51,811,963)
Net cash provided by financing activities	33,425,516	60,444,368
Net (decrease) increase in cash and cash equivalents	\$ (6,026,724)	\$ 8,632,405

### *Operating Activities*

During the nine months ended June 30, 2025, we used \$39.5 million of cash in operating activities resulting primarily from our net loss of \$49.1 million. This use of cash was partially offset by \$6.5 million of non-cash items such as stock-based compensation, loss from change in fair value of promissory notes, warrant inducement expenses, gain from change in fair value of warrant liability, loss on equity method investment and amortization expense. The net cash inflow of \$3.2 million from changes in our operating assets and liabilities was primarily due to a decrease in prepaid expenses of \$6.2 million associated mainly with ONS-5010/LYTENAVA development costs relating to clinical trial and drug development costs, and an increase in accounts payable and accrued expenses of \$3.0 million, primarily due to timing of payments, partially offset by an increase in inventory of \$4.1 million relating to commercial inventory manufactured during the period and accounts receivable of \$1.8 million.

During the nine months ended June 30, 2024, we used \$51.8 million of cash in operating activities resulting primarily from our net loss of \$81.1 million. This use of cash was partially offset by \$36.5 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of promissory notes, warrant related expense, gain from change in fair value of warrant liability, loss on equity method investment and amortization expense. The net cash outflow of \$7.2 million from changes in our operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses of \$1.2 million, and an increase in prepaid expenses of \$6.0 million for timing of payments associated with ONS-5010 development costs relating to clinical trial and drug development costs.

### *Financing Activities*

During the nine months ended June 30, 2025, net cash provided by financing activities totaled \$33.4 million. The primary sources of these funds included \$33.1 million in net proceeds from the issuance of the March 2025 Note, \$16.8 million from the exercise of common stock warrants related to the Warrant Inducement Transaction with GMS and other holders of Existing Warrants, \$12.1 million from the Public Offering, and \$5.3 million from sales of common stock under the ATM Offering. The proceeds from the March 2025 Note were utilized to fully repay the December 2022 Note, with a payment of \$32.9 million. In addition, the Company made cash debt repayments totaling \$1.0 million on the March 2025 Note during the period.

During the nine months ended June 30, 2024, net cash provided by financing activities was \$60.4 million, primarily attributable to \$60.4 million in net proceeds from private placements in March 2024 and April 2024 of an aggregate of 9,285,709 common stock shares and warrants to purchase an aggregate of 13,928,562 shares of common stock.

### **Description of Indebtedness**

On March 13, 2025, we issued the March 2025 Note for \$33,100,000 to Avondale pursuant to the SPA. Certain terms of the March 2025 Note were approved at our annual meeting of stockholders on March 11, 2025, and we used the proceeds from the March 2025 Note to pay off the December 2022 Note. On March 28, 2025, we filed a registration statement registering the resale of common stock issuable upon conversion of the March 2025 Note.

The March 2025 Note will initially bear interest at the prime rate as published in the Wall Street Journal, plus an additional 3%, subject to a floor of 9.5%. The March 2025 Note is scheduled to mature on July 1, 2026, and will be convertible into common stock. We are obligated to repay a minimum of \$3,000,000 of the outstanding balance of the March 2025 Note each calendar quarter starting with the second calendar quarter of 2025, subject to adjustments for conversions by Avondale and the payment of an exit fee of 7.5%, or the Quarterly Debt Reduction Obligations. Any amount converted by Avondale during a given calendar quarter in excess of the Quarterly Debt Reduction Obligations will be credited toward meeting the Quarterly Debt Reduction Obligations for the next quarter or quarters.

On June 26, 2025, we and Avondale entered into an agreement to temporarily amend the payment schedule for the Quarterly Debt Reduction Obligations for the calendar quarter ended June 30, 2025, which permits staged monthly payments of \$1,000,000, to be made on June 30, July 31, and August 31, 2025.

Commencing on the earlier of (i) six months following the issuance of the March 2025 Note and (ii) the date on which the Registration Statement is declared effective, or the Conversion Commencement Date, Avondale shall have the right to convert all or any portion of the outstanding balance under the March 2025 Note into shares of common stock, calculated

by dividing the amount of the March 2025 Note being converted by the Conversion Price (as defined below). Furthermore, we retain the right to convert any portion of the outstanding balance under the March 2025 Note into shares of common stock at the Conversion Price, provided certain conditions are met at the time of conversion, including, but not limited to, the condition that the daily volume-weighted average price of our common stock on Nasdaq equals or exceeds \$3.00 per share (subject to adjustments for stock splits and combinations) for a period of 30 consecutive trading days, and that the median daily dollar trading volume during the preceding 30 trading day period meets or exceeds \$1,000,000. We reserve the right to make payments (i) in cash, (ii) in shares of common stock, calculated as the applicable payment amount divided by the Conversion Price, or (iii) a combination of both cash and shares of common stock. Any cash payments made by us, including prepayments or payments made at maturity, will incur an additional fee of 7.5%.

The March 2025 Note stipulates that we shall not permit any conversion of the March 2025 Note if, following such conversion, Avondale and its affiliates would beneficially own shares of common stock exceeding 4.99% of the total number of outstanding shares as of that date, or the Beneficial Ownership Limitation. However, this limitation shall increase to 9.99% when our market capitalization falls below \$25,000,000. Avondale may, by written notice to us, adjust the Beneficial Ownership Limitation for itself, though any such adjustment will not take effect until the 61st day after such notice is received.

In the event of specific occurrences outlined in the March 2025 Note—such as our failure to fulfill payment obligations, non-compliance with the Quarterly Debt Reduction Obligations, insolvency or bankruptcy events, breaches of covenants in the SPA and the March 2025 Note, and unauthorized transactions without Avondale’s consent, collectively referred to as Trigger Events—Avondale reserves the right to increase the balance of the March 2025 Note by 10% in the case of a Major Trigger Event (as defined in the March 2025 Note) and by 5% for a Minor Trigger Event (as defined in the March 2025 Note). Should any Trigger Event persist without resolution for ten trading days following written notification from Avondale, this will constitute an event of default, such event, an Event of Default. Upon an Event of Default, Avondale may accelerate the March 2025 Note, resulting in all amounts becoming immediately due and payable, with interest accruing at a rate of 22% per annum until full payment is made.

Under the terms of the March 2025 Note, the “Conversion Price” is defined as \$2.26 per share prior to a Major Trigger Event (subject to adjustments for stock splits and combinations). Following a Major Trigger Event, the Conversion Price will be the lesser of (i) \$2.26 per share (subject to adjustments) or (ii) 90% of the lowest closing bid price over the three trading days preceding the conversion notice. Furthermore, if the Conversion Price falls below \$0.404 per share (subject to adjustments), we will be required to fulfill a conversion notice from Avondale in cash.

### **Critical Accounting Policies and Significant Judgments and Estimates**

The Critical Accounting Policies and Significant Judgments and Estimates included in our Form 10-K for the fiscal year ended September 30, 2024, filed with the SEC on December 27, 2024, have not materially changed except revenue recognition.

#### ***Revenue Recognition***

We recognize revenue from sales of a single product, LYTENAVA (bevacizumab gamma) (the “Product”) in accordance with ASC Topic 606 – *Revenue from Contracts with Customers*. Our revenue recognition analysis consists of the following steps: (i) identification of the promised goods in the contract; (ii) determination of whether the promised goods are performance obligations, including whether they are capable of being distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue as we satisfy each performance obligation.

LYTENAVA (bevacizumab gamma) became available for commercial sale and shipment to patients in Europe in fiscal year 2025. We sell the Product to several customers who are pharmaceutical wholesalers/distributors (the “Customers”) who in turn sell the Product directly to clinics, hospitals, and pharmacies. Revenue is recognized as the Product is physically delivered to the customers.

The transaction price that we recognize for LYTENAVA (bevacizumab gamma) revenue is our gross product sales reduced by our corresponding gross-to-net, or GTN, estimates using the expected value method, resulting in our reported “Revenues, net” in the accompanying Consolidated Statements of Operations. Revenues, net reflects the amount we ultimately expect to realize in net cash proceeds, taking into account our current period gross sales and related cash receipts, and the subsequent cash disbursements on these sales that we estimate for the various GTN categories discussed below. The GTN estimates are based upon information received from external sources, such as written or oral information obtained from customers with respect to their period-end inventory levels and sales to end-users during the period, in combination with management’s informed judgments. Due to the inherent uncertainty of these estimates, the actual amount of product returns, rebates and administrative fees may be materially above or below the amount estimated. The variance between actual amounts and estimated amounts may result in prospective adjustments to the reported net revenues.

Each of the GTN estimate categories are discussed below:

- Sales returns are estimated by the Company based on the relative risk of return based on expiration date, and other qualitative factors that can impact the volume of future returns, including competitive developments, product discontinuation, or new product introductions. The Company will consider the level of inventory in the distribution channel by monitoring inventories held at the distributor and wholesalers to assess whether historical rates of returns continue to be appropriate.
- Administrative fees are contractually charged by the wholesalers and are typically credited directly against amounts due to the Company.
- Rebates are contractually charged to the Company by customers, including a Voluntary Scheme for Branded Medicines Pricing, Access and Growth rebate with the National Health System in the UK.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

As a “Smaller Reporting Company,” this Item and the related disclosure are not required.

## **Item 4. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Because there are inherent limitations in all control systems, a control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. 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. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Our management, with the participation of our interim chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our interim chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

### **Changes in Internal Control over Financial Reporting**

During the third fiscal quarter ended June 30, 2025, we implemented new processes and controls in relation to the commercialization of LYTENAVA™ (bevacizumab gamma) in the UK and Germany, including processes and controls relating to revenue recognition and inventory which we plan to document the design and test the effectiveness of the controls during our fiscal year ending September 30, 2025. There were no further changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(f) under the Exchange Act) during third fiscal quarter ended June 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II. Other Information**

### **Item 1. Legal Proceedings**

On November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Exchange Act in connection with allegedly false and misleading statements made by us related to our BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneys' fees. On June 25, 2024, the defendants filed a motion to dismiss the amended class action complaint in its entirety. On February 6, 2025, the court entered an order granting the motion to dismiss and dismissing the complaint without prejudice and with leave to amend. On March 14, 2025, the plaintiffs filed their second amended class action complaint. On April 23, 2025, the defendants filed a motion to dismiss the plaintiffs' second amended class action complaint in its entirety. Defendants' motion to dismiss is currently pending before the court.

On October 10, 2024, certain of our officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the company to violate federal securities laws based on the same alleged misstatements as the securities class action. The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneys' fees, and other costs. The derivative action is currently stayed, pending the final resolution of the November 3, 2023 securities class action pending in the United States District Court for the District of New Jersey.

The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements if we do not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if we do prevail. We have not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits as there is still uncertainty as to whether the litigation will result in any liability. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.

From time to time, we may also become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no additional claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

### **Item 1A. Risk Factors**

Except as set forth below, as of June 30, 2025, there have been no material changes to the risk factors that were previously disclosed in Item 1A in the Company's Form 10-K for the year ended September 30, 2024 filed with the SEC on December 27, 2024.

***International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.***

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct

our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report and in our Annual Report for the fiscal year ended September 30, 2024.

***We have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months.***

We have incurred net losses in each year since our inception in January 5, 2010, including net losses of \$75.4 million and \$59.0 million for the years ended September 30, 2024 and 2023, respectively. We have had minimal revenue to date and have a substantial accumulated deficit and recurring operating losses. We have not generated material revenue from the sales of any product. Our success as a company is substantially dependent on our ability to generate revenue from the sales of ONS-5010/LYTENAVA, which has been approved for the treatment of wet AMD in the EU and UK.

We have devoted substantially all of our financial resources to identify, develop and manufacture our product candidates, including conducting, among other things, analytical characterization, process development and manufacture, formulation

and clinical trials, regulatory filing and communication activities and providing general and administrative support for these operations. To date, only one of our product candidates, ONS-5010/LYTENAVA, has been approved for sale in the EU and UK, and we have financed our operations primarily through the sale of equity securities and debt financings, as well as to a limited degree, payments under our co-development and license agreements. The amount of our future net losses will depend, in part, on our ability to continue to generate revenue from product sales, the rate of our future expenditures and our ability to obtain funding through equity or debt financing or our ability to enter into and receive funding under strategic licensing or co-development collaborations.

We expect to continue to incur significant expenses and operating losses for at least the next 12 months. We anticipate that our expenses may increase substantially if and as we:

- continue to commercialize and market ONS-5010/LYTENAVA in the EU and UK, and in other countries if the product is approved in these territories;
- continue the clinical development of ONS-5010/LYTENAVA;
- advance ONS-5010/LYTENAVA into additional clinical trials;
- change or add contract manufacturing providers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- seek regulatory and marketing approvals for ONS-5010/LYTENAVA in the United States and other markets if we successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and for which we retain such rights;
- seek to identify, assess, acquire or develop other product candidates that may be complementary to ONS-5010/LYTENAVA;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect and expand our intellectual property portfolio;
- engage in litigation, including the pending securities class action lawsuit, as well as any other potential litigation;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and any future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including but not limited to failed clinical trials, conflicting results, safety issues or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

***We have generated minimal revenue from product sales and may never be profitable.***

We have one product, ONS-5010/LYTENAVA, approved for commercialization in the EU and UK and have generated minimal revenue from product sales. Our ability to continue to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, ONS-5010/LYTENAVA for the treatment of wet AMD, and our other targeted indications, and as appropriate, any of our other product candidates. We currently estimate that we could potentially begin generating revenue from product sales in Europe as early as the first half of calendar 2025, but this depends heavily on our success in many areas, including but not limited to:

- Securing capital sufficient to continue to fund our commercialization efforts;
- continuing to commercialize ONS-5010/LYTENAVA and any other product candidates for which we or our partners obtain regulatory and marketing approval;
- maintaining and obtaining regulatory and marketing approvals for ONS-5010/LYTENAVA and any other product candidates for which we or our partners complete clinical trials;

- retaining our manufacturing partner for ONS-5010/LYTENAVA and any approved product candidates to support clinical development, regulatory requirements and the market demand for any such approved product candidates;
- obtaining third-party coverage and adequate reimbursements of ONS-5010/LYTENAVA and any other product candidates, if approved;
- obtaining market acceptance of ONS-5010/LYTENAVA and any other product candidates for which we obtain regulatory and marketing approval as viable treatment options;
- establishing or demonstrating in the medical community the safety and efficacy of ONS-5010/LYTENAVA and its potential advantages over and side effects compared to existing products used to treat wet AMD;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- attracting, hiring and retaining qualified personnel; and
- completing clinical development of ONS-5010/LYTENAVA for the treatment of wet AMD in the United States and the other targeted indications, and any other product candidates we may develop in the future.

We anticipate incurring significant costs to continue to commercialize ONS-5010/LYTENAVA and any of our other product candidates that may be approved for commercialization in the future. Our expenses could increase beyond our expectations if we are required by the FDA, or other regulatory authorities, supranational, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, preclinical or other types of studies in addition to those that we currently anticipate.

Our ability to continue to generate revenue from the sales of ONS-5010/LYTENAVA in the EU, UK or in any other country where the product is approved, or in relation to any other product candidate that may be approved, will be dependent, in part, upon:

- our ability to execute our sales and marketing strategy for ONS-5010/LYTENAVA in the EU and UK;
- our ability to maintain and manage the necessary sales, marketing and other capabilities and infrastructure that are required to successfully commercialize ONS-5010/LYTENAVA in the EU and UK;
- the size of the markets in the territories for which we gain regulatory approval;
- the number of competitors in such markets;
- the market acceptance of ONS-5010/LYTENAVA and any other product candidate that may be approved;
- the accepted price for the product;
- the ability to obtain coverage and adequate reimbursement for ONS-5010/LYTENAVA and any other product candidate that may be approved;
- the quality and performance of ONS-5010/LYTENAVA and any other product candidate that may be approved, including the relative safety and efficacy; and
- whether we own, or have partnered, the commercial rights for that territory.

If the market for ONS-5010/LYTENAVA or any other product candidates we may develop in the future, or our share of that market, is not as large as we expect, the number of indications approved by regulatory authorities is narrower than we expect or the target population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products to become profitable. If we are unable to successfully complete development and obtain regulatory approval for ONS-5010/LYTENAVA outside the EU and UK, our business will be harmed.

***We are highly dependent on the success of ONS-5010/LYTENAVA, our only product that has been approved in the EU and UK. If ONS-5010/LYTENAVA does not receive regulatory approval outside the EU and UK, or is not successfully commercialized, our business may be harmed.***

We currently have one product, ONS-5010/LYTENAVA, that is approved for commercial sale in the EU and UK. We may never be able to obtain regulatory approval for ONS-5010/LYTENAVA outside the EU or UK, develop other marketable products or be able to continue commercializing LYTENAVA in the EU or UK. We expect that a substantial portion of our efforts and expenditures in the foreseeable future will be devoted to the advancement of ONS-

5010/LYTENAVA, our only approved product and only product candidate in active development. We also expect that we will need to devote significant effort to the continued commercialization of LYTENAVA in the EU, UK, and other markets following regulatory approval, if received. We cannot assure you that we will be able to successfully obtain regulatory approval of ONS-5010/LYTENAVA outside of the EU and UK and develop sufficient commercial capabilities for ONS-5010/LYTENAVA if and when necessary. Accordingly, our business currently depends heavily on the successful regulatory approval of ONS-5010/LYTENAVA outside the EU and UK, and commercialization of ONS-5010/LYTENAVA.

We cannot be certain that ONS-5010/LYTENAVA will receive regulatory approval outside of the EU or UK, or be successfully commercialized even in the EU or UK, or any other targeted market in which we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market ONS-5010/LYTENAVA in the United States until we receive approval from the FDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.

Obtaining approval from the FDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of ONS-5010/LYTENAVA for many reasons, including:

- we may not be able to demonstrate that ONS-5010/LYTENAVA is effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of ONS-5010/LYTENAVA and any future product candidate, or may require that we conduct additional trials;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

There can be no assurance that our BLA or MAAs of ONS-5010/LYTENAVA for wet AMD, or planned future, clinical trials for other retina indications, will ultimately meet the requirements sufficient for us to receive regulatory approval outside of the EU and UK. For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. We received agreement from FDA under the SPA for the NORSE EIGHT trial protocol and completed enrollment in the trial in September 2024. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010.

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Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. We resubmitted the BLA to the FDA in February 2025 and in April 2025 we announced that the FDA set a PDUFA goal date for August 27, 2025. There can be no assurance that we will address the deficiencies identified in the CRL to the satisfaction of the FDA.

**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.

**Item 5. Other Information**

During the three months ended June 30, 2025, none of the Company's directors or Section 16 officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement" as such term is defined in Item 408(a) of Regulation S-K.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
3.1	<a href="#">Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024).</a>
3.2	<a href="#">Certificate of Amendment of the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's current report on Form 8-K filed with the SEC on March 14, 2025).</a>
3.3	<a href="#">Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's current report on Form 8-K filed with the SEC on March 26, 2021).</a>
10.1#	<a href="#">Executive Employment Agreement by and between Robert C. Jahr and Outlook Therapeutics, Inc, dated June 28, 2025 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on July 1, 2025).</a>
10.2	<a href="#">Master Services Agreement by and among Outlook Therapeutics, Inc., Outlook Therapeutics Ltd, and Alloga (Nederland) B.V., dated January 29, 2025 (portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K).</a>
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.</a>
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.</a>
32.1*	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant</a>

	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 Definition Linkbase Document.
101.LAB***	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE***	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104**	Cover Page Interactive Data File.

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# Indicates management contract or compensatory plan.

\* Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

\*\* The XBRL Instance Document and Cover Page Interactive Data File do not appear in the Interactive Data File because their XBRL tags are embedded within the Inline XBRL document.

\*\*\* Submitted electronically with the report.

#### **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.

#### **OUTLOOK THERAPEUTICS, INC.**

Date: August 14, 2025

By: /s/ Lawrence A. Kenyon  
Lawrence A. Kenyon  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Confidential

Portions of this Exhibit have been omitted because they are both not material and the type of information that the registrant customarily and actually treats as private or confidential. Information that has been omitted has been marked in this exhibit with, black boxes, in accordance with Regulation S-K, Item 601(b)(10)(iv).

MASTER SERVICES AGREEMENT

(1) ALLOGA (NEDERLAND) B.V.

and

(2) OUTLOOK THERAPEUTICS, INC.

and

(3) OUTLOOK THERAPEUTICS LTD

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**THE UNDERSIGNED**

1. **ALLOGA (NEDERLAND) B.V.**, a private company with limited liability (*in Dutch: besloten vennootschap met beperkte aansprakelijkheid*), with its registered office at Veghel, The Netherlands, and having its place of business at (5465 PR) Veghel at Kempkens 2200, registered at the trade register Chamber of Commerce under number 17108476, hereby duly represented by \_\_\_\_\_ and \_\_\_\_\_, hereinafter referred to as: “**Alloga**”; and
2. **OUTLOOK THERAPEUTICS, INC.**, a Delaware corporation, with offices at 111 S. Wood Ave, Unit #100, Iselin, New Jersey 08830, together with its Affiliate **OUTLOOK THERAPEUTICS LTD**, an Irish limited liability company with its registered office at 10 Earlsfort Terrace, Dublin 2, 002 T380, Ireland, together hereinafter together referred to as the “**Client**”; and

each referred to hereinafter as “**Party**” and jointly referred to as “**Parties**”.

**WHEREAS:**

- a. Alloga conducts, inter alia, pre-wholesale activities and in that context provides logistics services including title distribution, warehousing and related services, transport services, invoicing and collection services to its customers;
- b. the Client is the Marketing Authorisation Holder for the Products and is authorized to market its products listed in Annex 1 in the Territory;
- c. the Client wishes to engage Alloga as its exclusive supplier of distribution, warehousing and related services for the Products (as defined hereinafter) in the Territory; and
- d. the Parties have agreed to lay down the terms and conditions of such engagement in this Agreement.

**NOW IT IS HEREBY AGREED AS FOLLOWS:**

**1. Definitions**

- 1.1. In this Agreement the following terms and expressions have the following meanings, unless expressly stated otherwise in this Agreement:

**Affiliate** With respect to Alloga, any group company, being legal entities and companies that are linked to each other in a group, Alloga is affiliated with or in which Alloga has a participating interest, namely if it or one or more of its subsidiaries, alone or jointly, provide or cause to be provided capital to that legal entity for their own account in order to be permanently associated with that legal entity for the purpose of their own activities; and with respect to Client, any entity that directly or indirectly controls, is controlled by or is under common control with such Party. “**Control**”, “**controls**”, or “**controlled**” means the possession, directly or indirectly, of at least 50% of the share capital or voting rights or of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise;

**Agreement:** this agreement including all documents and Annexes;

- Agreement Year:** each 12 month period starting from the Effective Date and each anniversary of the Effective Date provided that the last Agreement Year shall end on the date of expiry or termination of this Agreement;
- Annex:** an annex to this Agreement:
- Annex 1: Products;
  - Annex 2: Warehousing and Related Services;
  - Annex 3: Transport Services;
  - Annex 4: Distribution Services;
  - Annex 5: KPIs;
  - Annex 6: Pricing and Invoicing details;
  - Annex 7: NOT USED;
  - Annex 8: PD Conditions;
  - Annex 9: NOT USED;
  - Annex 10: TLN Conditions;
  - Annex 11: List of Subcontractors;
  - Annex 12: Quality Agreement;
  - Annex 13: [REDACTED];
  - Annex 14: [REDACTED];
- Applicable Law** all relevant national, supranational, international, federal, state and local laws, statutes, rules, and regulations that are applicable to a Party's activities hereunder
- Auditor:** an auditor that is qualified and certified to inspect the Warehouse;
- Business Day:** a day which is not a Saturday or Sunday or a bank or public holiday in The Netherlands or New Jersey, U.S.A.;
- Clause:** a clause of this Agreement;
- Confidential Information:** all non-public proprietary information regarding the Client or Alloga in any form and of any kind, of which the Receiving Party knows or reasonably ought to know that it is confidential. This includes (but is not limited to) information relating to the operations of the Parties, their Products, their processes, their plans, their market opportunities, their customer and supplier lists, their financial documentation, their pricing information, their marketing techniques and materials, the subject

matter of this Agreement and any other information of a confidential nature that is acquired by the Receiving Party in the performance of this Agreement or otherwise in connection with this Agreement;

[REDACTED]

**Customer** the Client's approved customers in the Territory [REDACTED]

**Delivery Note** a note signed and dated by the Client or its nominee including a description of the Products in the shipment, the quantity of Product, and the batch number;

**Disclosing Party** the Party disclosing Confidential Information;

**Effective Date** the effective date of this Agreement is January 29, 2025 ;

[REDACTED]

**Exclusive Services** [REDACTED]

**Falsified Medicines Directive (FMD):** the Falsified Medicines Directive (Directive 2011/62/EU) which amended EU Directive 2001/83/EC, and Commission Delegated Regulation (EU) 2016/161 of October 2<sup>nd</sup>, 2015 supplementing Directive 2001/83/EC (the latter hereinafter referred to as "**Act**");

**Force Majeure:** any circumstance beyond the Parties' control [REDACTED]



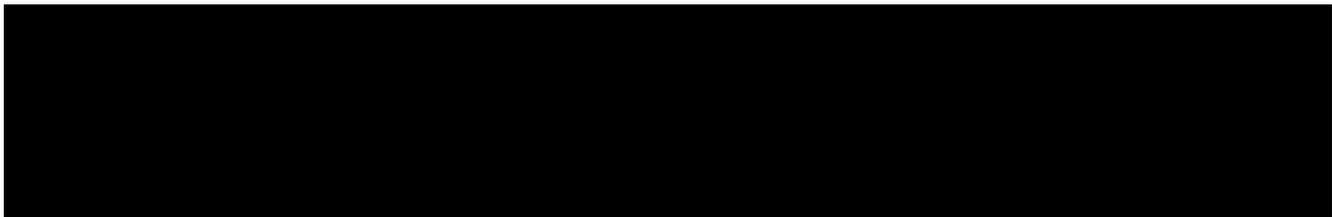
- GDP:** the Good Distribution Practices as currently set out in the European Commission Guidelines of November 5<sup>th</sup>, 2013 (343/01) and subsequent amendments, supplements, or replacements thereto;
- Global Trade Control Laws** all relevant laws, regulations and legislative instruments relating to economic sanctions and trade controls (including but not limited to U.S., U.K. and EU economic sanctions and trade controls);
- GMP:** the Good Manufacturing Practices as currently set out in Commission Directive 2003/94 and Volume 4 of Eudralex and subsequent amendments, supplements, or replacements thereto;
- Governmental or Regulatory Authority:** any court, tribunal, arbitrator, ministry, agency, commission, supranational authority, or other authority in the Territory;
- Initial Term:** has the meaning set out in Clause 13.1;
- KPIs:** Key Performance Indicators as agreed between the Parties and set out in Annex 5, which may be amended by prior mutual written agreement of the Parties' authorised representatives;
- LOI:** the letter of intent entered into by the Parties that was fully executed on [REDACTED]
- Marketing Authorisation:** the official authorisation to market and sell the Products in the Territory as granted by the appropriate Governmental or Regulatory Authority;
- Outbound Services Commencement Date:** means the date that the first order for Product is dispatched [REDACTED]
- PD Conditions:** the Physical Distribution Conditions as attached hereto as Annex 4, [REDACTED]
- Products:** the Client's products as listed in Annex 1;

[REDACTED]

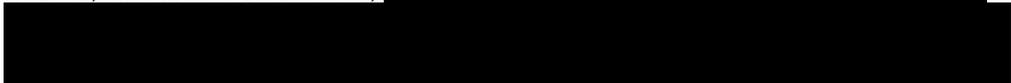
[REDACTED]



- Receiving Party** the Party receiving Confidential Information;
- Quality Agreement:** the agreement defining the technical and quality responsibilities of the Parties related to the production, testing and release of the Products to be executed by and between Parties in accordance with the terms of this Agreement;
- Sample:** supplies of Client products provided to Customers in strict compliance with the provisions of Article 96 of Directive 2001/83/EC;
- Sales Tax** any sales, goods, services, value-added, turnover, consumption, use or similar tax and any tax charged on the import or export of any goods or services;
- Sales Year:** any twelve-month period [REDACTED]
- Services:** the [REDACTED] Distribution Services, Warehousing and Related Services, the Transport Services and the invoicing and collection services together or, in the event that the Client does not purchase all of the aforementioned services, the combination of services that the Client purchases from Alloga;
- Services Fee:** the fee for the Services set out in Annex 6;
- Specifications:** the specifications related to the Services, as listed in the Warehousing and Related Services Annex (Annex 2), the Transport Services Annex (Annex 3) and the [REDACTED] Distribution Services Annex (Annex 4);
- Territory:** the European Union and the United Kingdom and any other country agreed between the Parties in writing from time-to-time;



- TLN Conditions:** Transport en Logistiek Nederland general conditions of payment concerning payments of transport, storage and other activities entrusted to the carrier, as filed with the registry of the district court (arrondissementsrechtbank) of The Hague, The Netherlands, file number 69/2002, as attached as Annex 10, [REDACTED]



- Trademark(s):** those trademarks owned, licensed or otherwise controlled by the Client or its Affiliates, including but not limited to their name and logo as well as any trademarks associated with the Products;
- Transport Services:** the transport services as described in Annex 3;
- Warehouse:** the location in which Alloga stores the Products;
- Warehousing and Related Services:** the warehousing and related services as described in Annex 2.
- Working Day** a day which is not a Saturday or Sunday or a bank or public holiday in The Netherlands

1.2 The following rules of construction and interpretation apply to this Agreement:

- (a) a reference to any legislation or regulation shall be construed as a reference to such legislation or regulation, including equivalent legislation or regulations in each applicable jurisdiction within the Territory, as it was binding, enforceable and in force at the execution of this Agreement;
- (b) the singular includes the plural and vice versa;
- (c) the headings of Clauses in and Annexes to the Agreement are for convenience only and shall not affect the interpretation of the respective rights and obligations of the Parties;
- (d) in the event provisions (or other contents) of an Annex conflict with provisions of this Agreement, the provisions of this Agreement shall prevail;
- (e) in the event provisions (or other contents) of the Quality Agreement conflict with provisions of this Agreement, the provisions of the Quality Agreement shall prevail only to the extent that these provisions govern the technical and quality responsibilities of the Parties imposed by applicable laws. In all other circumstances, the provisions of this Agreement shall prevail; and
- (f) in the event that an Alloga Affiliate is engaged to undertake Services in the Territory, where applicable, references to "Alloga" in this Agreement shall be construed as references to the relevant Alloga Affiliate carrying out the Services.

## 2. Provision of the Services

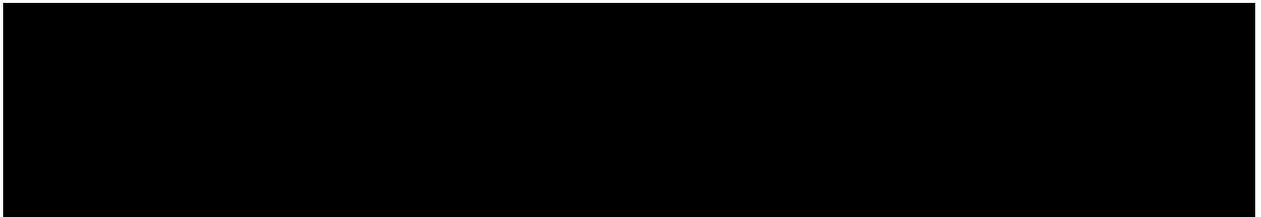
2.1. The Client appoints Alloga to be, and Alloga agrees to act as, the Client's exclusive supplier of the Exclusive Services during the term of this Agreement

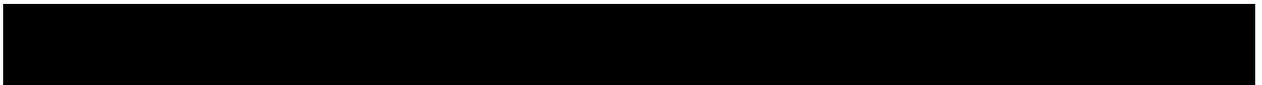
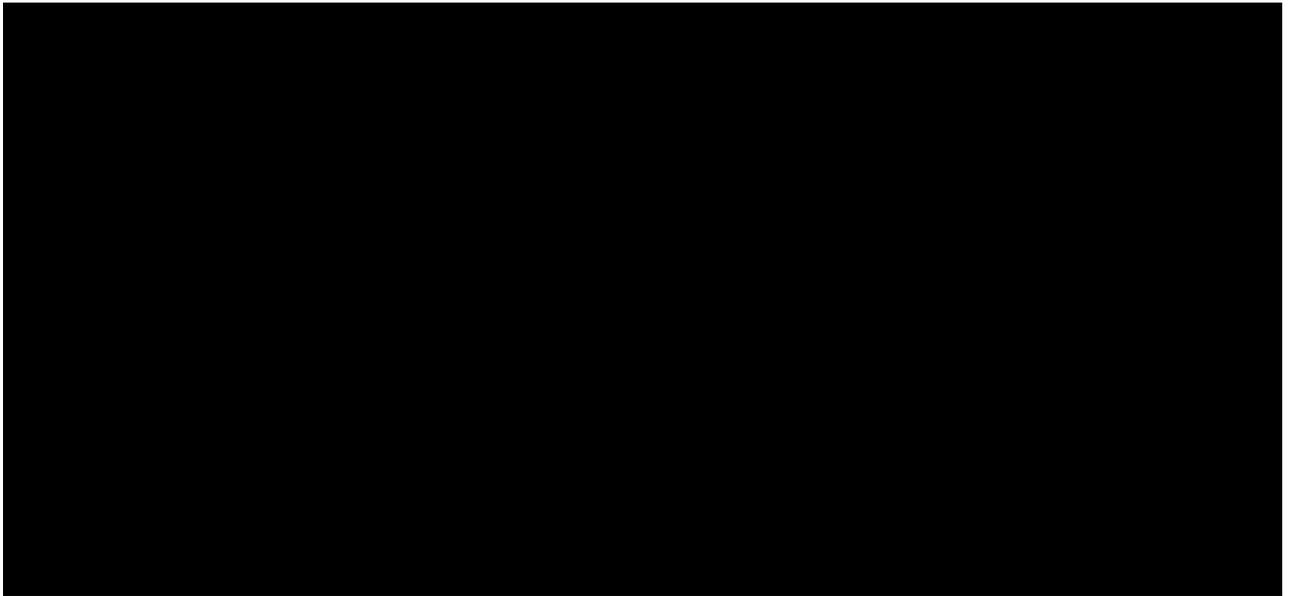


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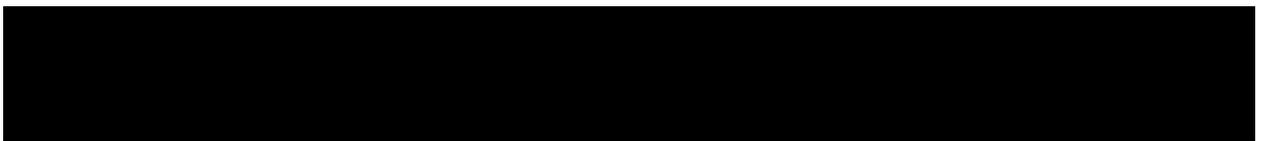


2.3.

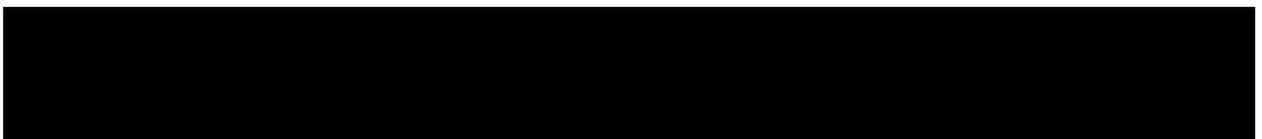




2.4.



2.5.



2.6. All Services shall be carried out in accordance with:

- (a) the Specifications;
- (b) the KPIs; and





3.8. [Redacted]

3.9. [Redacted]

3.10. [Redacted]

3.11. [Redacted]

3.12. Further terms and conditions relating to the fulfilment of sales to Customers by Alloga, including but not limited to (i) service fees and payment terms for [Redacted] Distribution Services; (ii) Product returns; and (iii) Product recalls and withdrawals are set out in the [Redacted] Distribution Services Annex (Annex 4).

**4. Transport, Warehousing and Related Services**

Transport Services

4.1. Alloga shall provide to the Client (and the Client shall accept from Alloga) the Transport Services in the Territory as further detailed in the Quality Agreement.

4.2. [Redacted]

4.3. Further terms and conditions relating to the provision by Alloga of (i) the Warehousing and Related Services are set out in Annex 2; and (ii) the Transport Services are set out in Annex 3.

**5. Obligations of the Parties**

5.1. The Client has the following obligations:



- (a) [Redacted]
- (b) [Redacted]
- (c) [Redacted]
- (d) [Redacted]
- (e) [Redacted]
- (f) [Redacted]
- (g) [Redacted]
- (h) [Redacted]
- (i) [Redacted]

5.2. [Redacted]

- (a) [Redacted]



(b)

[Redacted]

(c)

[Redacted]

5.3. Alloga has the following obligations:

(a)

[Redacted]

(b)

[Redacted]

(c)

[Redacted]

(d)

[Redacted]

(e)

[Redacted]

(f)

[Redacted]

5.4.

[Redacted]



[Redacted]

5.5.

[Redacted]

5.6.

[Redacted]

6. **Compliance: FMD / Sanctions and Trade Controls**

➤ **FMD**

6.1. The Parties shall comply with the FMD and any future (regulatory) amendments made to the FMD.

6.2.

[Redacted]

6.3.

[Redacted]

6.4.

[Redacted]

6.5.

[Redacted]

6.6.

[Redacted]

6.7.

[Redacted]

6.8.

[Redacted]



6.9. Alloga shall comply with any obligations placed on distributors in the FMD or otherwise applicable to the Services in the Territory.

➤ **Sanctions and Trade Controls**

6.10. Client and Alloga each:

- (a) covenants that it will perform its obligations and other activities under this Agreement in full compliance with all applicable Global Trade Control Laws; and
- (b) warrants that it has, and covenants that it will continue to have, adequate procedures in place to ensure its compliance with applicable Global Trade Control Laws;

6.11. [Redacted]

6.12. [Redacted]

(i) [Redacted]

(ii) [Redacted]

(iii) [Redacted]

(iv) [Redacted]

6.13. [Redacted]

(a) [Redacted]



(b)

[Redacted]

[Redacted]

[Redacted]

6.15. Each Party will promptly notify the other in writing if they become aware that any of the representations made in this Clause are no longer accurate (including, where applicable in the case of Client, that any license used to export product to particular destinations or recipients is no longer applicable) and shall provide such information as the other Party reasonably requests about the shipment in such a situation.

**7. Fees and payment**

7.1. The fees for the Services payable by the Client to Alloga (the “**Service Fees**”) for each relevant country in the Territory are set out in the Pricing and Invoicing Annex (Annex 6). The Parties hereby agree that the Service Fees are consistent with fair market value in an arm’s length transaction for the Services.

7.2.

[Redacted]

7.3.

[Redacted]

7.4.

[Redacted]



7.5. Further terms and conditions relating to the Service Fees, including but not limited to (i) the Service Fee validity period; (ii) [redacted]; (iii) [redacted]; (iv) invoicing and payment arrangements; and (v) [redacted] are set out in the relevant Pricing and Invoicing Annex (Annex 6).

7.6. [redacted]

7.7. [redacted]

7.8. [redacted]

**8. Audit, inspection and record keeping**

8.1. The Client has the right to have the relevant part of any Warehouse where its Products are stored, audited and inspected for Alloga's compliance with (i) GDP and GMP, (ii) applicable regulations on human medicines and (iii) this Agreement at its own cost and no more than [redacted]

[redacted]

8.2. The Client shall provide Alloga with the Auditor's qualifications and certifications no later than [redacted] before the audit and inspection for approval such approval not to be unreasonably withheld, delayed or conditioned.

8.3. [redacted]

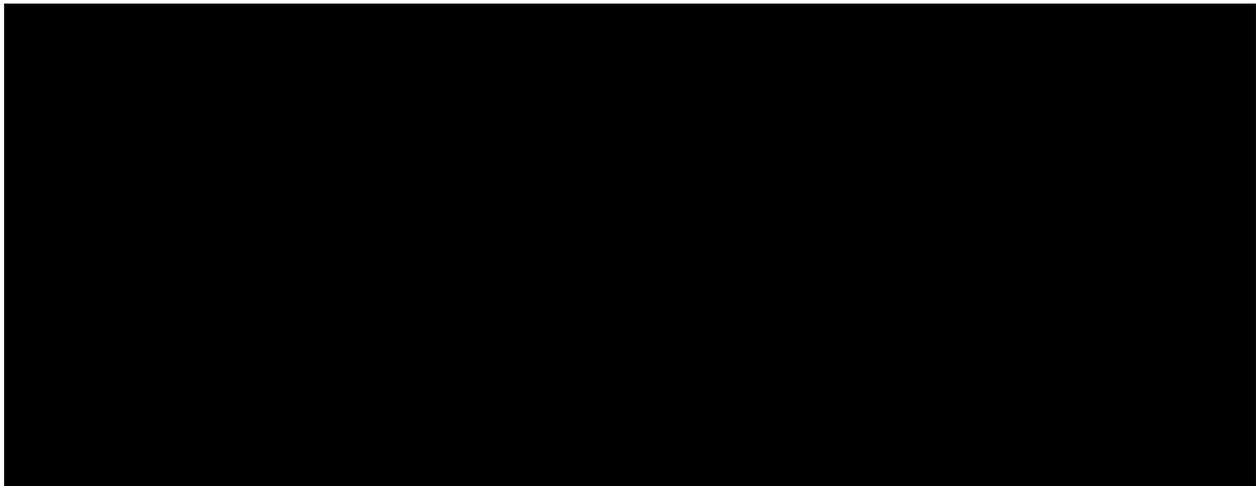
8.4. [redacted]

8.5. [redacted]



8.6.

8.7.



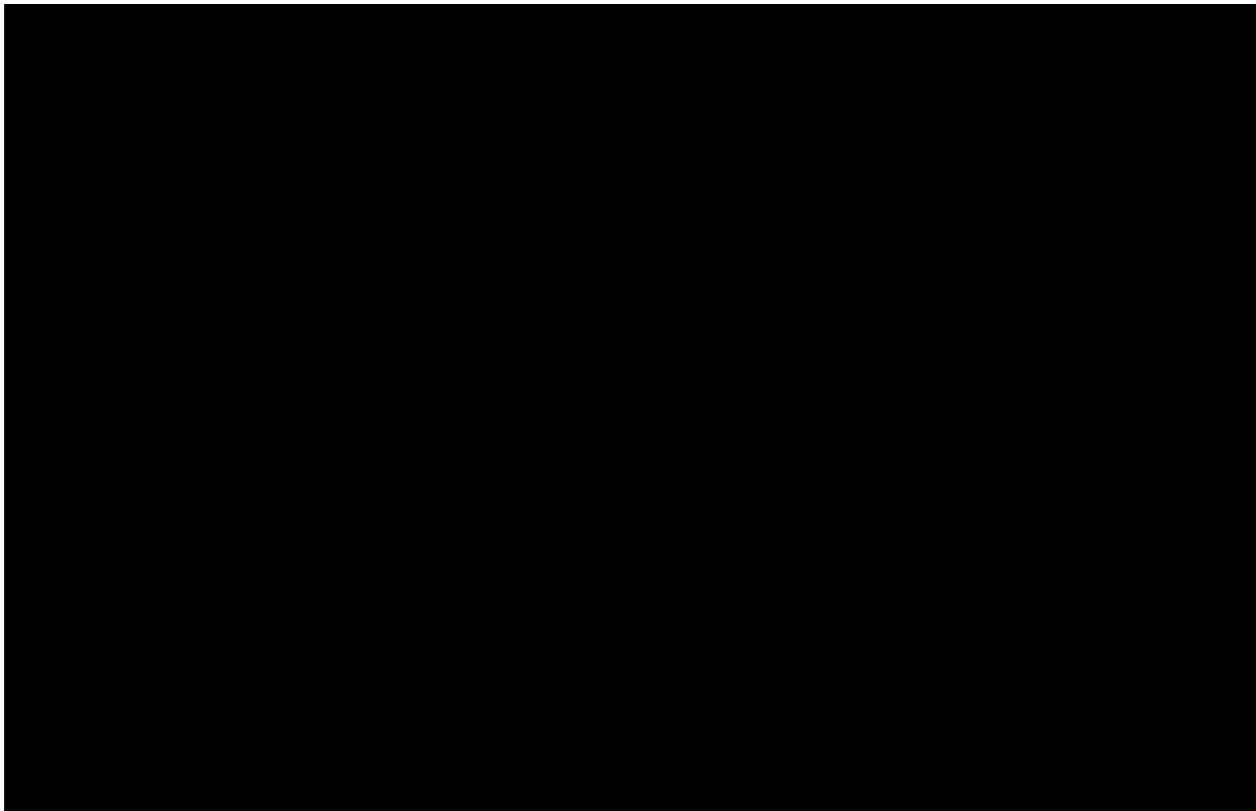
9. **Third parties and sub-contractors**

9.1.

9.2.

9.3.

9.4.



10. **Force Majeure**



10.1. In the event of Force Majeure affecting the ability of either Party to meet its obligations under this Agreement, the Party shall notify the other Party in writing as soon as reasonably possible after becoming aware thereof.

[Redacted]

If either Party is unable to meet its obligations under this Agreement for a period of [Redacted] or more by reason of Force Majeure:

(a) [Redacted]

(b) [Redacted]

**11. Liability**

11.1. [Redacted]

(a) [Redacted]

(b) [Redacted]

11.2. [Redacted]

(a) [Redacted]

(b) [Redacted]

(i) [Redacted]



[Redacted]

(ii)

[Redacted]

(c)

[Redacted]

(i)

[Redacted]

(ii)

[Redacted]

(d)

[Redacted]

(i)

[Redacted]

(ii)

[Redacted]

[Redacted]

11.3.

[Redacted]

11.4.

[Redacted]

11.5.

[Redacted]



11.6. [REDACTED]

**12. Protective covenants**

- 12.1. The Parties agree to protect the secrecy of and not to disclose to any third party any Confidential Information during the term of this Agreement and [REDACTED] thereafter, unless such information:
- (a) was publicly known prior to the time of disclosure by the Disclosing Party to the Receiving Party,
  - (b) becomes publicly known after disclosure by the Disclosing Party to the Receiving Party other than by breach of any confidentiality obligation under this Agreement,
  - (c) is disclosed to a tax authority in connection with the tax affairs or a reporting obligation of the Receiving Party;
  - (d) is required by applicable law or regulations to be disclosed by the Receiving Party (or one of its shareholders), or
  - (e) needs to be disclosed to third parties contracted by a Party for the benefit of (the execution of) this Agreement (such as but not limited to a contracted Auditor). In this event, the Receiving Party shall contractually bind the third party to the same confidentiality obligations. The Receiving Party shall remain responsible and liable towards the Disclosing Party for any breach of the confidentiality obligations by such third party.
- 12.2. No Party will make any public disclosure or issue any press releases pertaining to this Agreement without having first obtained the prior written consent of the other Party.
- 12.3. The industrial and/or intellectual property rights to the trademarks, service marks, trade names, domain names, logos, (applications for) patents, models, drawings, drafts, tools and/or all other documents which in any way relate or may be related to any product, service, work, method or process of a Party or to any Confidential Information shall be owned by that Party at all times.
- 12.4. Without the prior written consent of the other Party, neither Party is entitled to make use of or refer to any trademark, trade name, domain name, patent, design, copyright, or other intellectual property right of the other Party.
- 12.5. Each Party agrees that it will not do or omit anything for the benefit of, in the name of or on behalf of the other Party that could cause the other Party to be guilty of or implicated in any offence under any applicable anti-corruption legislation.

**13. Term and termination**

- 13.1. Term. Unless terminated early in accordance with its terms, the Agreement shall remain in full force and effect for [REDACTED] from the Effective Date (the “**Initial Term**”). Thereafter, the term of this Agreement shall each time be automatically renewed for successive periods of [REDACTED]



[REDACTED]

14.3. [REDACTED]

**15. Data Protection**

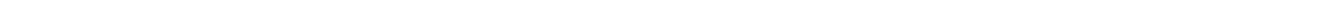
- 15.1. Nothing in this Agreement will limit or restrict either Party's obligations under applicable data privacy laws, in particular the EU and UK General Data Protection Regulations (GDPR and UK GDPR respectively).
- 15.2. To the extent that Personal Data (as defined in GDPR) will be shared between the Parties, in particular in connection with their respective obligations under the Quality Agreement, the Parties acknowledge and agree that the terms of the Data Processing Agreement entered into between [REDACTED] shall govern such Processing (as defined in GDPR) of Personal Data.

**16. Miscellaneous**

- 16.1. This Agreement and any other documents referred to in this Agreement constitute the whole and only agreement between the Parties relating to the provision of the Services (with the express exception of the LOI) and, except as expressly stated in those documents, supersedes and replaces any prior drafts, agreements and arrangements of any nature whatsoever relating thereto.
- 16.2. Any variation, amendment to or waiver of this Agreement shall be binding only if in writing and signed by the Parties.
- 16.3. Parties agree that if any provision of this Agreement is held to be invalid or unenforceable, this will not invalidate any of the remaining provisions of this Agreement. The Parties will replace the invalid or unenforceable provision with a valid and enforceable provision that shall come closest to the intention(s) of the original provision.
- 16.4. It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) shall not treat or report the relationship between the Parties arising under this Agreement as a partnership for tax purposes, unless required by Applicable Law.

**17. Notices**

- 17.1. All notices pursuant to this Agreement shall be in writing and may be given or made by any Party to the other Party by delivery to the addresses set out below, or such other address as



may be notified from time to time by the relevant Party to the other Party in accordance with this Clause

(a) Any notices delivered to Alloga shall be addressed as follows:

Alloga (Nederland) B.V.

[REDACTED]  
Kempkens 2200  
5465 PR Veghel  
The Netherlands

(b) Any notices delivered to the Client shall be addressed as follows:

Outlook Therapeutics Inc.

[REDACTED]  
111 Wood Avenue South  
Suite #100  
Iselin, New Jersey 08830  
United States of America

e.mail: [REDACTED] (a copy by email shall be required for, but not constitute, notice)

**18. Applicable law and choice of forum**

- 18.1. This Agreement is governed by and construed under Dutch law, with the exclusion of the Vienna Sales Convention (CISG).
- 18.2. Any dispute which may arise out of or in connection with this Agreement shall be exclusively settled by the competent courts in Amsterdam, The Netherlands.

*[signatures follow]*

**THIS AGREEMENT IS EXECUTED** by the authorized representatives of the Parties as of the Effective Date.

**ALLOGA (NEDERLAND) B.V.**

Signed by:  
*Rob van Ras*  
-----  
Signer Name: Rob van Ras  
Signing Reason: I approve this document  
Signing Time: 1/29/2025 | 6:45:46 AM PST  
67937485CF1840CDA760CFEB090D7DC3

R.A.A.L van Ras Proxy Holder  
Director

Signed by:  
*Rob Peters*  
-----  
Signer Name: Rob Peters  
Signing Reason: I approve this document  
Signing Time: 1/29/2025 | 7:13:39 AM PST  
D67CA3F6E93A44EAAF2F18C93544236

Mr.G.M.H. Peters  
Director

**OUTLOOK THERAPEUTICS, INC.**

Signed by:  
*Jeff Evanson*  
-----  
Signer Name: Jeff Evanson  
Signing Reason: I approve this document  
Signing Time: 1/29/2025 | 6:28:22 AM PST  
E4E3AF5A87BC43A5AC6FA2CDAD758BA6

Jeff Evanson  
Chief Commercial Officer

Signed by:  
*Lawrence Kenyon*  
-----  
Signer Name: Lawrence Kenyon  
Signing Reason: I approve this document  
Signing Time: 1/29/2025 | 6:27:22 AM PST  
C24060DA1E744AEBAC9F9D23AD145531

Lawrence Kenyon  
CFO and interim CEO



**ANNEXURES**

Annex 1: Products;

Annex 2: Warehousing and Related Services;

Annex 3: Transport Services;

Annex 4: [REDACTED] Distribution Services;

Annex 5: KPIs;

Annex 6: Pricing and Invoicing details;

[Annex 7: [REDACTED];]

Annex 8: PD Conditions;

Annex 9: NOT USED;

Annex 10: TLN Conditions;

Annex 11: List of Subcontractors;

Annex 12: Quality Agreement;

Annex 13: [REDACTED];

Annex 14: [REDACTED]

ANNEX 1  
**PRODUCTS**

Description	Size	Unit	Indication
LYTENA (bevacizumab gamma)	25 mg/mL solution for injection	Vial	Treatment of neovascular (wet) age- related macular degeneration (AMD) in adults

ANNEX 2  
WAREHOUSING AND RELATED SERVICES – ALLOGA NETHERLANDS

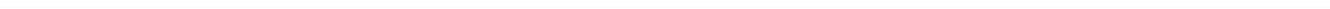
**ALLOGA'S OBLIGATIONS**

Within the terms of this Agreement Alloga shall:

**1 Warehouse Facility**

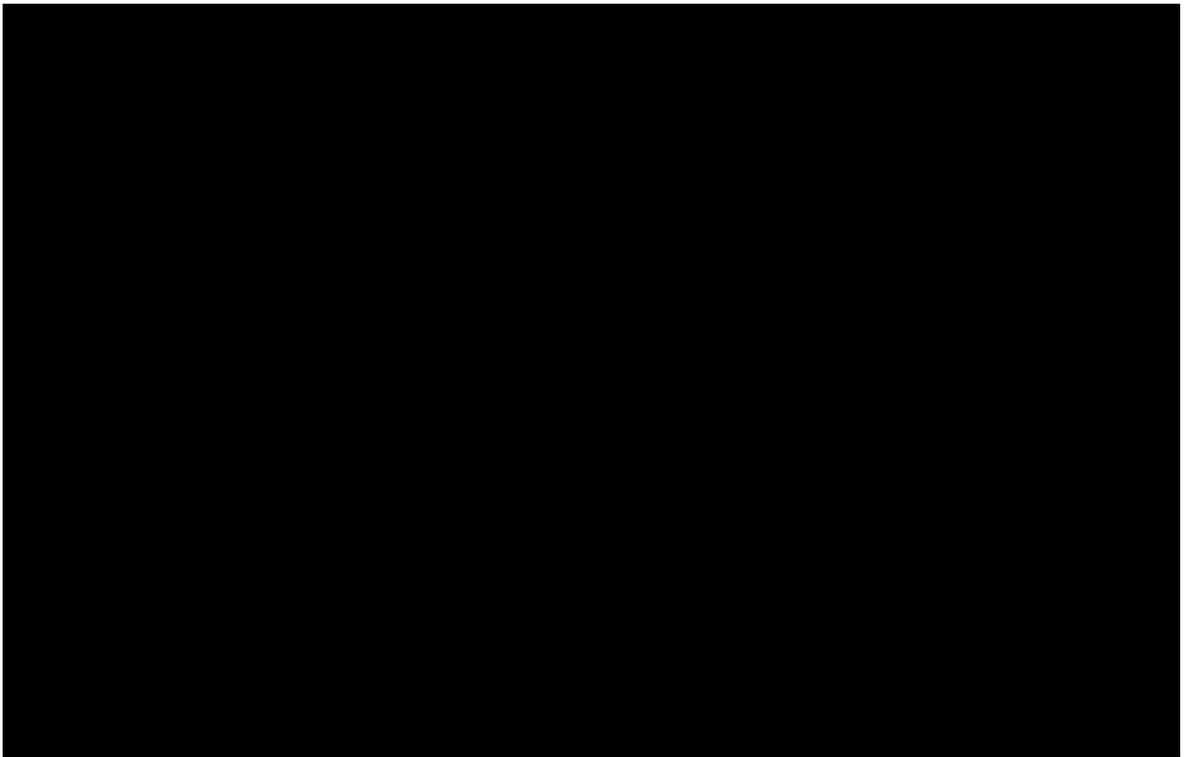
Provide a warehouse which meets with the requirements of the provisions of the Human Medicines Regulations 2012, European Commission guidelines on the Good Distribution Practice of medicinal products for human use (2013/C 343/01), and all other relevant laws and regulations throughout the term of this Agreement.

**2 Warehousing Services**





b) **Storage:**



c)



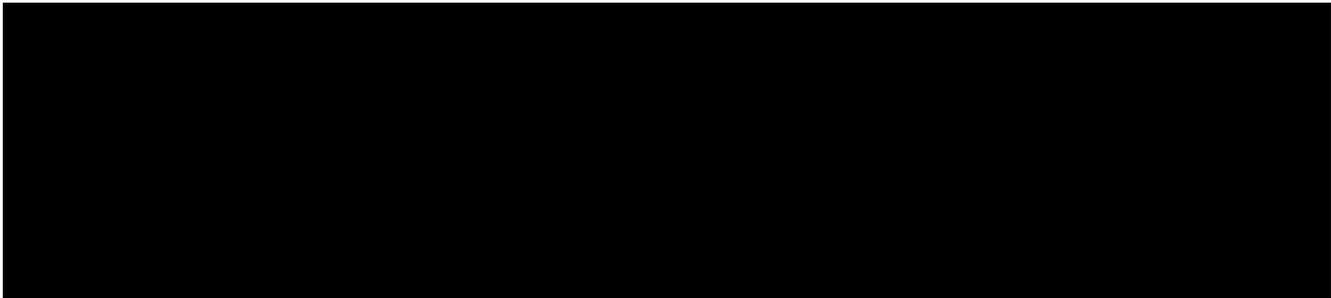


**d) Order Taking:**

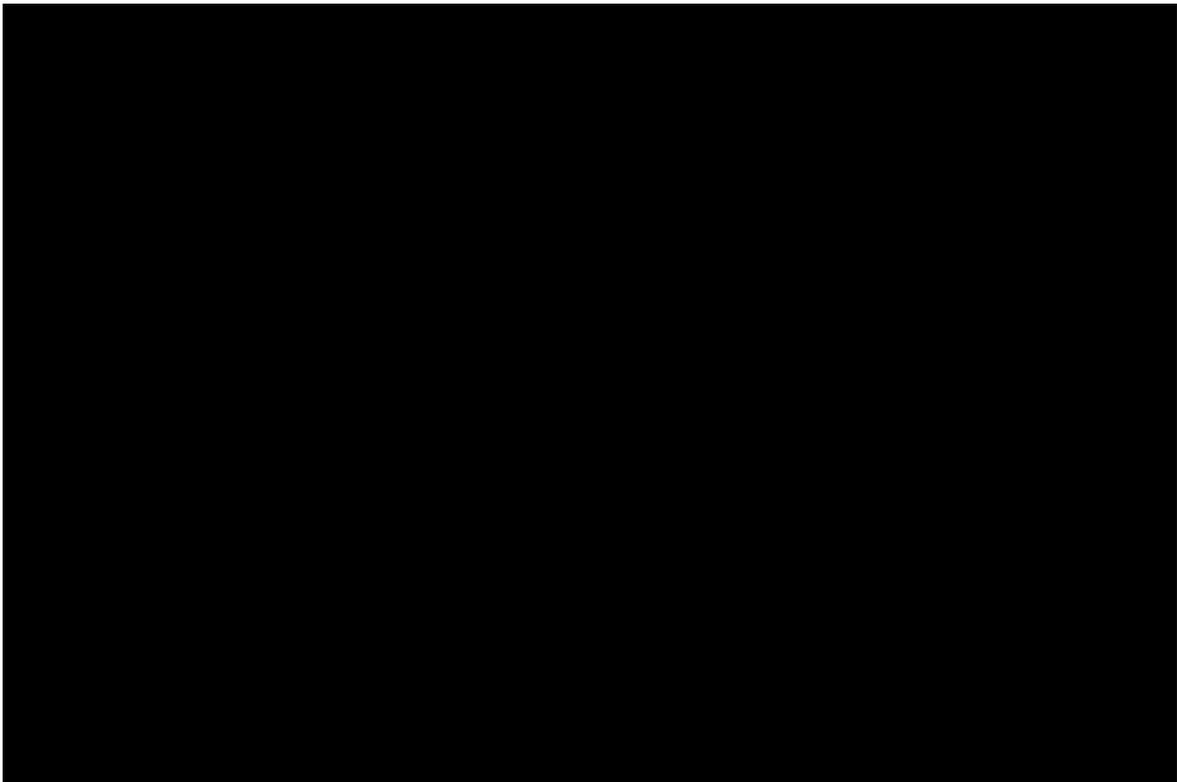


**e) Order Picking, Packing and Distribution for the Territory:**

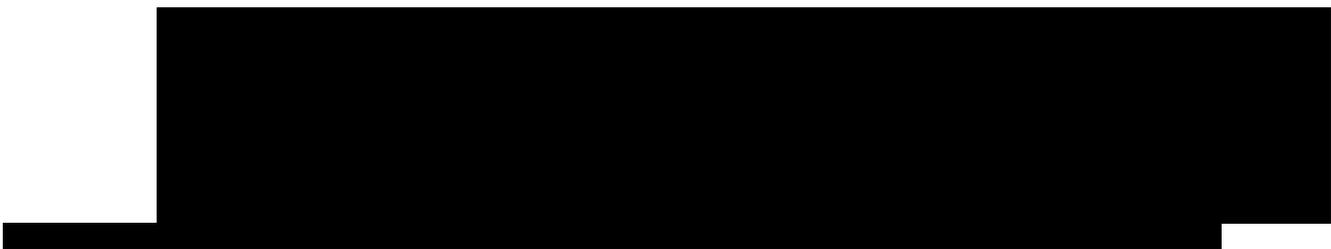




**f) Inventory management:**



**g) Client Complaints.**



**3 Management and Systems**



**THE CLIENT'S OBLIGATIONS**

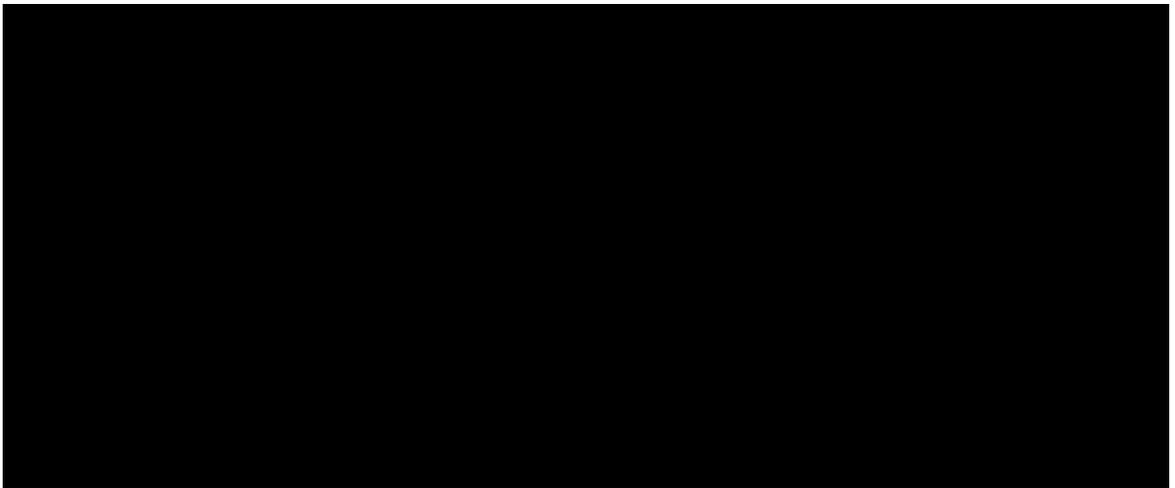
Within the terms of this Agreement the Client shall:

**1. Warehouse Facility**



**2. Warehousing Services**

**a) Goods receipt:**



- [Redacted]

b) **Storage:**

- [Redacted]

c) **Customer Qualification and Setup:**

- [Redacted]
- [Redacted]

d) **Order Taking:**

- [Redacted]

e) **Order Picking, Packing and Distribution for the Territory:**

- [Redacted]

f) **Inventory management:**

- [Redacted]

g) **Client Complaints.**

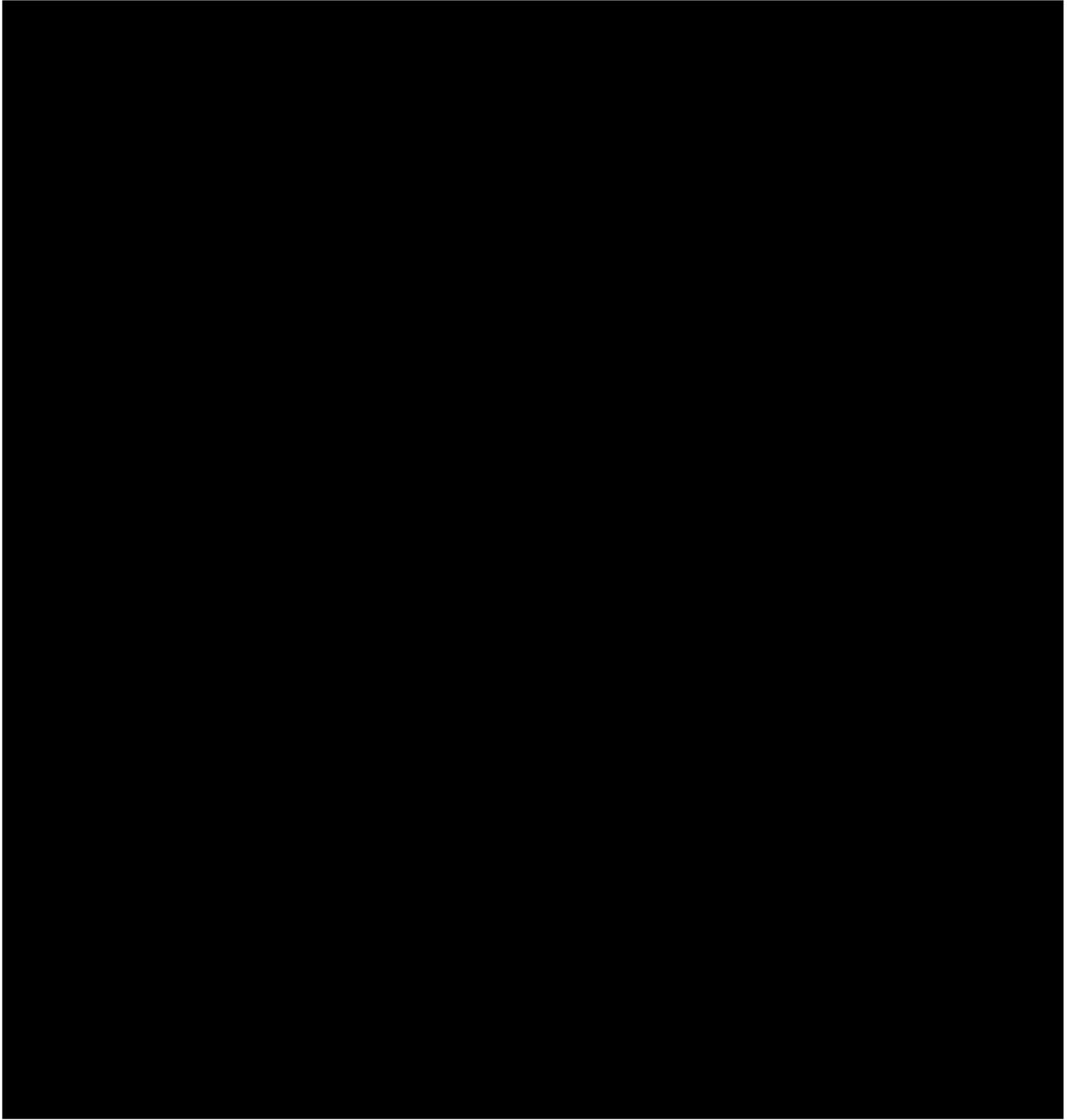
- [Redacted]

3. **Management and Systems**

[Redacted]



ANNEX 3  
TRANSPORT SERVICES - NETHERLANDS



Confidential



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Pagina **35** van **60**



ANNEX 4  
[REDACTED] DISTRIBUTION SERVICES

A. Customers

[REDACTED] [REDACTED]  
[REDACTED] [REDACTED]

B. Forecasts

[REDACTED] [REDACTED]  
[REDACTED] [REDACTED]  
[REDACTED] [REDACTED]

C. Short-Shelf Life

[REDACTED] [REDACTED]

D.

[REDACTED]  
[REDACTED] [REDACTED]

E.

[REDACTED]  
[REDACTED] [REDACTED]



[Redacted]

■ [Redacted]

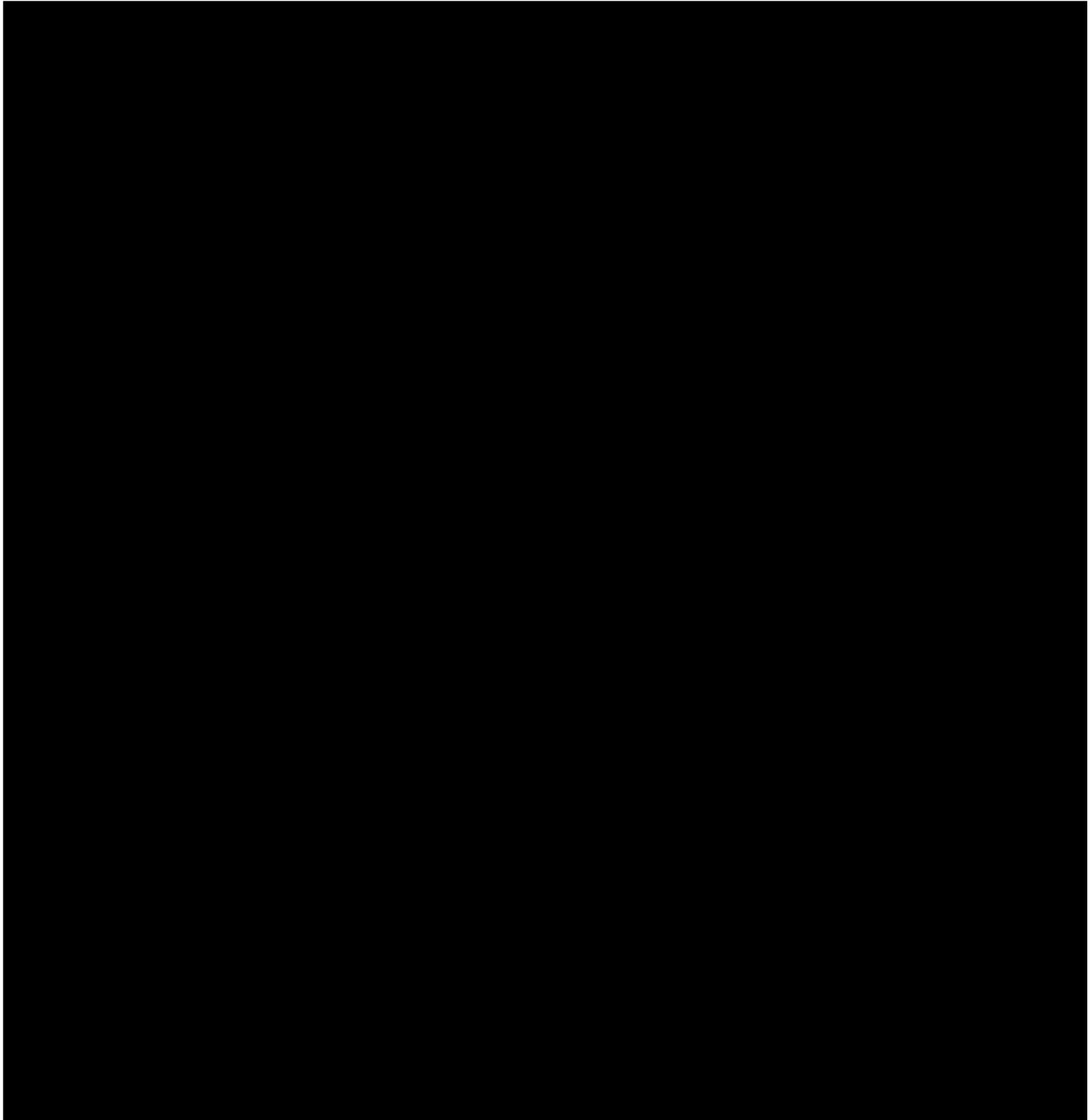
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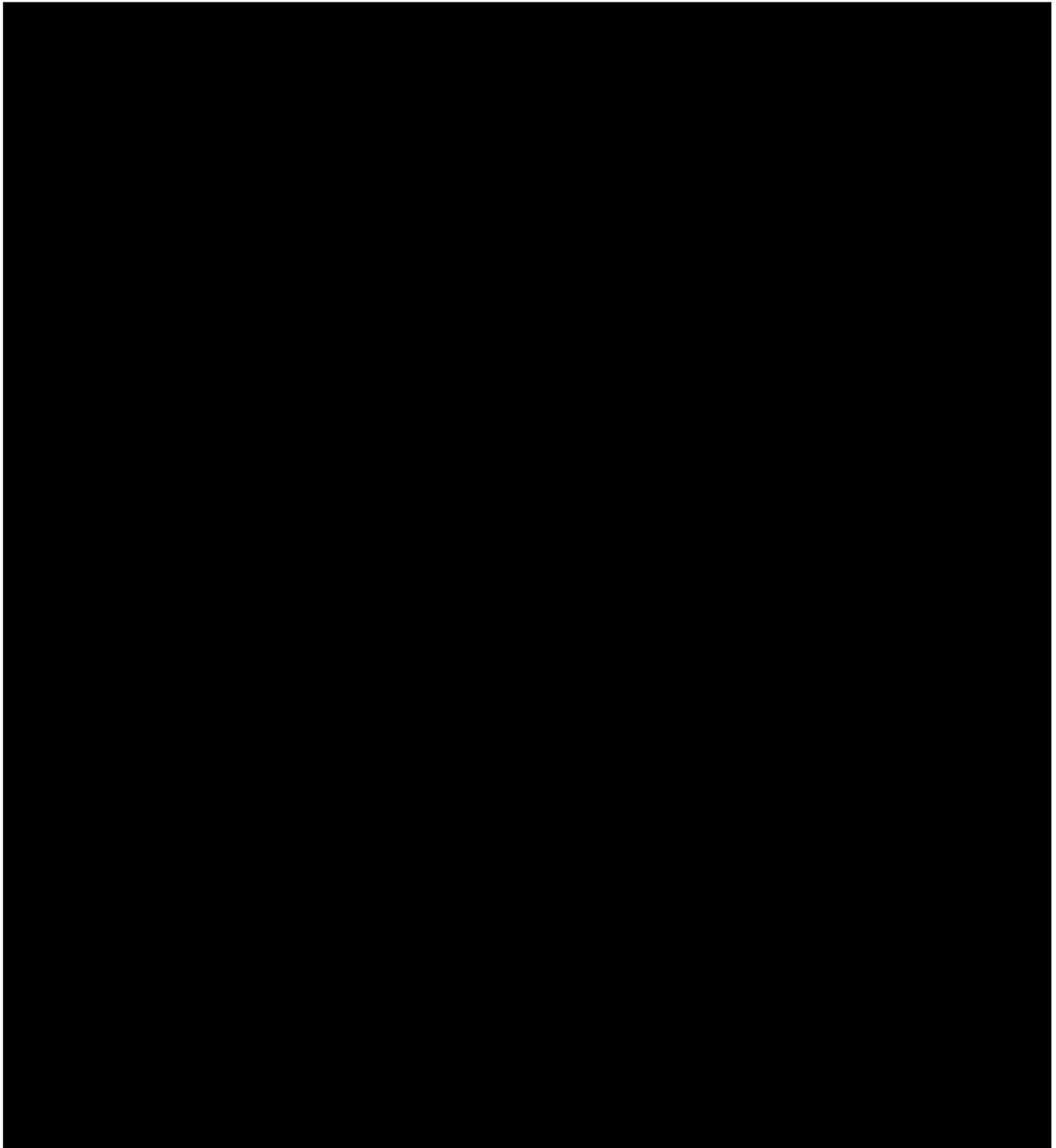
■ [Redacted]

■ [Redacted]

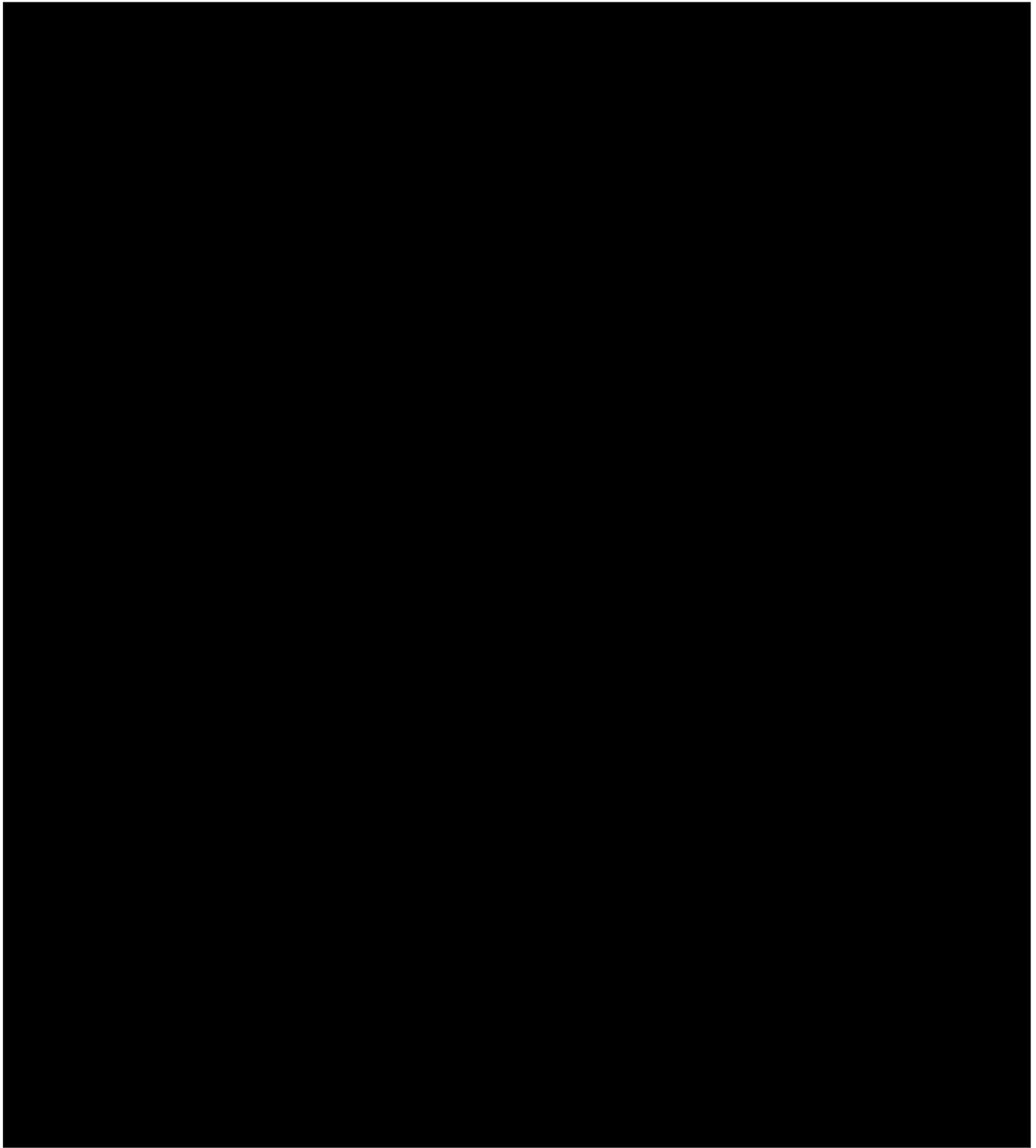


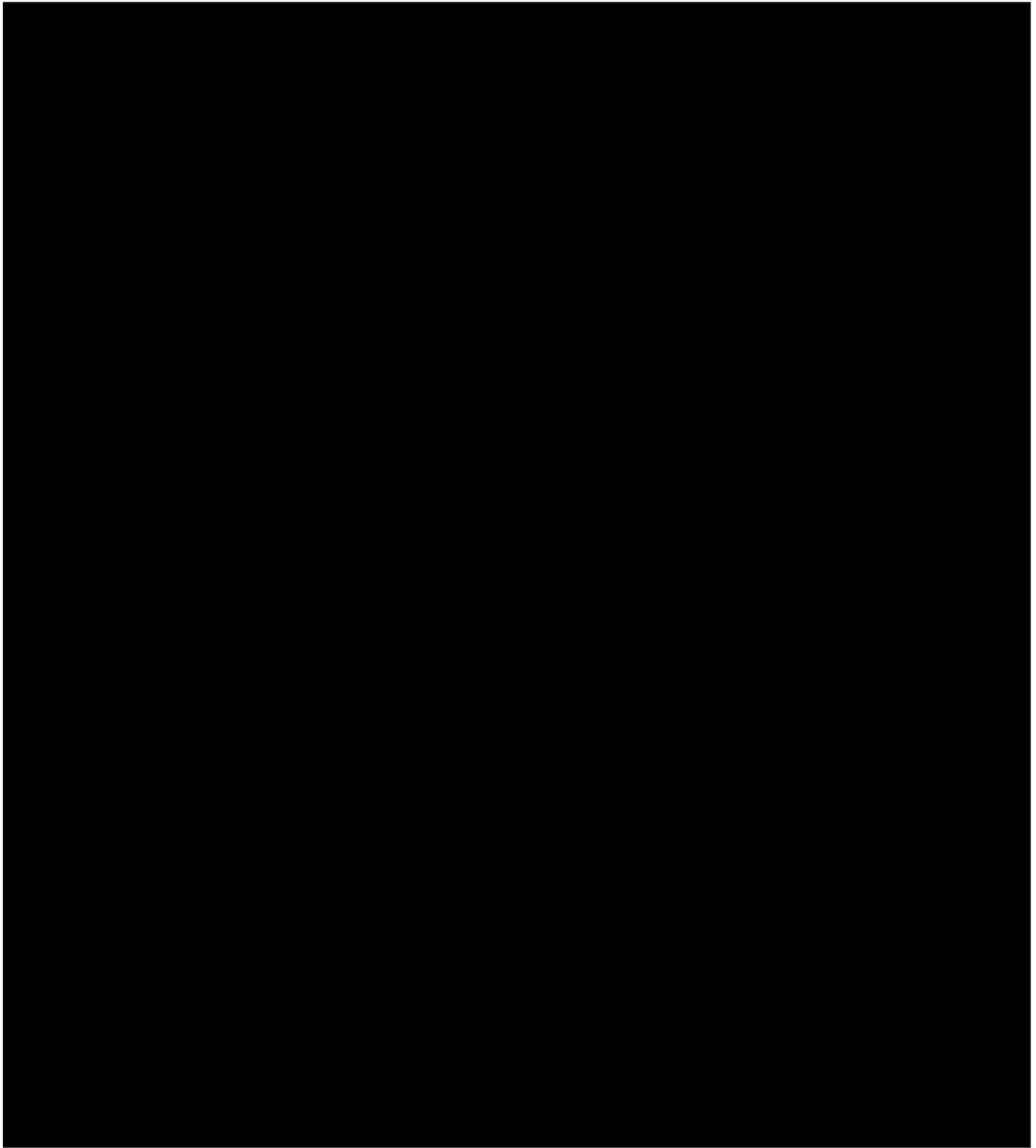
PERFORMANCE STANDARDS – NETHERLANDS

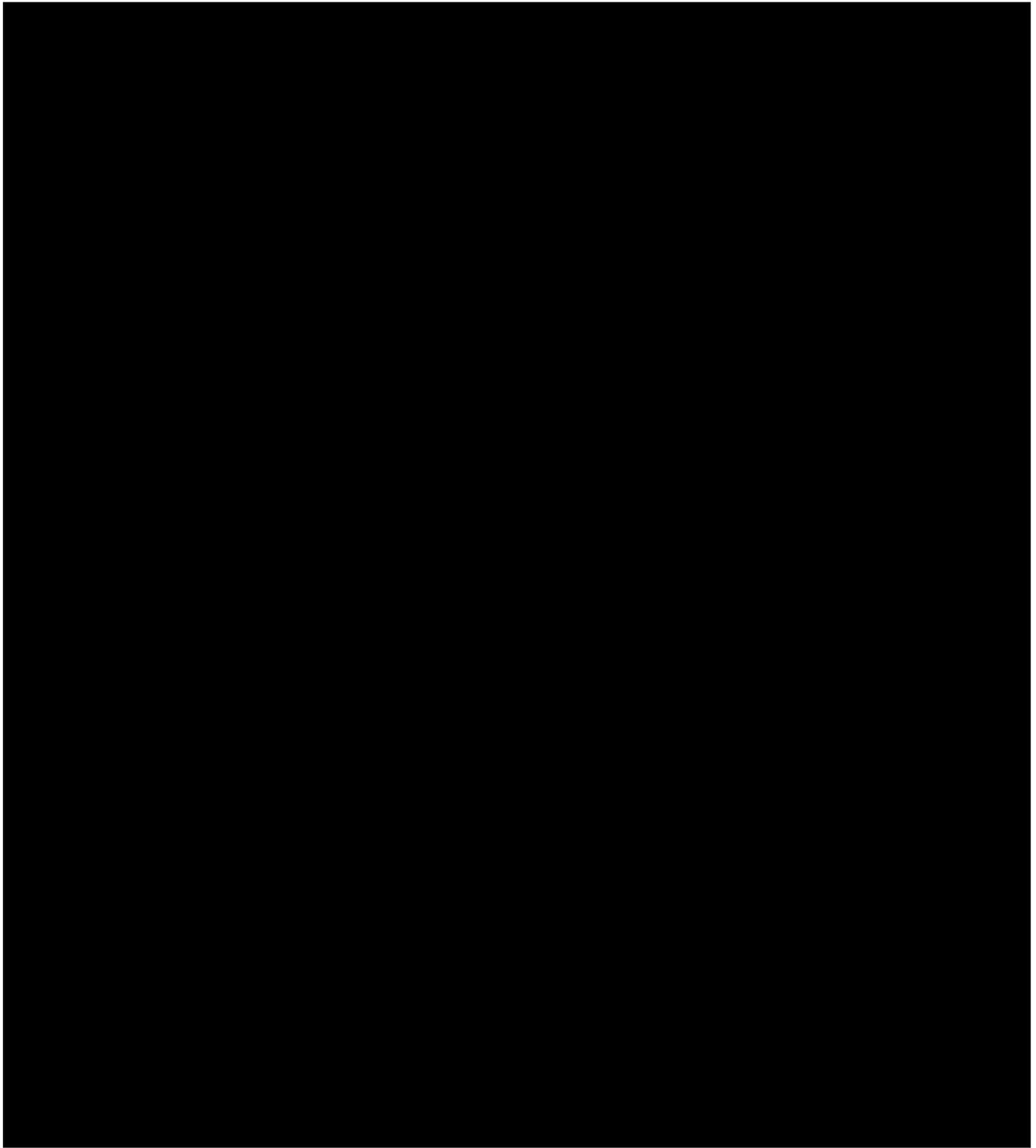


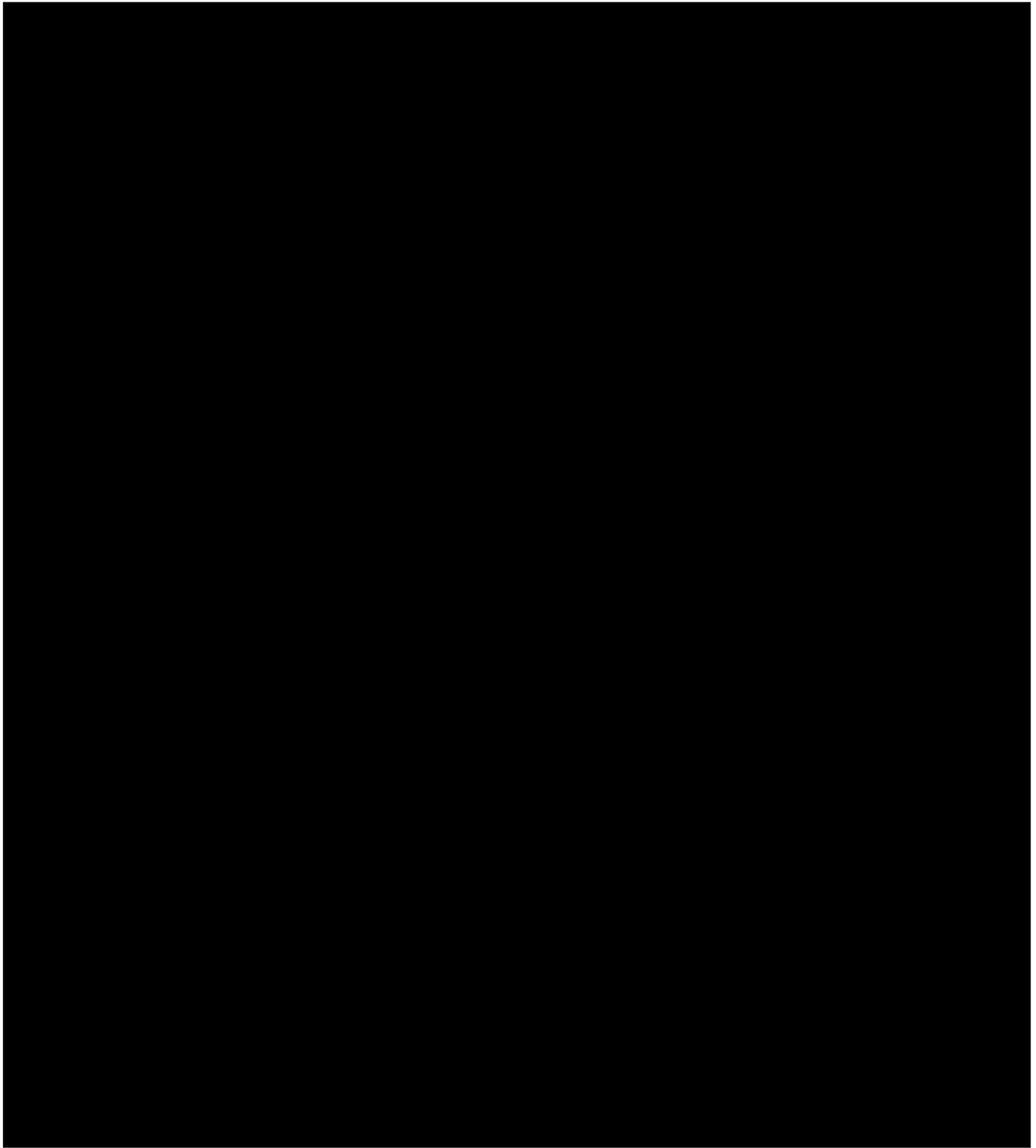


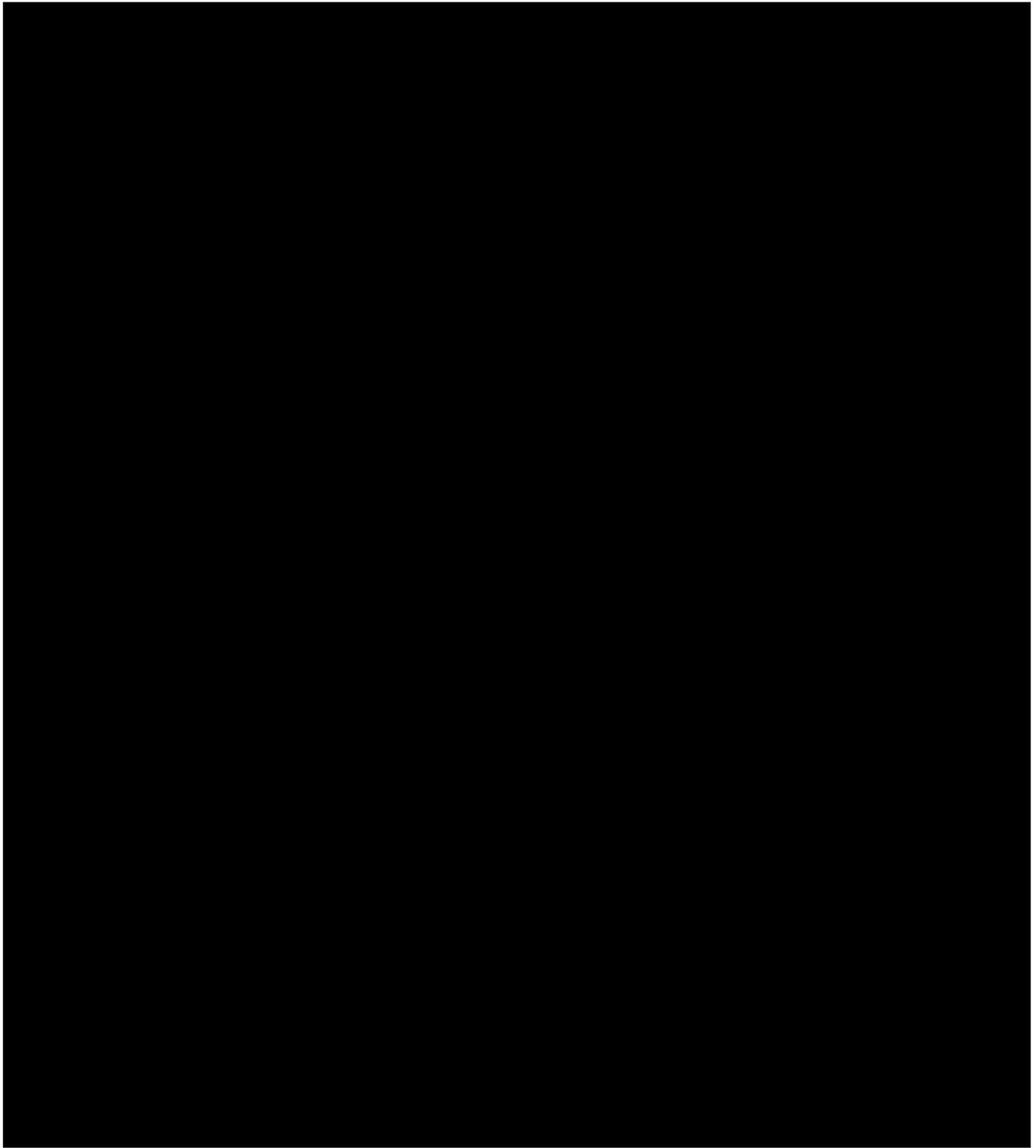


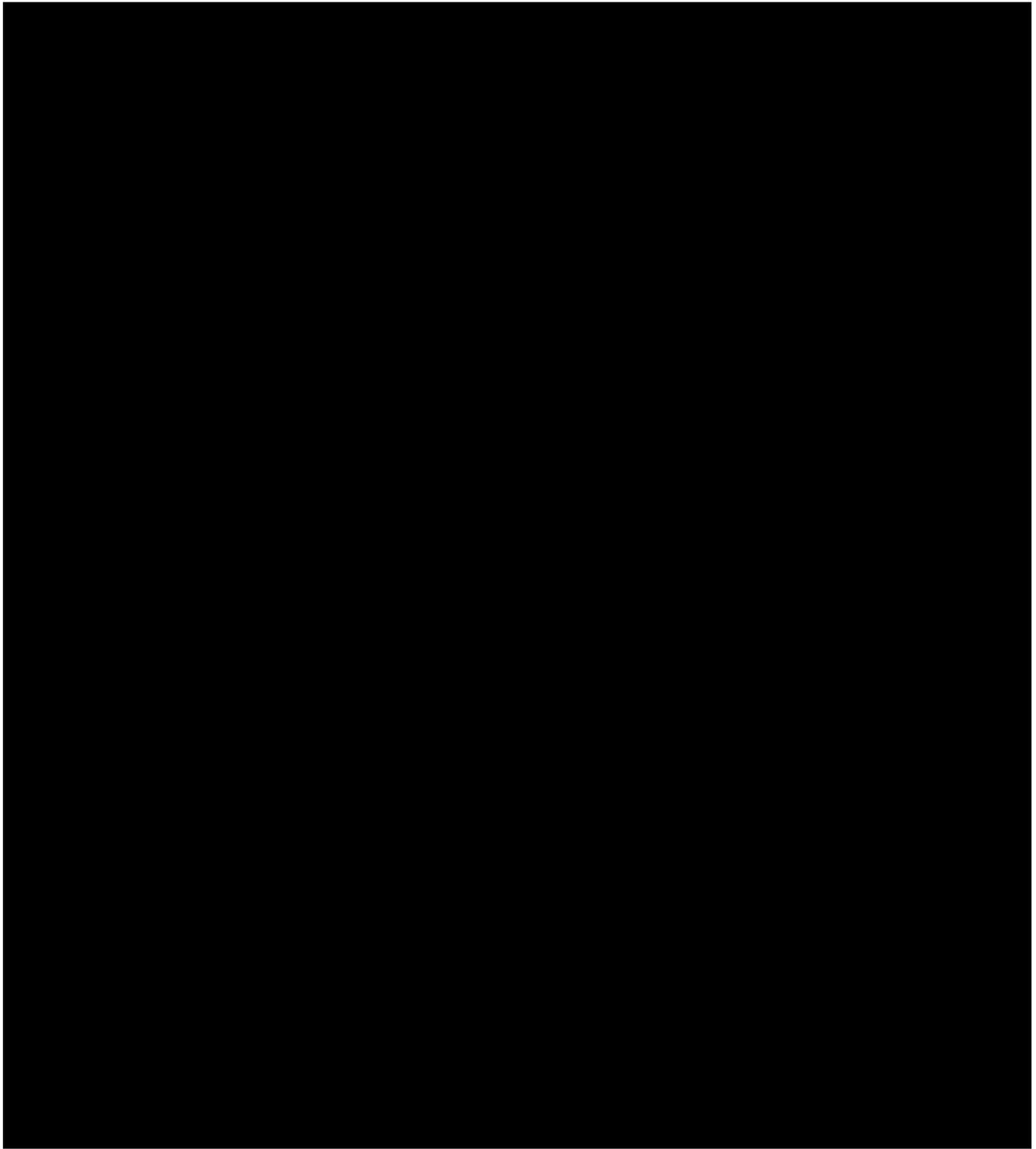


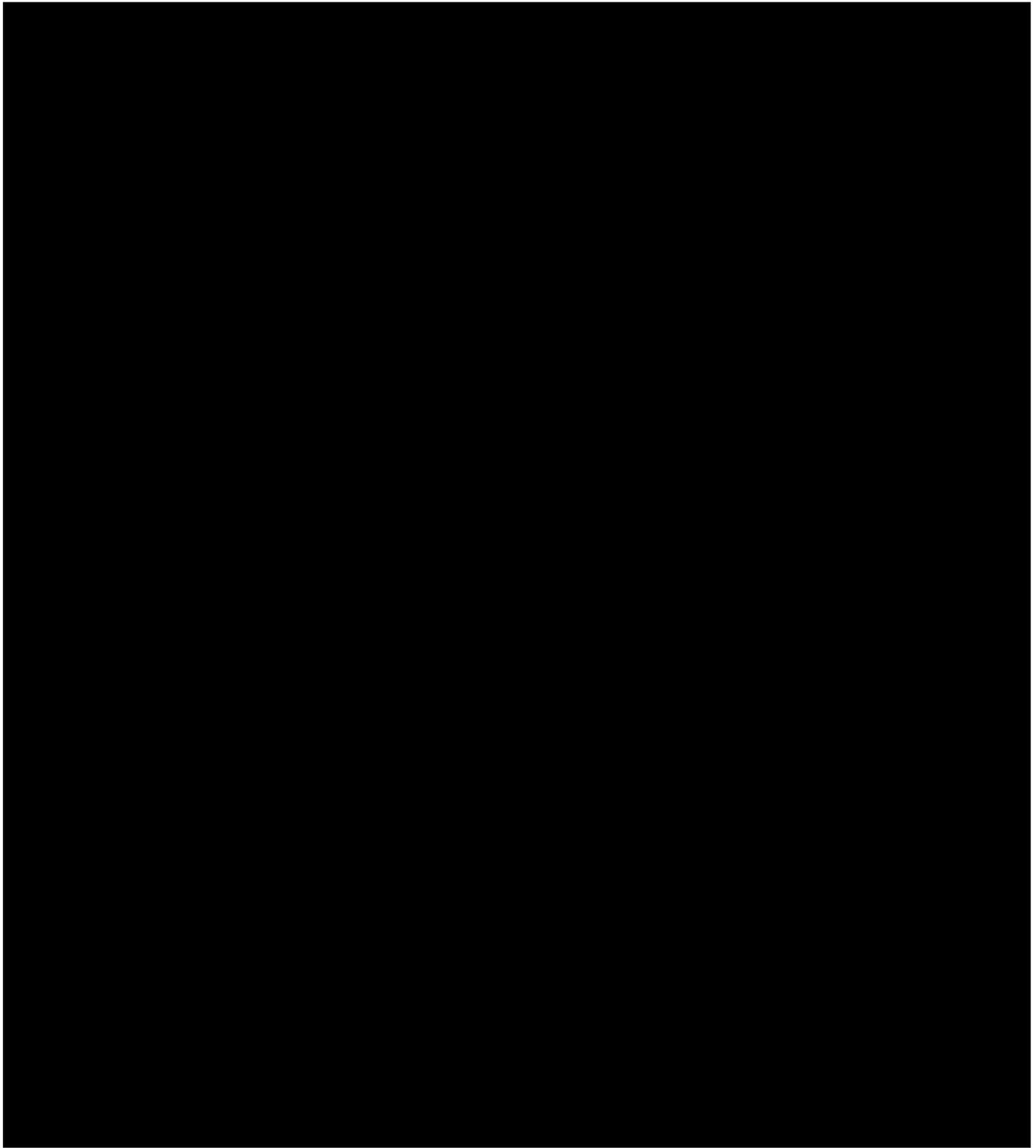


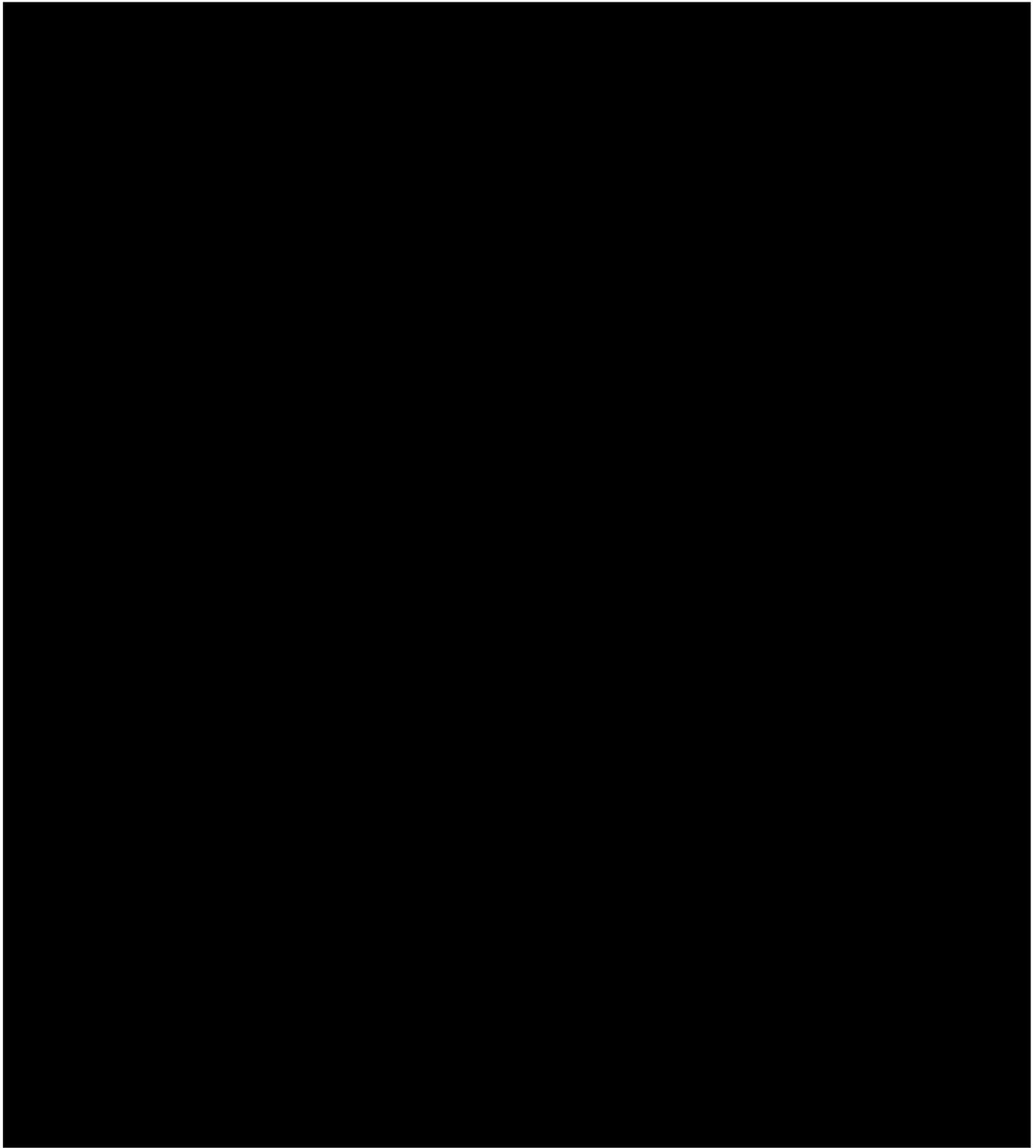


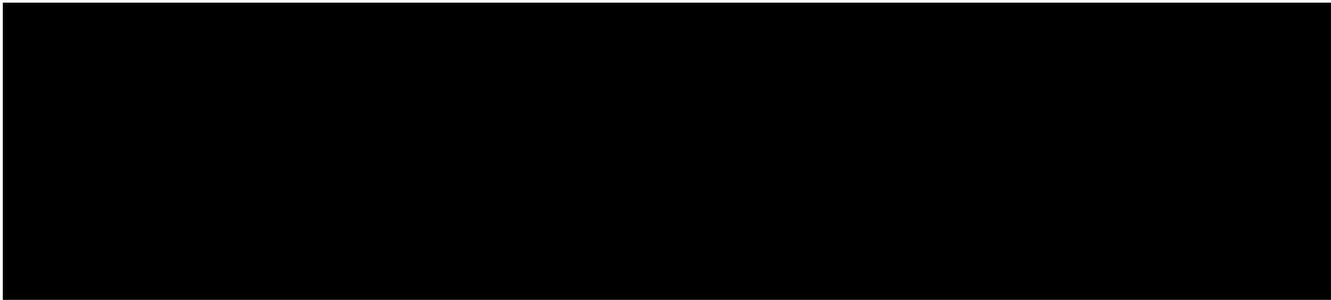






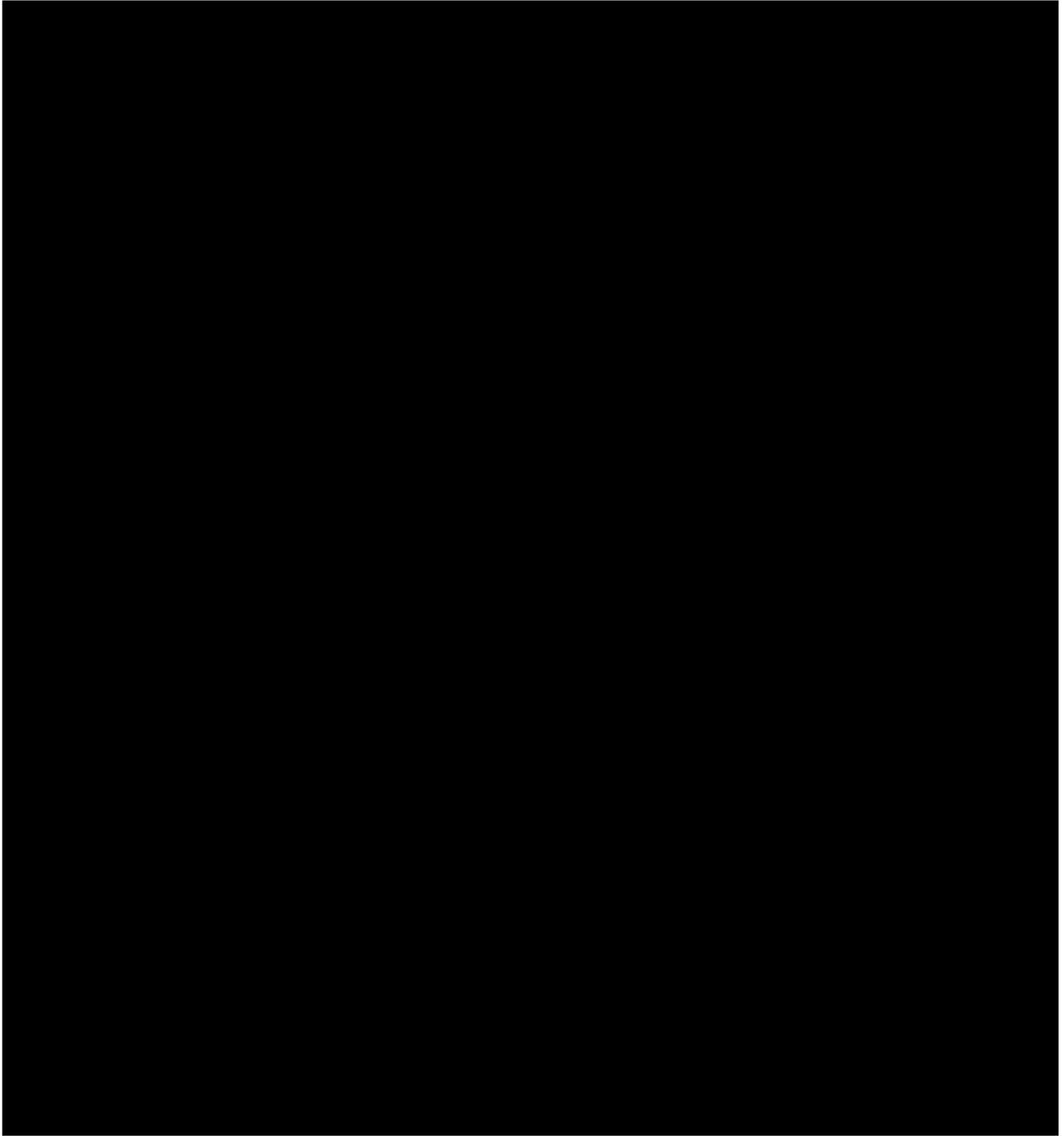


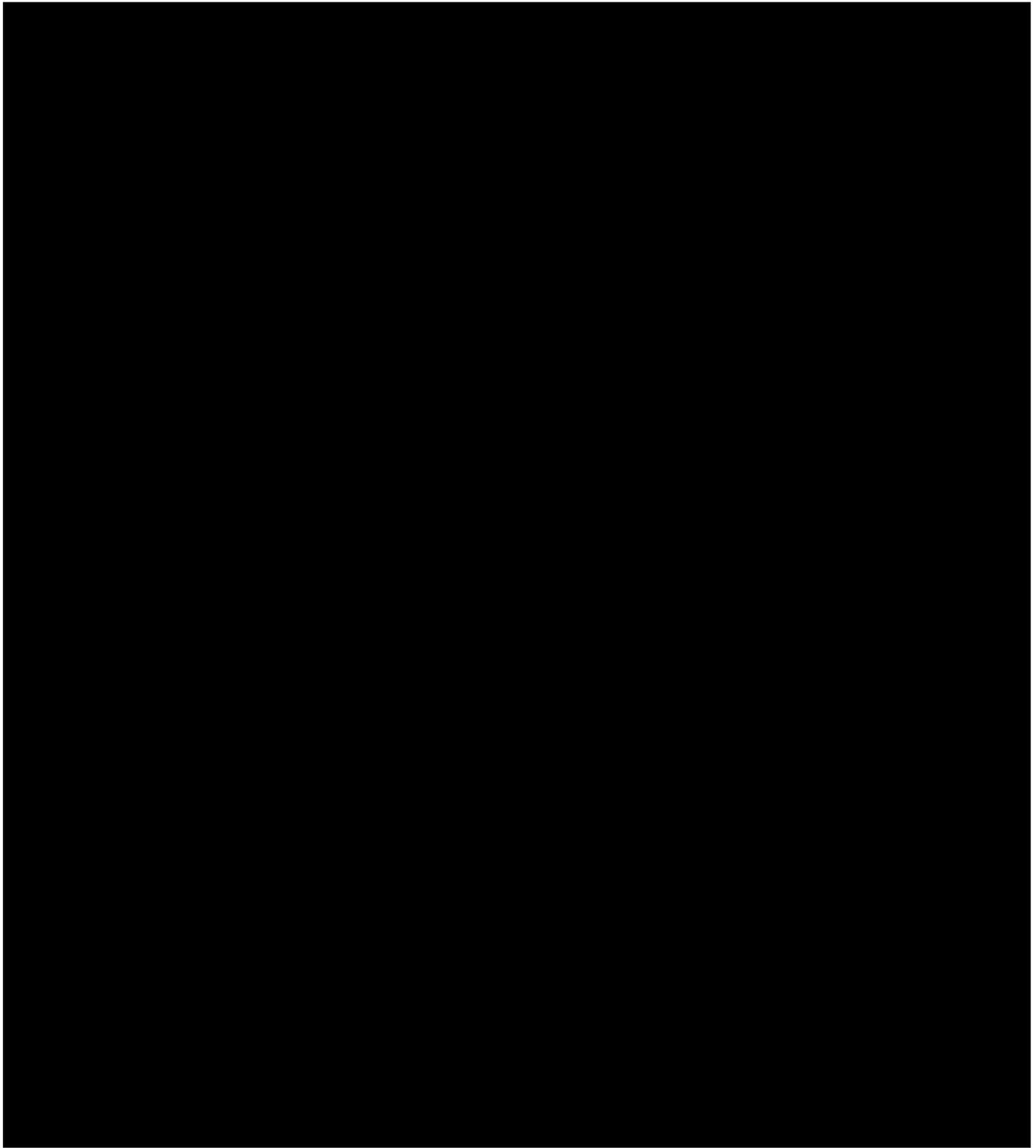




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ANNEX 8  
PD CONDITIONS

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## P.D.-conditions

Physical Distribution Conditions



**In Stichting vervoeradres, established in 1946, the following bodies work together:**

**evofenedex**, Shippers Association for companies in trade and manufacturing

**CBRB**, Dutch Central Office for Rhine and Inland Navigation

**Koninklijke BLN-Schuttevaer**, Dutch Association for Inland Navigation

**Transport en Logistiek Nederland**, Dutch Association for Transport and Logistics

**Goederenvervoer Nederland** (*Goods Transport, the Netherlands*)

The Physical Distribution Conditions have been deposited at the Griffie (the secretariat) of the Arrondissementsrechtbank (regional court of justice) at Amsterdam and Rotterdam, The Netherlands.

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## Article 1

### Definitions

In these conditions

1. **p.d.-conditions** means general physical distribution conditions.
2. **AVC** means the most recent version of the Algemene Vervoerscondities 2002 [General Conditions of (Road) Transport 2002 in the Netherlands], established by Stichting vervoeradres and deposited at the secretariats of the regional courts in Amsterdam and Rotterdam.
3. **BW** means Burgerlijk Wetboek [Civil Code] of the Netherlands.
4. **CMR** means Convention on the Contract for the International Carriage of Goods by Road (CMR) (Geneva, 19 May 1956), as supplemented by the 1978 Protocol.
5. **physical distribution contract** means the contract by which the physical distributor commits himself opposite the principal to perform physical distribution.
6. **physical distribution** means an interrelated series of activities, such as transport, acceptance, warehousing, delivery, stock supervision and control, order execution, order assembling, preparation for dispatch, invoicing, in respect of cargoes, as well as the related data exchange and management, in so far as agreed between the physical distributor and his principal.
7. **supplementary activities** means activities ordered, but not agreed when concluding the original physical distribution contract.
8. **addressee** means the person (or entity) to whom the physical distributor must deliver by virtue of the contract.
9. **acceptance** means the moment when the physical distributor has accepted cargoes.
10. **delivery** means the moment when the addressee has accepted the cargoes.
11. **force majeure [force major]** means circumstances in so far as a diligent physical distributor has been unable to avoid and in so far as such physical distributor has been unable to prevent the consequences thereof.
12. **working days** means all calendar days except Saturdays, Sundays, and generally recognised Christian and national holidays.

## Article 2

### Scope of application

1. The p.d.-conditions apply to the physical distribution contract and supplementary activities in so far as they do not conflict with mandatory law.
2. In so far as not provided for in these p.d.-conditions, the CMR as well as the not with CMR conflicting provisions of Book 8 title 13 BW and the AVC apply to physical distribution and the supplementary activities.

**Obligations of the physical distributor**

The physical distributor is obliged to:

1. perform physical distribution and the supplementary activities.
2. accept the cargoes agreed at the agreed location, at the agreed time and in the agreed manner with the transport document and other documents provided by the principal, and to deliver these cargoes in the condition as in which accepted or in the condition agreed.  
  
Failing an agreed period of acceptance or delivery the activities must be carried out within the time which a diligent physical distributor needs, counting from the moment receipt or delivery have been asked for. This period will be the agreed period.
3. designate one or more contact persons and to mention these to the principal.
4. execute stocking and other activities in the space as agreed or otherwise fit for the purpose.
5. take all necessary measures with regard to the cargoes, including measures not directly related to the physical distribution, for account of the principal, and to consult, if possible, the principal on them in advance.
6. insure his third party liability and, on request of the principal but for his own account, his liability deriving from the p.d.-conditions with a reliable insurer, and to provide a copy of the insurance policy to the principal at his request.
7. to insure the cargoes at the written request of the principal and on his behalf, showing also the desired coverage, with a reliable insurer, and to provide a copy of the insurance policy to the principal at his request.
8. to allow access to the space where the cargoes are for the principal and persons designated by him, provided:
  - the physical distributor being present,
  - a request has been made in advance,
  - the visit conforms to the in-house rules of the physical distributor.
9. not displace the cargoes in stock unless the execution of the physical distribution contract or maintenance/ repairs of the space concerned necessitate such displacement.
10. ask for instructions from the principal prior to accepting cargoes apparently damaged. If no such instructions can be obtained in due time, the physical distributor is entitled to refuse accepting the cargoes damaged.
11. guarantee the adequacy of materials used in the execution of the physical distribution contract.
12. respect confidentiality vis-à-vis third parties of facts and data known to him through the physical distribution contract.

#### Article 4

##### **Liability of the physical distributor**

1. If cargoes and their packing are not delivered in the same or the agreed order and condition as in which they were accepted by the physical distributor, the latter is liable for this material damage, unless force majeure, and without prejudice to further relevant provisions in these conditions. The onus of proving material damage is on the principal.
2. The physical distributor is not liable for damage to cargoes in so far as such damage has been caused by stocking in the open air on order of the principal.
3. The liability of the physical distributor for material damage as meant in subpara 1 is limited to 8 1/3 special drawing rights (SDR) per kilogram missing or damaged cargoes, subject to an absolute maximum of an amount as to be agreed by the parties when concluding the physical distribution contract. If such amount has not been included, the maximum amount of 453.780 applies for each event or series of events of one same cause of damage.
4. If the physical distributor does not complete the physical distribution and/or supplementary activities at the agreed time (or within the agreed period) and location and in the agreed manner, he is, without prejudice to subpara 1 of this article, obliged to still complete these in the agreed manner and at no additional cost of the principal.

If the principal has incurred additional cost owing to the failure of the physical distributor to complete the physical distribution and/or supplementary activities in the agreed manner, at the agreed time and location, then he is liable for these cost to a maximum amount as agreed when concluding the physical distribution contract. If no such maximum has been agreed, the physical distributors liability for these cost shall amount 681 per event.

5. If the physical distributor omits to designate one or more contact persons as meant in art. 3.3, the signatory of the physical distribution contract on behalf of the physical distributor shall be considered the contact person.
6. The physical distributor is not liable for damage caused by information and orders given by or to other persons than those meant in subpara 5 of this article.
7. If the physical distributor fails repeatedly to fulfill his obligations, then the principal may, without prejudice to his right to indemnity as determined in subparas 1, 2, 3 and 4 of this article, terminate the physical distribution contract after giving written notice of termination and at the end of which the physical distributor has yet not fulfilled his obligations.

As indemnity of the losses caused by such termination, the physical distributor is indebted an amount as agreed when concluding the physical distribution contract.

8. Except for the liability laid down in this article and in articles 21 and 23.4 of CMR, the physical distributor is not liable for any damage but to the cargoes.

## Article 5

### **Obligations of the principal**

The principal is obliged:

1. to designate one or more contact persons and to mention their names to the physical distributor.
2. to furnish all information concerning the cargoes and their treatment as he can or as he ought to and which he knows or ought to know to be essential to the physical distributor, unless he may assume that the physical distributor knows or ought to know the information.

The principal guarantees the correctness of information furnished by him.

3. to put the agreed cargoes at the disposal of the physical distributor at the agreed location and time and in the agreed manner, together with a transport document and other documents which the law requires from the principal.
4. to pay, within the credit period agreed, the agreed price for the physical distribution, and all cost spent by the physical distributor in performing the supplementary activities, and to cover the latter's expenses as meant in art. 3.5.
5. to safeguard the physical distributor against all third party damage claims lodged owing to acts and omissions by the principal, his servants and all other persons whose services the principal had made use of.
6. to vouch for material which he has put at the disposal of the physical distributor.
7. at termination of the physical distribution contract, to accept all his objects still in possession of the physical distributor, not later than the last working day of the validity period of the contract, and after payment of any amount still due or to become due.

For amounts which may become due after termination of the contract, the principal may satisfy by providing sufficient security.

8. to observe confidentiality vis-à-vis third parties of all facts and data of which he is aware through the physical distribution contract.

## Article 6

### **Liability of the principal**

1. The principal is liable for all damage caused by the persons and objects which the physical distributor in conformity with article 3.8 of these conditions is obliged to give access to his premises.
2. If the principal omits to designate one of more contact persons as meant in article 5.1 of these conditions, the signatory on behalf of the principal of the physical distribution contract is considered the contact person.
3. The principal is not liable for damage caused by information and instructions furnished by or to other persons than those meant in subpara 2 of this article.
4. If the principal does not furnish timely information concerning cargoes and their treatment as meant in article 5.2 of these conditions, or does not supply the agreed cargoes at the agreed time (or within the agreed period), in the agreed manner and at the agreed location, accompanied by the documents required as meant

in article 5.3 of these conditions, then he is obliged to still perform all this as soon as possible, free of charge and in the agreed manner.

If the physical distributor has incurred costs as a result of the failure of the principal as meant in article 5.2 and 3 of these conditions, then the principal is liable for these costs to a maximum to be agreed when concluding the physical distribution contract. If such maximum has not so been agreed, the principals liability amounts to a maximum amount 681 per event.

5. If the principal fails to meet repeatedly his obligations, the physical distributor may, without prejudice to his right to indemnity, terminate the physical distribution contract after having put the principal on ultimate written notice and if the principal has not yet met his obligations at the expiry of the notice.

As indemnity of the damage caused by such termination the principal is indebted an amount due as to be agreed when concluding the physical distribution contract.

6. If the principal does not meet his obligations as meant in article 5.7, article 17 AVC applies analogously.

#### Article 7

##### **Time limitation**

1. All claims based on the physical distribution contract, including all claims stemming from a cash-on-delivery condition, are subject to the time limitation of twelfth months.
2. The time limitation period starts from the day after the day when the cargoes were delivered or ought to have been delivered, failing which from the day after the day when the claim first originated.

#### Article 8

##### **Credit conditions**

1. All amounts due by the physical distributor and by the principal, whatever their cause, are payable within the agreed period, or such a period failing within fourteen days from the invoice date.
2. If the principal or the physical distributor does not pay within the agreed period or such period failing within fourteen days from the invoice date, he is liable to pay the legal interest according to art. 6:119 BW with effect from the day when the payment should have been made to and including the day of payment.
3. The physical distributor or the principle is entitled to invoice all necessary extrajudicial and judicial cost made to collect the amount meant in subpara 1. The extrajudicial cost are due from the moment when the principal or the physical distributor fails to pay and the claim for payment has been transmitted to a third party to collect.
4. An appeal for compensation of claims for payment of amounts arising from the physical distribution contract, of amounts due occasioned otherwise by the physical distribution or of amounts related to the cargoes with claims based otherwise is not permitted.
5. In any event, all amounts meant in subpara 1 of this article may be claimed forthwith, and- in deviation of subpara 4 - may be susceptible to compensation if:
  - a. the principal or the physical distributor are in a state of bankruptcy or have been granted suspension of payment;
  - b. the principal or physical distributor
    1. offers an arrangement to his creditors;

2. essentially fails to meet his obligations;
3. gives notice of the physical distribution contract under art. 4.7 or art. 6.5;
4. ceases the operation of his enterprise or- in case of a legal personality or a limited company - if that one is dissolved.

#### Article 9

##### **Security**

1. The physical distributor has a right of lien on goods and documents in his possession in connection with the contract of physical distribution against any person who demands delivery of same. This right does not fall to him if, at the moment of receipt of the goods for physical distribution, he had reason to doubt the right of the principal to make the goods available for physical distribution to him.
2. The right of lien applies likewise to what burdens the goods by way of cash on delivery as well as to the cash on delivery fee to which he is entitled, in regard to which he is not obliged to accept security.
3. The physical distributor may also exercise the right of lien against the principal for reason of what is yet due to him in connection with previous contracts of physical distribution.
4. Likewise, the physical distributor may exercise the right of lien against the consignee who in this capacity became a party to previous contracts of physical distribution for reason of what is yet due to him in connection with these contracts.
5. If when settling the invoice a dispute arises over the amount due or if there is need for a calculation to be made for the determination of what is due that cannot be made quickly, then the one who demands delivery is obliged to pay forthwith the part which the parties agree is due and to put up security for the part in dispute or the amount of which has not yet been fixed.
6. All the goods, documents and currency values in possession of the physical distributor in connection with the contract of physical distribution serve him as pawn for all claims which he has against the principal.
7. Except for the cases in which the principal is in a state of bankruptcy or in which he has been granted suspension of payment or in which he has been declared subject to a debt reorganisation scheme for natural persons, the physical distributor has never the right to sell the objects in pawn without permission by the court of justice in accordance with art.3:248 para 2 BW.

#### Article 10

##### **Competent court of justice**

1. All contracts to which the p.d.-conditions apply are subject to Dutch Law.
2. Unless para 3 of this article applies, all disputes which might arise in connection with the physical distribution contract, except those belonging to the competency of the county court (kantongerecht) and except those in appeal, are judged by the competent court in the statutory domicile of the physical distributor. However, if the statutory domicile of the physical distributor is outside the Netherlands, then the Rotterdam court of justice is competent.

3. All disputes arising between the parties in connection with the present agreement, or in connection with further consequential agreements may be solved in accordance with the Reglement of the Stichting Arbitrage voor Logistiek (rules of the foundation arbitration in logistics), domiciling at The Hague, the Netherlands.

**Explanatory note**

*As from 1 September 2011, cases submitted for arbitration to the Arbitration Institute for Logistics will be referred to the arbitration body, TAMARA.*

*TAMARA specialises in arbitration in the areas of transport, storage, logistics, international trade, and in the shipping and shipbuilding industry. In order to ensure that the interests of road transport and logistics services are safeguarded, Stichting Vervoeradres sits on the Board of TAMARA.*

*Do you wish to avail of the services of TAMARA? If yes, you will need to include the following arbitration clause in your contract of carriage:*

*'Any dispute arising in connection with this Agreement between the Parties established in the Netherlands shall be settled in compliance with the CMR Convention and in accordance with the regulations of the TAMARA foundation based in Rotterdam.'*

example  
**Physical distribution contract**

The undersigned:

limited company \_\_\_\_\_

domiciled \_\_\_\_\_

for the purpose of the present contract legally represented by

\_\_\_\_\_

hereinafter referred to as "principal"

and

limited company \_\_\_\_\_

domiciled \_\_\_\_\_

for the purpose of the present contract legally represented by

\_\_\_\_\_

hereinafter referred to as "physical distributor",

whereas the principal wants to entrust the physical distribution of (part of) his merchandise to the physical distributor,  
have agreed as hereafter:

Article 1  
**General**

The principal gives order to the physical distributor and the latter accepts the order to provide physical distribution of the following commodities:

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Article 2  
**Description of the commodities**

The description of the cargoes is as follows:

commodity \_\_\_\_\_

weight \_\_\_\_\_

value \_\_\_\_\_

dimensions \_\_\_\_\_

(particular) characteristics \_\_\_\_\_

Article 3  
**Volume**

Except for particular circumstances, the principal offers an average of \_\_\_\_\_ parcels/cubic meter/pallets/liters (other units)\* per week/month/year to the physical distributor. In the event of any deviation from this provision, the principal and the physical distributor shall consult each other concerning the consequences.

Article 4  
**Detailed description of the physical distribution activities**

The physical distributor commits himself to perform the following activities:

1. Transport. The following instructions/provisions apply:

---

2. Stocking and related activities. The following instructions/provisions apply:

---



3. Stock supervision and control. The following instructions/provisions apply:

---

4. Reconditioning. The following instructions/provisions apply

---

5. Sundry activities. The following instructions/provisions apply

---

#### Article 5

##### Prices

The rates are:

1. 1 for all physical distribution activities the total amount of \_\_\_\_\_ per \_\_\_\_\_ (unit to be completed),

or

1. 2 for transport activities:

a. domestic transport \_\_\_\_\_ per \_\_\_\_\_ (unit to be completed)

b. international transport \_\_\_\_\_ per \_\_\_\_\_ (unit to be completed) for stocking and other activities enumerated in art. 4 \_\_\_\_\_ per \_\_\_\_\_ (unit to be completed)

2. During the validity of the present contract, the amounts may/may not\* be modified.

3. In the positive alternative hereabove, modification takes place only once per annum in the course of the month \_\_\_\_\_ Price adjustments shall be based on the cost developments as established by NEA, EVO and the physical distributor.

4. All prices are exclusive of VAT.

#### Article 6

##### Contact persons

Contact persons in the sense of art. 3.3 and 5.1 of the physical distribution conditions attached are:

· on the side of the principal

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· on the side of the physical distributor

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Article 7  
**Location**

The location (space), in the sense of art.3.4 of the physical distribution conditions attached, where stocking and other activities within the framework of the physical distribution contract must be performed is the following:

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Article 8  
**Insurance**

Conform to art.3.6 + 7 of the physical distribution conditions, the physical distributor is obliged to take insurance as follows:

1. an insurance against third party liability;
  - \*\*\* · a liability insurance based on the physical distribution conditions attached;
  - \*\*\*· a cargo insurance

Article 9  
**Duration of the contract**

1. The present contract covers a period of \_\_\_\_\_ years and enters into force on \_\_\_\_\_
2. At expiry as per subpara 1 of this article, the present contract is renewed, each time again, by tacit agreement, for \_\_\_\_\_ years, unless either party gives notice of termination. In such event, a notice period of \_\_\_\_\_ month(s) must be observed. Notice of termination must be given by registered mail.

Article 10

**Liability system**

The parties accept/deviate from\* the liability system as per the physical distribution conditions\*\*.

In the event of such deviation the physical distributors liability is as under:

the limitation in the sense of:

art.4.3 is \_\_\_\_\_

art.4.4 is \_\_\_\_\_

art.4.7 is \_\_\_\_\_

art.6.4 is \_\_\_\_\_

art.6.5 is \_\_\_\_\_

Article 11

**Arbitration**

Parties wish/do not wish\* to have disputes arising in connection with the present agreement solved in arbitration in accordance with art. 10 para 3 of the Physical Distribution Conditions.

Article 12

**Physical distribution conditions**

To the exclusion of any other general conditions, the physical distribution conditions as attached are part of and apply to the present contract in so far as it does not explicitly deviates from them. A copy of these conditions has been attached hereto and is considered to constitute part of the present agreement.

date and place

---

signed  
the principal

signed  
the physical distributor

---

\* delete the non-applicable  
\*\* as published by Stichting vervoeradres  
\*\*\* tick where appropriate

Stichting Vervoeradres represents shippers' and carriers' joint interests under public and/or private law, in an independent and impartial manner. It assists carriers and shippers in concluding transport contracts in a legally binding and balanced fashion, by providing standards for legal documents (consignment notes) and texts (General Terms and Conditions and examples of clauses/contracts). The application of these standards helps reduce the incidence of conflicts regarding the actual execution of logistics contracts. Furthermore, the standards contribute to the prevention of breaches of the law.

**Beurtvaartadres** 

Beurtvaartadres facilitates its clients' use of the range of services it supplies by providing optimum supervision, with a view to reducing the administrative costs incurred in the logistics sector. It does by taking the worries off the client's hands, by means of providing both intuitive, digital solutions and knowledge sessions on the best possible use of (the standard) documents.

Beurtvaartadres's future in the logistics chain relies on its ability to create added value throughout the chain by providing, facilitating, issuing, exchanging and safeguarding data relating to logistics transactions. We perform these duties in the capacity of an authority in the issue of logistics forms.



Stichting  Vervoeradres



Centraal Bureau voor de  
Rijn- & Binnenvaart

e:vo:ofenedex:



ANNEX 9  
**NOT USED**

306299544 ████████

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ANNEX 10  
TLN CONDITIONS

306299544 [REDACTED]

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## TRANSPORT EN LOGISTIEK NEDERLAND GENERAL CONDITIONS OF PAYMENT

Concerning payments of transport, storage and other activities entrusted to the carrier, as filed with the registry of the district court (Arrondissementsrechtbank) of The Hague on 2 July 2002, file number 69/2002.

### Article 1 Freight payment

1. The sender is obliged to pay the freight and further costs which burden the goods at the moment of handing over the consignment note or of the goods having been received by the carrier.
2. If freight payable at destination has been agreed, the consignee is obliged to pay the freight, the costs due owing to other reasons relating to the carriage and further costs burdening the goods on delivery of the goods by the carrier; if the consignee did not pay these upon the first reminder, he and the sender are severally obliged to pay.  
If, in case of a consignment on the condition freight payable at destination, the sender has mentioned in the consignment note that no delivery may be performed without payment of the freight, the costs due owing to other reasons relating to the carriage and further costs burdening the goods, the carrier, if no payment is made, must ask the sender for further instructions which he is obliged to follow up, in so far as reasonably possible, against compensation of costs and damage and possibly payment of a reasonable reward, unless these costs have arisen by his own fault.
3. The carrier has the right to charge all inevitable extra-judicial and judicial expenses made to collect the freight and other amounts, as mentioned in paras 1 and 2, to the one who is debtor of the freight and other costs. The extra-legal collection expenses are due as from the moment when the debtor fails to pay and the claim has

been referred to a third party for collection.

4. The freight, the costs due owing to other reasons relating to the carriage and further costs burdening the goods are due also if the goods are not delivered at destination or only partly, damaged or delayed.
5. An appeal to set off claims to pay freight, costs due owing to other reasons relating to the carriage and further costs burdening the goods against claims on some other account is not permitted.
6. If the sender has not fulfilled his obligations mentioned in the present article, then the carrier is entitled to suspend departure of the vehicle, and in this event the damage arising from it are considered as costs burdening the goods.

### Article 2 Right of lien

1. The carrier has a right of lien on goods and documents in his possession in connection with the contract against any person who demands delivery of same. This right does not fall to him if, at the moment of receipt of the goods for carriage, he had reason to doubt the right of the principal to make the goods available for carriage to him.
2. The right of lien applies likewise to what burdens the goods by way of cash on delivery as well as to the cash on delivery fee to which he is entitled, in regard to which he is not obliged to accept security.
3. The carrier may also exercise the right of lien against the principal for reason

of what is yet due to him in connection with previous contracts of carriage.

4. Likewise, the carrier may exercise the right of lien against the consignee who in this capacity became a party to previous contracts of carriage for reason of what is yet due to him in connection with these contracts.

5. If when settling the invoice a dispute arises over the amount due or if there is need for a calculation to be made for the determination of what is due that cannot be made quickly, then the one who demands delivery is obliged to pay forthwith the part which the parties agree is due and to put up security for the part in dispute or the amount of which has not yet been fixed.

#### **Article 3 Right of pawn**

1. All the goods, documents and currency values in possession of the carrier in

connection with the contract of carriage and/or other operations serve him as pawn for all claims which he has against the principal.

4. Except for the cases in which the principal is in a state of bankruptcy or in which he has been granted suspension of payment or in which he has been declared subject to a debt reorganisation scheme for natural persons, the carrier has never the right to sell the objects in pawn without permission by the court of justice in accordance with art.3:248 para 2 BW.

#### **Article 4 Interest for delay**

Parties are due legal interest according to art. 6:119 BW on an amount due.

#### **Article 5**

These general conditions can be quoted as "Transport en Logistiek Nederland general conditions of payment".

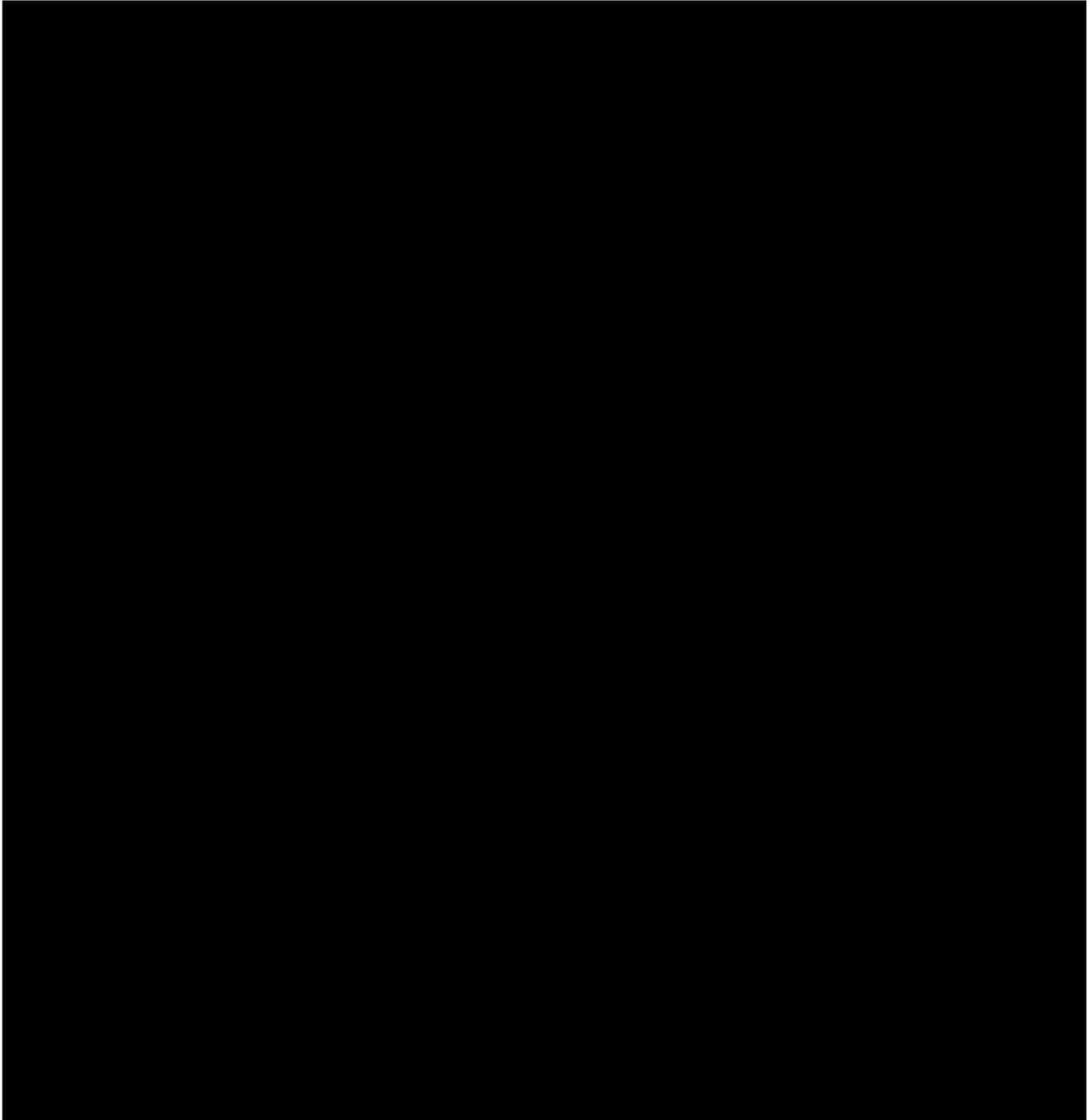
Transport en Logistiek Nederland  
Boris Pasternaklaan 2  
2719 DA Zoetermeer

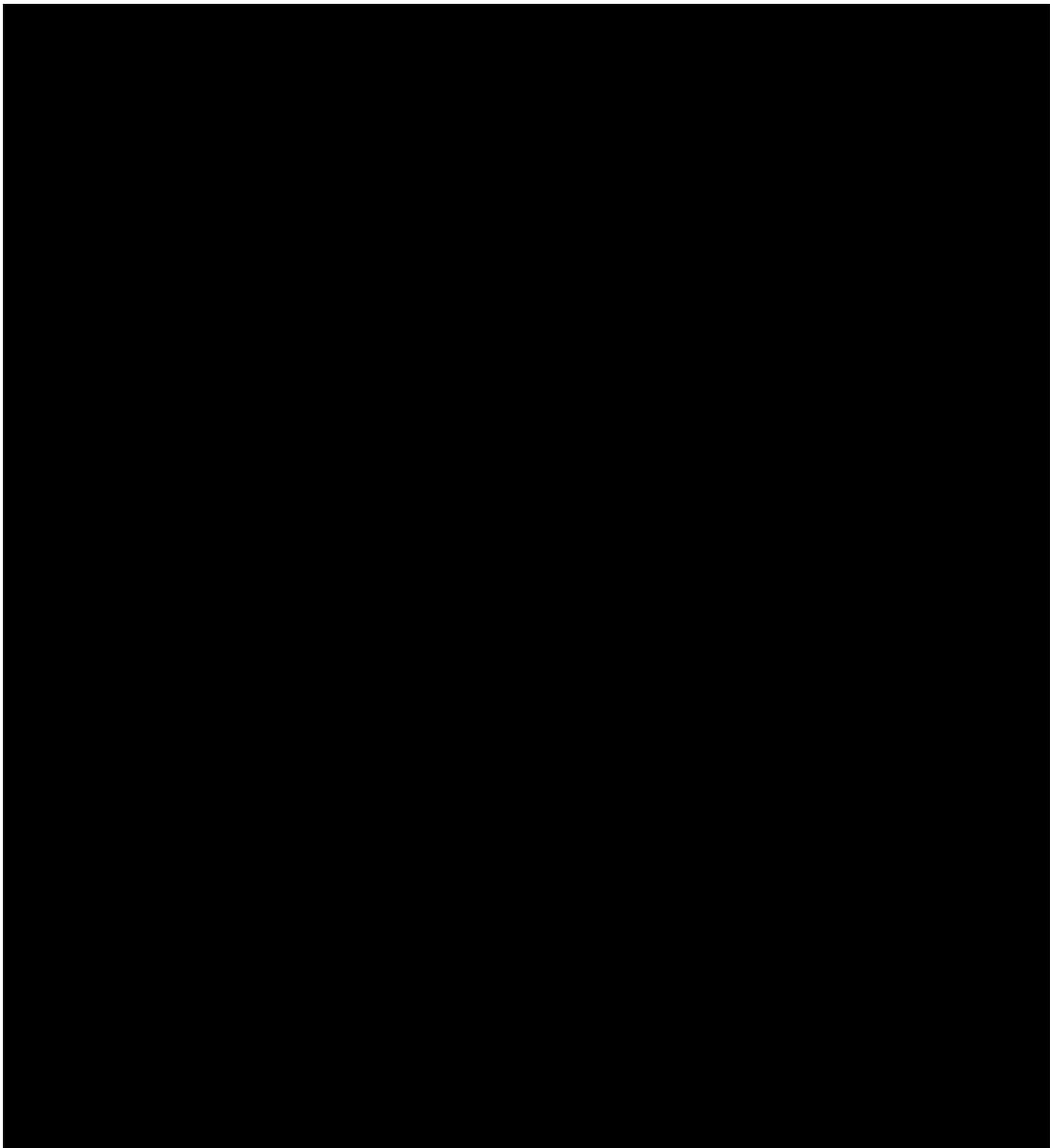
Postal address:  
P.O. Box 3008  
2700 KS Zoetermeer

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ANNEX 11  
SUBCONTRACTORS

LIST OF SUBCONTRACTORS FOR ALLOGA NETHERLANDS

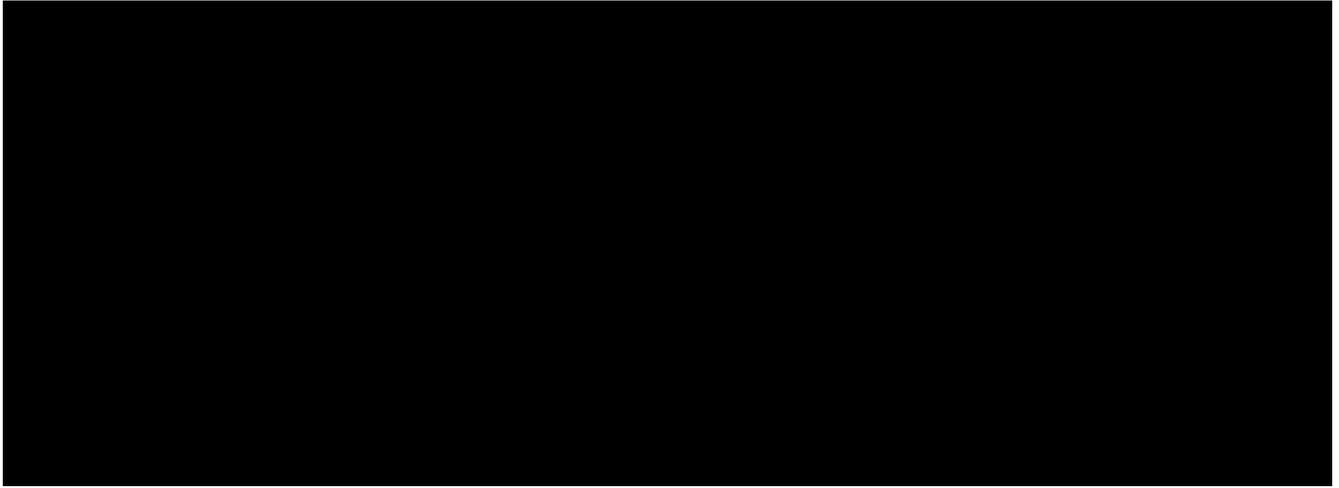


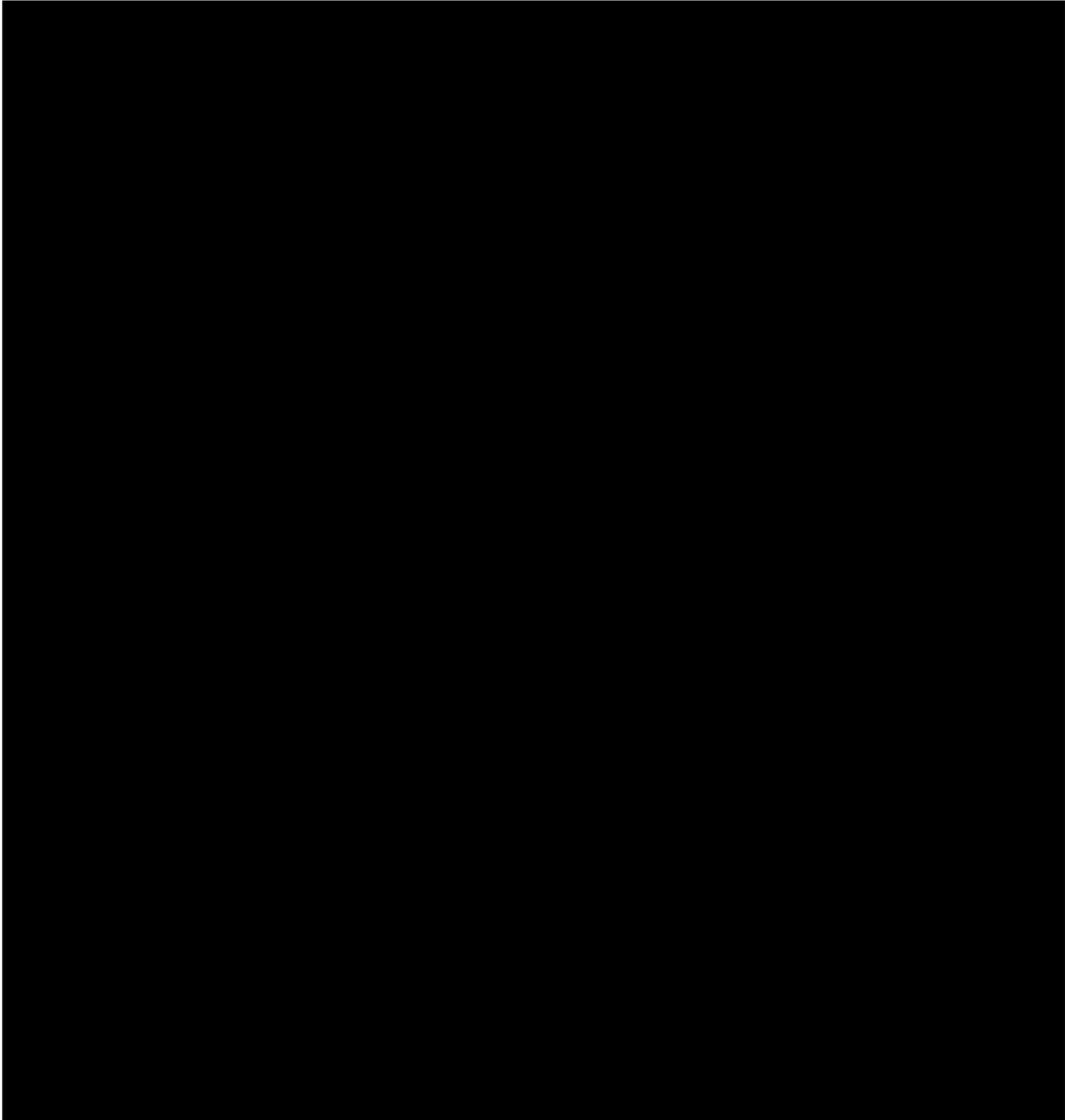


**QUALITY AGREEMENT**

The Parties have entered into a Quality and Technical Agreement in respect of the Services with a date of final signature of [REDACTED], and shall have and maintain the Quality Agreement during the term of this Agreement.

306299544 [REDACTED]







306299544 [redacted]



## CERTIFICATIONS

I, Robert C. Jahr, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2025

By: /s/ Robert C. Jahr  
Robert C. Jahr  
Chief Executive Officer  
(Principal Executive Officer)

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## CERTIFICATIONS

I, Lawrence A. Kenyon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2025

By: /s/ Lawrence A. Kenyon  
Lawrence A. Kenyon  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc. (the "Company") for the period ended June 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: August 14, 2025

By: /s/Robert C. Jahr

Robert C. Jahr  
Chief Executive Officer  
(Principal Executive Officer)

*"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Outlook Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."*

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Outlook Therapeutics, Inc. (the "Company") for the period ended June 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: August 14, 2025

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

Chief Financial Officer

(Principal Financial and Accounting Officer)

*"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Outlook Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."*

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