
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**FORM S-3
REGISTRATION STATEMENT**
*UNDER
THE SECURITIES ACT OF 1933*

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 Number)

**111 S. Wood Avenue, Unit #100
Iselin, New Jersey 08830
(609) 619-3990**
(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

Lawrence A. Kenyon
Chief Financial Officer and Interim Chief Executive Officer
Outlook Therapeutics, Inc.
111 S. Wood Avenue, Unit #100
Iselin, New Jersey 08830
(609) 619-3990
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:
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Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
 Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of Securities Act.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED February 28, 2025

PROSPECTUS



7,074,637 shares of Common Stock

This prospectus covers the offer and resale by the selling stockholders identified in this prospectus of up to an aggregate of 7,074,637 shares of our common stock issuable upon the exercise of outstanding Tranche A warrants to purchase shares of our common stock, or the Tranche A Warrants, held by the selling stockholders, all of which were issued by us at the closing of a warrant inducement transaction on January 17, 2025.

We are not selling any shares of common stock under this prospectus and will not receive any proceeds from the sale by the selling stockholders of such shares. We will, however, receive the net proceeds of any Tranche A Warrants exercised for cash.

Sales of shares of common stock by the selling stockholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both.

We are paying the cost of registering the shares of common stock pursuant to this prospectus as well as various related expenses. The selling stockholders are responsible for all broker or similar commissions related to the offer and sale of their shares.

Our common stock is listed on The Nasdaq Capital Market, or Nasdaq, under the symbol "OTLK." On February 27, 2025, the last reported sale price of our common stock was \$1.38 per share.

Investing in our common stock involves a high degree of risk. Before making an investment decision, please read the information under "[Risk Factors](#)" on page 6 of this prospectus and under similar headings in any amendment or supplement to this prospectus or in any filing with the Securities and Exchange Commission that is incorporated by reference herein.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2025

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration process. Under this registration statement, the selling stockholders may sell from time to time in one or more offerings the common stock described in this prospectus.

We have not, and the selling stockholders have not, authorized anyone to provide you with information other than the information that we have provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or any sale of our common stock. Our business, financial condition and results of operations may have changed since those dates.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference herein, contains, and any applicable prospectus supplement or free writing prospectus including the documents we incorporate by reference therein may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this prospectus, 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 these statements by forward-looking 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. These forward-looking statements include, but are not limited to, statements concerning the following:

- the initiation, timing, progress and results of our clinical trials of our lead product candidate, ONS-5010/LYTENAVATM;
- our reliance on our contract manufacturing organizations and other vendors;
- whether the results of our clinical trials will be sufficient to support domestic or global regulatory approvals;
- our ability to obtain and maintain regulatory approval for ONS-5010/LYTENAVA in the United States and other markets;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved, for commercial use;
- our ability to fund our working capital requirements, and our expectations regarding our current cash resources, including with respect to the closing of the refinancing of our outstanding convertible note;
- 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;
- 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;
- the factors that may impact our financial results; and
- our estimates regarding the sufficiency of our cash resources and our need for additional funding.

These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss in greater detail many of these risks under the heading “Risk Factors” contained in this prospectus, any applicable prospectus supplement, in any free writing prospectuses we may authorize for use in connection with a specific offering, and in our most recent Annual Report on Form 10-K and in our most recent Quarterly Report on Form 10-Q, which are incorporated by reference into this prospectus in their entirety, as well as any amendments thereto reflected in subsequent filings with the SEC. 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, 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.

Forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. 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 resulting as expressed or implied in such forward-looking statements. You should read this prospectus, any applicable prospectus supplement, together with the documents we have filed with the SEC that are incorporated by reference and any free writing prospectus that we may authorize for use in connection with this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

PROSPECTUS SUMMARY

This summary highlights certain information about us, the Warrant Inducement Transaction (as defined below) and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before making an investment decision. For a more complete understanding of our company, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus and any applicable prospectus supplement, including the factors described under the heading “Risk Factors” on page 6 of this prospectus, as well as the information incorporated herein by reference, before making an investment decision.

Unless the context indicates otherwise, references in this prospectus to “Outlook,” “Outlook Therapeutics,” “the Company,” “we,” “us,” “our” and similar references refer to Outlook Therapeutics, Inc.

Company Overview

We are a biopharmaceutical company working to launch the first ophthalmic formulation of bevacizumab approved by the European Commission in the European Union, or EU, the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, or UK, and the U.S. Food and Drug Administration, or FDA, for use in retinal indications. Our initial goal is to launch directly in the EU and UK, and, if approved, to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD. Our plans also include seeking approval and launching the product in Japan and other markets. On May 27, 2024, we received a marketing authorization from the European Commission for ONS-5010/LYTENAVA for the treatment of wet AMD. The authorization is valid throughout the European Economic Area, or the EEA, and provides eight years of data exclusivity and 10 years of market exclusivity. On July 8, 2024, we also received marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK, followed by a recommendation by the UK National Institute for Health and Care Excellence, or NICE, for LYTENAVA™ (bevacizumab gamma), as an option for the treatment of wet AMD on December 4, 2024. Outside of the United States, we are currently moving ahead with our plans to launch directly in the initial markets of Germany and the UK in the second quarter of calendar 2025.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010/LYTENAVA with the European Medicines Agency, or EMA. The MAA was submitted as a ‘full-mixed marketing authorization application’ based on Article 8.3 of Directive 2001/83/EC. On March 22, 2024, the EMA’s Committee for Medicinal Products for Human Use, or CHMP issued a positive opinion concerning the authorization of ONS-5010/LYTENAVA (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration, or wet AMD, in the EU. 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. Additionally, in April 2024, we submitted a MAA to the MHRA in the UK seeking approval of ONS-5010/LYTENAVA (bevacizumab gamma) for the treatment of wet AMD. The submission was completed 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. These RRs include a positive opinion by the EMA’s CHMP concerning an application for grant of marketing authorization for the same product in the EU. In July 2024, the MHRA granted marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD 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, an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. 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, we identified the approaches needed to resolve the CMC comments in the CRL. We believe that we have addressed the open CMC items and have concluded a series of Type C and Type D meetings with the FDA 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 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. Analysis of the complete week 12 data set for NORSE EIGHT has now been completed and provided additional evidence of improvement in vision and biological activity. We plan to resubmit the BLA for ONS-5010/LYTENAVA in the first quarter of calendar 2025.

Our BLA and MAA submissions 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 is 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. The primary endpoint is 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. We plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. If approved, we expect to receive 12 years of regulatory exclusivity in the United States.

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 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.

Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted a standard BLA and are not using the biosimilar drug regulatory pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved in the United States, we believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of unapproved bevacizumab. In the United States, 66.3% of retina physicians state off-label repackaged bevacizumab is their most commonly used first-line anti-VEGF (ASRS 2022 Membership Survey Presented at ASRS NY 2022).

The Warrant Inducement Transaction

On January 16, 2025, we entered into warrant exercise inducement offer letter agreements, or the Inducement Letters, with certain holders, or the Holders, of existing warrants to purchase our common stock, exercisable for an aggregate of 7,074,637 shares of common stock, or the Existing Warrants, pursuant to which the Holders agreed to exercise in a warrant inducement transaction, or the Warrant Inducement Transaction, their Existing Warrants at a reduced exercise price of \$2.51 per share, or the Reduced Exercise Price, in exchange for our agreement to issue new warrants to purchase common stock, or the Inducement Warrants.

The closing of the Warrant Inducement Transaction, or the Closing, occurred on January 17, 2025, following the satisfaction of the closing conditions set forth in the Inducement Letters.

In accordance with the Inducement Letters and in consideration for the immediate exercise of the Existing Warrants for cash at the Reduced Exercise Price, the Holders received two Inducement Warrants for each Existing Warrant exercised. The Inducement Warrants are exercisable for an aggregate of up to 14,149,274 shares of common stock, or the Inducement Warrant Shares, at an exercise price of \$2.26 per share. Half of the Inducement Warrants representing warrants to purchase up to 7,047,637 shares of common stock, or the Tranche A Warrants, were immediately exercisable and expire on January 17, 2030. The remaining Inducement Warrants, or the Tranche B Warrants, will be exercisable upon the effective date of an amendment, or the Share Increase Amendment Effective Date, to the Company's Certificate of Incorporation, or Charter, increasing the number of authorized shares of common stock issuable thereunder, or the Share Increase Amendment, by at least the maximum aggregate number of shares of common stock potentially issuable in the future pursuant to the Tranche B Warrants, without regard to any exercise limits set forth therein and the effect of potential future adjustments to exercise price. The Share Increase Amendment will be filed with the Secretary of State of the State of Delaware upon the receipt of the requisite stockholder approval at our 2025 annual meeting of stockholders. The Tranche B Warrants will expire five years from the Share Increase Amendment Effective Date.

The Inducement Warrants will only be exercisable for cash, except in limited circumstances. A Holder may not exercise the Inducement Warrants 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 us.

At the Closing, we received gross proceeds of \$17.8 million from the exercise of the Existing Warrants, and may receive up to an additional \$32 million of gross proceeds upon cash exercise of the Tranche A Warrants and Tranche B Warrants, in each case before deducting capital markets advisory fees and offering expenses.

We intend to use the net proceeds from the Warrant Inducement Transaction to fund our ONS-5010 clinical development programs, European commercial launch of LYTENAVATM and for working capital and general corporate purposes.

Existing investors and entities affiliated with certain directors of the Company are party to an Inducement Letter. GMS Ventures & Investments, affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, exercised an aggregate of 3,458,571 Existing Warrants for an aggregate Reduced Exercise Price of approximately \$8.7 million in exchange for Inducement Warrants to purchase 6,917,142 shares of common stock.

In connection with the Warrant Inducement Transaction, we agreed to prepare and file, within 45 days following the date of the Inducement Letters, a registration statement with the SEC to register for resale the shares of common stock underlying the Tranche A Warrants held by the selling stockholders.

For more information regarding the Warrant Inducement Transaction, see our Current Report on [Form 8-K](#) filed with the SEC on January 16, 2025 and incorporated herein by reference.

Risks Associated with our Business

Our business is subject to numerous risks, as described under the heading “Risk Factors” contained in this prospectus, any applicable prospectus supplement and in any free writing prospectuses we have authorized for use in connection with a specific offering, and under similar headings in the documents that are incorporated by reference into this prospectus.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in the Exchange Act. As a smaller reporting company, we are eligible to take advantage of certain exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation. We will be able to take advantage of the scaled disclosures available to smaller reporting companies for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Company Information

We initially incorporated in January 2010 in New Jersey as Oncobiologics, Inc., and in October 2015, we reincorporated in Delaware by merging with and into a Delaware corporation. In November 2018, we changed our name to Outlook Therapeutics, Inc. Our headquarters are located at 111 S. Wood Avenue, Unit #100, Iselin, New Jersey 08830, and our telephone number at that location is (609) 619-3990. Our website address is www.outlooktherapeutics.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this prospectus.

The Offering

Common stock offered by the selling stockholders	7,074,637 shares of our common stock issuable upon the exercise of the Tranche A Warrants held by the selling stockholders.
Terms of the offering	Each selling stockholder will determine when and how it will sell the common stock offered in this prospectus, as described in “Plan of Distribution.”
Use of proceeds	We will not receive any proceeds from the sale of the shares underlying the Tranche A Warrants covered by this prospectus. We will, however, receive the net proceeds of any Tranche A Warrants exercised for cash.
Risk factors	See “Risk Factors” on page 6 for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq symbol	“OTLK”

The selling stockholders named in this prospectus may offer and sell up to 7,074,637 shares of our common stock underlying the Tranche A Warrants. Our common stock is currently listed on Nasdaq under the symbol “OTLK.” Shares of our common stock that may be offered under this prospectus will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling stockholders of any of the common stock covered by this prospectus. We will, however, receive the exercise price of \$2.26 per share of any of the Tranche A Warrants exercised for cash. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders for offer and resale, we are referring to the shares of common stock issuable upon exercise of the Tranche A Warrants issued in the Warrant Inducement Transaction as described above. When we refer to the selling stockholders in this prospectus, we are referring to the selling stockholders identified in this prospectus and, as applicable, their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully review the risks and uncertainties described under the heading “Risk Factors” in our [Annual Report on Form 10-K for the fiscal year ended September 30, 2024](#), as updated by our subsequent annual, quarterly and other reports and documents that are incorporated herein by reference in their entirety, as well as any amendment or updates to our risk factors reflected in subsequent filings with the SEC, including any applicable prospectus supplement, before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Please also read carefully the section above titled “Special Note Regarding Forward-Looking Statements.”

USE OF PROCEEDS

We will not receive any of the proceeds from the sale or other disposition of the shares held by the selling stockholders pursuant to this prospectus. Upon any exercise of the Tranche A Warrants for cash, the applicable selling stockholder would pay us the exercise price set forth in the Tranche A Warrants.

Each Tranche A Warrant has an exercise price equal to \$2.26 per share, and if all 7,074,637 Tranche A Warrants are exercised on a cash basis, we will receive proceeds of approximately \$16 million. We expect to use any such proceeds primarily to fund our ONS-5010 clinical development programs, European commercial launch of LYTENAVATM and for working capital and general corporate purposes. The Tranche A Warrants are exercisable beginning on January 17, 2025 and expire on January 17, 2030.

The Tranche A Warrants are only exercisable for cash, except where there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the shares issuable upon exercise of Tranche A Warrants, in which case the Tranche A Warrants may be exercised on a cashless basis. If any of the Tranche A Warrants are exercised on a cashless basis, we would not receive any cash payment from the applicable selling stockholder upon any such exercise.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of shares of our common stock to be sold by the selling stockholders pursuant to this prospectus. Other than registration expenses, the selling stockholders will bear their own broker or similar commissions payable with respect to sales of shares of our common stock.

SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders are those issuable to the selling stockholders upon exercise of the Tranche A Warrants issued in the Warrant Inducement Transaction. For additional information regarding the issuance of Tranche A Warrants, see the section “Prospectus Summary—Warrant Inducement Transaction” above. We are registering the resale of shares of common stock issuable upon exercise of the Tranche A Warrants in order to permit the selling stockholders to offer the shares for resale from time to time. Except for the ownership of the Tranche A Warrants and for the selling stockholders whose other relationships are provided in “Certain Relationships and Related Party Transactions,” the selling stockholders have not had any material relationship with us within the past three years.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our common stock. Generally, a person “beneficially owns” shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by each of the selling stockholders. This information has been obtained from the selling stockholders or in Schedules 13G or 13D and other public documents filed with the SEC. The second column lists the number of shares of common stock beneficially owned by each selling stockholder based on its ownership of Tranche A Warrants, as of January 24, 2025, assuming exercise of the Tranche A Warrants held by the selling stockholders on that date, without regard to any limitations on exercises, unless otherwise indicated. The Tranche A Warrants are exercisable only for cash, except in limited circumstances, at any time and expire on January 17, 2030. The percentage of shares owned prior to and after the offering in the third and sixth columns are based on 32,017,179 shares of common stock outstanding as of January 24, 2025. The percentage of shares owned prior to the offering in the third column assumes the exercise of the Tranche A Warrants by each selling stockholder in computing such stockholder’s percentage ownership, but not for the purpose of computing the percentage ownership of any other person. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

In accordance with the terms of the Inducement Letters, this prospectus generally covers the resale of the maximum number of shares of common stock issuable upon exercise of the Tranche A Warrants issued in the Warrant Inducement Transaction. This maximum amount is determined as if the outstanding Tranche A Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC and without regard to any limitations on the exercise of the warrants. Under the terms of the Tranche A Warrants, a selling stockholder may not exercise the Tranche A Warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99%, 9.99% or 19.99%, as applicable to each holder, of the number of shares of our common stock outstanding following such exercise (for purposes of the denominator, immediately after giving effect to the issuance of shares of common stock to be issued upon the applicable exercise of such Tranche A Warrant). The number of shares in the second and fifth columns do not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See the section “Plan of Distribution.”

Name and Address	Before Offering		After Offering		
	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	Maximum Number of Shares Offered	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
GMS Ventures & Investments ⁽¹⁾ Zahran Street, 7th Circle Zahran Plaza Building, 4th Floor P.O. Box 142904, Amman, Jordan 11844	12,725,216	35.9%	3,458,571	9,266,645	28.9%
Altium Healthcare Long Short Onshore Fund LP ⁽²⁾ 152 W 57 th Street, 20 th Floor, New York, NY 10019	1,714,284	5.2%	857,142	857,142	2.7%
Armistice Capital, LLC ⁽³⁾ 510 Madison Avenue, 7th Floor, New York, NY 10022	1,595,427	4.8%	1,071,427	524,000	1.6%
Gravitas Capital LP ⁽⁴⁾ 34 Shrewsbury Avenue, Red Bank, NJ 07701	396,426	1.2%	198,213	198,213	*
Entities affiliated with Sarosca Farm ⁽⁵⁾ 100 West Putnam - Slagle House, Greenwich, CT 06830	569,758	1.8%	203,571	366,187	1.1%
Schonfeld Global Master Fund L.P. ⁽⁶⁾ 590 Madison Avenue, 23rd Floor, New York, NY 10022	857,142	2.6%	428,571	428,571	1.3%
Entities affiliated with Sphera ⁽⁷⁾ 4 Yitzhak Sadeh, Entrance A, 29th Floor, Tel Aviv 6777520, Israel	1,714,284	5.2%	857,142	857,142	2.7%

* Represents beneficial ownership of less than one percent.

- (1) Consists of 12,725,216 shares of common stock held by GMS Ventures & Investments, of which (a) 9,266,645 are shares of common stock held prior to, or issued upon exercise of the Exercised Warrants in, the Warrant Inducement Transaction and (b) 3,458,571 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 3,458,571 are shares of common stock issuable upon exercise of Tranche B Warrants. GMS Ventures & Investments, a Cayman Islands exempted company, is a private investment vehicle and wholly owned subsidiary of GMS Holdings. Ghiath M. Sukhtian, or Sukhtian, a natural person, is the holder of a controlling interest in GMS Holdings. By virtue of such relationship, Sukhtian may be deemed to beneficially own the securities held by GMS Ventures for purposes of Rule 13d-3 under the Exchange Act.
- (2) Consists of 1,714,284 shares of common stock held by Altium Healthcare Long Short Onshore Fund LP, of which (a) 857,142 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 857,142 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 857,142 are shares of common stock issuable upon exercise of Tranche B Warrants. Altium Capital Management LLC, the investment manager of Altium Healthcare Long Short Onshore Fund LP, has voting and investment power over these securities. Jacob Gottlieb is the managing member of Altium Healthcare Long Short GP LLC, which is the general partner of Altium Healthcare Long Short Onshore Fund LP. Jacob Gottlieb disclaims beneficial ownership over these securities. The shares of common stock issuable upon exercise of the Tranche A Warrants held by Altium are subject to a beneficial ownership limitation of 4.99%.
- (3) Consists of 1,595,427 shares of common stock held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the “Master Fund”), of which (a) 524,000 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 1,071,427 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 1,071,427 are shares of common stock issuable upon exercise of Tranche B Warrants. The securities are directly held by the Master Fund and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC (“Armistice Capital”), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The shares of common stock issuable upon exercise of the Tranche A Warrants held by Armistice Capital are subject to a beneficial ownership limitation of 4.99%.
- (4) Consists of 396,426 shares of common stock held by Gravitas Capital LP (“Gravitas”), of which (a) 198,213 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 198,213 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 198,213 are shares of common stock issuable upon exercise of Tranche B Warrants. The shares of common stock issuable upon exercise of the Tranche A Warrants held by Gravitas are subject to a beneficial ownership limitation of 19.99%.
- (5) Consists of (i) 399,768 shares of common stock held by Sarosca Farm LLC, of which (a) 281,192 are shares of common stock held prior to, or issued upon exercise of the Exercised Warrants in, the Warrant Inducement Transaction and (b) 118,576 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction, (ii) 67,204 shares of common stock held by Sarosca Farm II LLC of which (a) 33,602 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 33,602 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction and (iii) 102,786 shares of common stock held by Sarosca Farm III LLC, of which (a) 51,393 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 51,393 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 203,571 shares of common stock issuable upon exercise of Tranche B Warrants. Michael Zimmerman has voting and dispositive power over the shares of common stock owned by Sarosca, and may therefore be deemed to be the beneficial owner of the shares. Mr. Zimmerman disclaims beneficial ownership of the shares except to the extent of his pecuniary interest. The shares of common stock issuable upon exercise of the Tranche A Warrants held by Sarosca are subject to a beneficial ownership limitation of 19.99%.
- (6) Consists of 857,142 shares of common stock held by Schonfeld Global Master Fund L.P. (“Schonfeld Master”), of which (a) 428,571 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 428,571 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 428,571 shares of common stock

issuable upon exercise of Tranche B Warrants. The shares of common stock issuable upon exercise of the Tranche A Warrants held by Schonfeld Master are subject to a beneficial ownership limitation of 4.99%. Schonfeld Strategic Advisors LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of Schonfeld Master as a general partner or investment manager and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or Schonfeld Master that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or any other purpose.

- (7) Consists of (i) 1,457,142 shares of common stock held by Sphera Biotech Master Fund LP (“Sphera Biotech”), of which (a) 728,571 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 728,571 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction and (ii) 257,142 shares of common stock held by Sphera Global Healthcare Master Fund (“Sphera Global” and together with Sphera Biotech, the “Sphera Funds”), of which (a) 128,571 are shares of common stock issued upon exercise of the Exercised Warrants in the Warrant Inducement Transaction and (b) 128,571 are shares of common stock issuable upon exercise of Tranche A Warrants issued in the Warrant Inducement Transaction. Does not include 857,142 shares of common stock issuable upon the exercise of Tranche B Warrants. Sphera Biotech GP LP (“Sphera General Partner”) is the general partner of Sphera Biotech. Sphera Global Healthcare Management LP is the general partner of the Sphera General Partner, and acts as the Investment Manager for the Sphera Funds, and holds voting and investment power over the shares held by each of them. Accordingly, Sphera Global Healthcare Management LP may be deemed to have beneficial ownership of the shares held by the Sphera Funds. Sphera Global Healthcare Management LP disclaims beneficial ownership of such shares, except to the extent of its pecuniary interest therein. The shares of common stock issuable upon exercise of the Tranche A Warrants held by each of the Sphera Funds are subject to a beneficial ownership limitation of 9.99%.

Certain Relationships and Related Party Transactions

As discussed in greater detail above under the section “Prospectus Summary—Warrant Inducement Transaction,” on January 16, 2025, we entered into Inducement Letters with the selling stockholders pursuant to which, on January 17, 2025, we sold Tranche A Warrants and Tranche B Warrants to purchase shares of common stock to the selling stockholders and agreed to file a registration statement to enable the resale of the shares of common stock covered by this prospectus. In the Warrant Inducement Transaction, GMS Ventures & Investments, affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, exercised an aggregate of 3,458,571 Existing Warrants for an aggregate Reduced Exercise Price of approximately \$8.7 million in exchange for Inducement Warrants to purchase 6,917,142 shares of common stock. Other than the foregoing, none of the selling stockholders or any persons having control over such selling stockholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares or other securities.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their respective Securities covered hereby on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the Securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling Securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the Securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such Securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

A selling stockholder may also sell Securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by a selling stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from a selling stockholder (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

A selling stockholder may enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

A selling stockholder and any broker-dealers or agents that are involved in selling the Securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the Securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the Securities. We have agreed to indemnify any selling stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the Securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the Securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The Securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the Securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by a selling stockholder or any other person. We will make copies of this prospectus available to a selling stockholder and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

EXPERTS

The consolidated financial statements of Outlook Therapeutics, Inc. as of September 30, 2024 and 2023, and for the years then ended, have been incorporated by reference herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the September 30, 2024 consolidated financial statements contains an explanatory paragraph that states that the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

LEGAL MATTERS

Certain legal matters, including the validity of the shares of common stock offered pursuant to this registration statement, will be passed upon for us by Cooley LLP, Chicago, Illinois.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You should rely only on information contained in this prospectus or incorporated by reference into this prospectus. We have not authorized any person to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered by this prospectus.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public at the SEC's website at <http://www.sec.gov>.

We maintain a website at <http://www.outlooktherapeutics.com>. Information contained in or accessible through our website does not constitute a part of this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information and documents listed below that we have filed with the SEC (Commission File No. 001-37759):

- our Annual Report on Form 10-K for the fiscal year ended September 30, 2024, filed with the SEC on [December 27, 2024](#), or the 2024 Form 10-K, and amended on [January 23, 2025](#);
- our Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 filed with the SEC on [February 14, 2025](#);
- our Current Reports on Form 8-K, filed with the SEC on [November 27, 2024](#), [December 4, 2024](#), [December 16, 2024](#), [January 16, 2025](#), [January 31, 2025](#), and [February 28, 2025](#), to the extent the information in such reports is filed and not furnished; and
- the description of our common stock set forth in our registration statement on Form 8-A, filed with the SEC on [April 29, 2016](#), as amended on [May 11, 2016](#), including any further amendments thereto or reports filed for the purposes of updating this description, including [Exhibit 4.1 of the 2024 Form 10-K](#).

We also incorporate by reference any future filings (other than Current Reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the filing of the registration statement of which this prospectus is a part and prior to effectiveness of the registration statement and (ii) after the effectiveness of the registration statement of which this prospectus is a part but prior to the termination of all offerings of securities covered by this prospectus (Commission File No. 001-37759). Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to Outlook Therapeutics, Inc., Attention: Corporate Secretary, 111 S. Wood Avenue, Unit #100, Iselin, New Jersey 08830. Our phone number is (609) 619-3990. You may also view the documents that we file with the SEC and incorporate by reference in this prospectus on our corporate website at www.outlooktherapeutics.com. The information on our website is not incorporated by reference and is not a part of this prospectus.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following is a statement of the estimated expenses to be incurred by us in connection with the registration of the securities under this registration statement, all of which will be borne by us.

Securities and Exchange Commission Registration Fee	\$	1,658
Legal Fees and Expenses	\$	50,000
Accounting Fees and Expenses	\$	22,500
Miscellaneous	\$	2,500
Total	\$	76,658

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended. Our restated certificate of incorporation provides for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws provide for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with our directors and executive officers, whereby we have agreed to indemnify our directors and executive officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or executive officer was, or is threatened to be made, a party by reason of the fact that such director or executive officer is or was our director, officer, employee or agent, provided that such director or executive officer acted in good faith and in a manner that the director or executive officer reasonably believed to be in, or not opposed to, the our best interest. At present, there is no pending litigation or proceeding involving any of our directors or executive officers regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, that might be incurred by any director or officer in his or her capacity as such.

Item 16. Exhibit Index.

Exhibit No.	Description
<u>3.1</u>	<u>Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's quarterly report on Form 10-Q filed with the SEC on May 15, 2024).</u>
<u>3.2</u>	<u>Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K filed with the SEC on March 26, 2021).</u>
<u>4.1</u>	<u>Form of Inducement Letter (incorporated by reference to Exhibit 10.1 to Registrant's current report on Form 8-K filed with the SEC on January 16, 2025).</u>
<u>4.3</u>	<u>Form of Tranche A Inducement Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on January 16, 2025).</u>
<u>5.1</u>	<u>Opinion of Cooley LLP.</u>
<u>23.1</u>	<u>Consent of independent registered public accounting firm.</u>
<u>23.2</u>	<u>Consent of Cooley LLP (included in legal opinion filed as Exhibit 5.1).</u>
<u>24.1</u>	<u>Power of Attorney (included on signature page).</u>
<u>107</u>	<u>Filing fee table.</u>

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (a)(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Filing Fee Table" exhibit to the effective registration statement;
 - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- provided, however,* that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser:
- (i) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
 - (ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

- (b) The undersigned registrant undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person of the registrant in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Iselin, New Jersey, on February 28, 2025.

OUTLOOK THERAPEUTICS, INC.

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

Chief Financial Officer, Interim Chief Executive Officer, Treasurer and Secretary

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lawrence A. Kenyon, his or her true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for him and her and in his and her name, place and stead, in any and all capacities, to (i) act on, sign, and file with the SEC any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act, and (iv) take any and all actions that may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Lawrence A. Kenyon</u> Lawrence A. Kenyon	Chief Financial Officer, Interim Chief Executive Officer, Treasurer, Secretary and Director <i>(Principal Executive, Financial and Accounting Officer)</i>	February 28, 2025
<u>/s/ Faisal G. Sukhtian</u> Faisal G. Sukhtian	Chairman	February 28, 2025
<u>/s/ Ralph H. Thurman</u> Ralph H. Thurman	Lead Independent Director	February 28, 2025
<u>/s/ Gerd Auffarth</u> Gerd Auffarth	Director	February 28, 2025
<u>/s/ Yezan Haddadin</u> Yezan Haddadin	Director	February 28, 2025
<u>/s/ Julia A. Haller</u> Julia A. Haller	Director	February 28, 2025
<u>/s/ Kurt J. Hilzinger</u> Kurt J. Hilzinger	Director	February 28, 2025
<u>/s/ Julian Gangolli</u> Julian Gangolli	Director	February 28, 2025
<u>/s/ Andong Huang</u> Andong Huang	Director	February 28, 2025



Yvan-Claude Pierre
+1 212 479 6721
yypierre@cooley.com

February 28, 2025

Outlook Therapeutics, Inc.
111 S. Wood Avenue, Unit #100
Iselin, New Jersey 08830

Ladies and Gentlemen:

We have acted as counsel to Outlook Therapeutics, Inc., a Delaware corporation (the "**Company**"), in connection with the filing by the Company of a Registration Statement on Form S-3 (the "**Registration Statement**") with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Securities Act**"), including a related prospectus included in the Registration Statement (the "**Prospectus**"), covering the registration for resale of up to 7,074,637 shares of common stock, \$0.01 par value (the "**Common Stock**"), of the Company (the "**Warrant Shares**") issuable upon the exercise of outstanding Tranche A warrants (the "**Warrants**"). The Warrants were issued by the Company pursuant to those certain warrant exercise inducement offer letter agreements dated as of January 16, 2025, by and between the Company and certain holders of existing warrants to purchase the Company's Common Stock (the "**Letter Agreements**").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, the Letter Agreements, the Warrants, the Company's certificate of incorporation and bylaws, each as currently in effect, and such other records, documents, opinions, certificates, memoranda and instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state antifraud law, rule or regulation relating to securities or to the sale or issuance thereof.

With respect to the Warrant Shares, we express no opinion to the extent that future issuances of securities of the Company, adjustments to outstanding securities of the Company or other matters cause the Warrants to be exercisable for more shares of Common Stock than the number available for issuance by the Company. Further, we have assumed that the exercise price of the Warrants will not be adjusted to an amount below the par value per share of the Common Stock.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Warrant Shares, when issued and paid for in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable.

COOLEY LLP 55 HUDSON YARDS, NEW YORK, NY 10001-2157,
T: (212) 479-6000, F: (212) 479-6275 COOLEY.COM

Our opinion is limited to the matters expressly set forth in this letter, and no opinion has been or should be implied, or may be inferred, beyond the matters expressly stated. This opinion speaks only as to law and facts in effect or existing as of the date hereof, and we have no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances that may hereafter come to our attention or any changes in law that may hereafter occur.

We hereby consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

COOLEY LLP

By: /s/ Yvan-Claude Pierre
Yvan-Claude Pierre

COOLEY LLP 55 HUDSON YARDS, NEW YORK, NY 10001-2157,
T: (212) 479-6000, F: (212) 479-6275 COOLEY.COM

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated December 27, 2024, with respect to the consolidated financial statements of Outlook Therapeutics, Inc., incorporated herein by reference, and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ KPMG LLP

Philadelphia, Pennsylvania

February 28, 2025

Calculation of Filing Fee Tables

Form S-3
(Form Type)

Outlook Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered(1) (2)	Proposed Maximum Offering Price Per Share(3)	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Common Stock, par value \$0.01 per share	457(c)	7,074,637	\$1.53	\$10,824,194.61	0.00015310	\$1,657.19
	Total Offering Amounts					\$10,824,194.61		\$1,657.19
	Total Fees Previously Paid							—
	Total Fee Offsets							—
	Net Fee Due							\$1,657.19

- (1) The shares of common stock will be offered for resale by the selling stockholders pursuant to the prospectus contained herein. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “*Securities Act*”), this registration statement also covers any additional number of shares of common stock issuable upon stock splits, stock dividends, or other distribution, recapitalization or similar events with respect to the shares of common stock being registered pursuant to this registration statement.
- (2) This registration statement registers the resale of 7,074,637 shares of common stock of the Registrant issuable upon the exercise of outstanding Tranche A warrants to purchase shares of common stock held by the selling stockholders.
- (3) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based on average of high and low price per share of the common stock as reported on The Nasdaq Capital Market on February 24, 2025.