Filed pursuant to 424(b)(3)
Registration No. 333-278959

PROSPECTUS

2,776,867 shares of Common Stock

This prospectus covers the offer and resale by Syntone Ventures LLC, or the selling stockholder, of up to an aggregate of 2,776,867 shares of our common stock, which consists of (i) 800,000 shares of our common stock held by the selling stockholder that were issued by us at the closing of a private placement on June 2, 2020 (as adjusted for a 1-for-20 reverse stock split that we effected in March 2024, or the Reverse Stock Split), (ii) 41,152 shares of our common stock held by the selling stockholder that were issued by us at the closing of a private placement on July 15, 2020 (as adjusted for the Reverse Stock Split), (iii) 150,000 shares of our common stock held by the selling stockholder that were issued by us at the closing of a private placement on February 3, 2021 (as adjusted for the Reverse Stock Split) and (iv) the following securities held by the selling stockholder that were issued by us at the closing of a private placement on April 15, 2024: (a) 714,286 shares of our common stock and (b) 1,071,429 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our common stock.

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

Sales of shares of common stock by the selling stockholder 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 stockholder 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 stockholder, 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 stockholder is 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 May 3, 2024, the last reported sale price of our common stock was $8.60 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 7 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 May 6, 2024

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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 stockholder may sell from time to time in one or more offerings the common stock described in this prospectus.

We have not, and the selling stockholder has 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 contains 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;
- 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 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;
- the rate and degree of market acceptance of our current and future product candidates, including our commercialization strategy and manufacturing capabilities for ONS-5010;
- 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 expectations and 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 the 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 inflation, high 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 Private Placements (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 7 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 U.S. Food and Drug Administration, or the FDA, for use in retinal indications. Our goal is to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of wet age-related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO. Our plans also include seeking approval and launching the product in the United Kingdom, Europe, Japan and other markets, either directly into those markets or through a strategic partner. If approved, we expect to receive 12 years of regulatory exclusivity in the United States and up to 10 years of market exclusivity in the European Union.

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 March 2022, we submitted a BLA with the FDA for ONS-5010 (LYTENAVA (bevacizumab-vikg)), 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 on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a Prescription Drug User Fee Act, or PDUFA, 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 our 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 was also requiring the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010, as well as additional requested CMC data indicated in the CRL to approve ONS-5010 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. 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 BLA. In January 2024, we received confirmation that the FDA has 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. The first subject was enrolled in NORSE EIGHT in January 2024. In addition, through a Type A meeting and additional interactions, we have identified the approaches needed to resolve the CMC comments in the CRL. We are working to address the open items and expect to resolve these comments prior to the expected completion of NORSE EIGHT.

Separately, in October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010 with the European Medicines Agency, or the EMA. On December 22, 2022, our MAA was validated for review by the EMA. The MAA was submitted as a 'full-mixed marketing authorisation 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, and a decision by the European Commission is expected within approximately 67 days following the CHMP opinion. ONS-5010 is our sole product candidate in active development.

Our initial BLA submission for ONS-5010 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 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 and positive proof-of-concept topline results from NORSE ONE, a clinical experience study. NORSE TWO is our pivotal Phase 3 clinical trial comparing ONS-5010 (bevacizumab-vikg) to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010 met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant. In the intent to treat, or ITT, primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% ($p = 0.0052$). The primary endpoint was also statistically significant and clinically relevant in the secondary per protocol, or PP, dataset ($p = 0.04$) where the percentages were almost identical, at 41.0% with ONS-5010, and 24.7% with ranibizumab. The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant ($p = 0.0035$). A mean change of 11.2 letters in BCVA score was observed with ONS-5010, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset ($p = 0.01$) with a mean change with ONS-5010 of 11.1 letters versus 7.0 letters with ranibizumab. Additionally, the majority of ONS-5010 subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA ≥ 0), with at least 80% of ONS-5010 subjects maintaining BCVA each month. Results were also positive for the remaining NORSE TWO secondary endpoints with 56.5% ($p = 0.0016$) of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% ($p = 0.0116$) of ONS-5010 subjects gaining ≥ 5 letters of vision. NORSE THREE is an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010 were available for the initial ONS-5010 BLA submission with the FDA. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010. The NORSE BLA registration program is also being used to support our MAA submission in the European Union.

As we agreed with the FDA in the SPA, NORSE EIGHT will be 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 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint will be mean change in BCVA from baseline to week 8. The first subject was enrolled in NORSE EIGHT in January 2024. We expect NORSE EIGHT topline results and potential resubmission of the ONS-5010 BLA by the end of calendar year 2024.

Additionally, 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 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. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010 to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010 to treat DME. We intend to initiate these studies following the anticipated FDA approval of our BLA for wet AMD.

Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major global markets, we submitted a standard BLA, and are not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of unapproved bevacizumab. In the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022).

Reverse Stock Split

Effective March 13, 2024 at 5:00 p.m. Eastern Time, we effected a 1-for-20 reverse stock split, or the Reverse Stock Split, and proportionate reduction in the number of authorized shares of our common stock.

Private Placements

The May 2020 Private Placement

On May 22, 2020, we entered into a Stock Purchase Agreement, or the May 2020 Purchase Agreement, with Syntone Ventures LLC, or Syntone, pursuant to which we agreed to issue and sell, in a private placement, or the May 2020 Private Placement, an aggregate of 16,000,000 shares of our common stock at a purchase price of $1.00 per share (without giving effect to the Reverse Stock Split), for aggregate gross proceeds of $16 million. The May 2020 Private Placement closed on June 2, 2020.

In connection with the May 2020 Private Placement, under the May 2020 Purchase Agreement, we agreed to prepare and file one or more registration statements with the SEC to register for resale the shares of common stock purchased by Syntone in the May 2020 Private Placement. We have granted Syntone customary indemnification rights in connection with any registration statement filed pursuant to the May 2020 Purchase Agreement. Syntone has also granted us customary indemnification rights in connection with any registration statement filed pursuant to the May 2020 Purchase Agreement.

The June 2020 Private Placement

On June 22, 2020, we entered into a Securities Purchase Agreement with Syntone, pursuant to which we agreed to issue and sell, in a private placement, or the June 2020 Private Placement, an aggregate of 823,045 shares of our common stock at a purchase price of $1.215 per share (without giving effect to the Reverse Stock Split), for aggregate gross proceeds of $1 million. The June 2020 Private Placement closed on July 15, 2020.

The 2021 Private Placement

On January 21, 2021, we entered into a Securities Purchase Agreement with Syntone, pursuant to which we agreed to issue and sell, in a private placement, or the 2021 Private Placement, an aggregate of 3,000,000 shares of our common stock at a purchase price of $1.00 per share (without giving effect to the Reverse Stock Split), for aggregate gross proceeds of $3 million. The 2021 Private Placement closed on February 3, 2021.

The 2024 Private Placement

On January 22, 2024, we entered into a securities purchase agreement, or the 2024 Purchase Agreement, with Syntone, pursuant to which we agreed to issue and sell to Syntone, and Syntone agreed to purchase, in a private placement, or the 2024 Private Placement, an aggregate of $5 million in shares of our common stock, together with the shares of common stock purchased in each of the May 2020 Private Placement, June 2020 Private Placement and 2021 Private Placement, the Shares, and, for each share issued in the 2024 Private Placement, Syntone received accompanying warrants to purchase up to one and a half shares of common stock, or the Warrants and, together with the Shares, the Securities. We refer to the May 2020 Private Placement, June 2020 Private Placement, 2021 Private Placement and the 2024 Private Placement collectively as the Private Placements.

In addition, on January 22, 2024, we entered into a securities purchase agreement, or the Concurrent Purchase Agreement, with the institutional and accredited investors named therein, including GMS Ventures and Investments, an existing investor affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, pursuant to which the investors agreed to purchase $60 million of shares of common stock, and, for each share of common stock issued under the Concurrent Purchase Agreement, accompanying warrants to purchase up to one and a half shares of common stock, on substantially the same terms as those set forth in the 2024 Purchase Agreement and the Warrants, or the Concurrent Private Placement. The Concurrent Private Placement closed on March 18, 2024.

The closing of the 2024 Private Placement, or the 2024 Closing, occurred on April 15, 2024, following the satisfaction of the closing conditions set forth in the 2024 Purchase Agreement, including the approval by the Company's stockholders of certain matters relating to the 2024 Private Placement and Syntone's receipt of certain regulatory approvals. In accordance with the 2024 Purchase Agreement, we issued 714,286 shares of our common stock and accompanying Warrants to purchase 1,071,429 shares of our common stock. The purchase price per share of common stock and accompanying Warrant was $7.00 (which is equal to $0.35 per share of common stock and accompanying Warrant, the closing price of the common stock on The Nasdaq Capital Market on the trading day immediately prior to the execution of the 2024 Purchase Agreement, as adjusted for the Reverse Stock Split).

The Warrants have a per share exercise price equal to $7.70. The Warrants are exercisable only for cash, except in limited circumstances, at any time after the date of issuance, or the Issue Date, and will expire on April 15, 2029. Syntone may not exercise the Warrants if Syntone, together with its affiliates, would beneficially own more than 19.99% of the outstanding common stock immediately after giving effect to such exercise.

In addition, we may require Syntone to exercise the Warrants for cash under certain circumstances as follows: (i) if the volume-weighted average price of our common stock equals or exceeds $20.00 per share (subject to adjustment in the event of stock splits, combinations or similar events) for 30 consecutive days, or the Stock Price Condition, at any time after we publicly announce topline data from our NORSE EIGHT clinical trial evidencing satisfaction of the trial's primary endpoints, or the NORSE EIGHT Announcement, upon the consent of a majority of the members of our Board of Directors, or the Board, we may require Syntone to exercise up to 20% of the aggregate number of Warrants issued to Syntone on the Issue Date; and (ii) we may require up to the remainder of the Warrants be exercised (A) if the Stock Price Condition is satisfied at any time after we publicly announce approval from the FDA of the BLA for ONS-5010, upon the consent of a majority of the members of the Board or (B) if the Stock Price Condition is satisfied at any time after the NORSE EIGHT Announcement, upon the unanimous consent of the members of the Board present at duly called meeting.

At the 2024 Closing, we received gross proceeds of $5 million, and may receive up to an additional $8 million of gross proceeds upon cash exercise of the Warrants, in each case before deducting offering expenses.

We intend to use the net proceeds from the 2024 Private Placement to fund our ONS-5010 clinical development programs, to fund the NORSE EIGHT clinical trial, and for working capital and other general corporate purposes.

Existing investors and entities affiliated with certain directors of the Company are party to the 2024 Purchase Agreement and the Concurrent Purchase Agreement. Syntone, affiliated with Andong Huang, a director of the Company, purchased shares of common stock and Warrants for an aggregate purchase price of approximately $5 million. GMS Ventures and Investments, affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, purchased securities in the Concurrent Private Placement for an aggregate purchase price of approximately $16.1 million.

In connection with the 2024 Private Placement, we entered into a registration rights agreement, or the Registration Rights Agreement, with the Syntone pursuant to which we agreed to prepare and file, within five days following the 2024 Closing, one or more registration statements with the SEC to register for resale the shares of common stock and Warrants purchased by Syntone in the 2024 Private Placement. We have granted Syntone customary indemnification rights in connection with any registration statement filed pursuant to the Registration Rights Agreement. Syntone has also granted us customary indemnification rights in connection with any registration statement filed pursuant to the Registration Rights Agreement.

For more information regarding the 2024 Private Placement, see our Current Report on Form 8-K filed with the SEC on January 24, 2024 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 the 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 485 Route 1 South, Building F, Suite 320, 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 stockholder	2,776,867 shares of common stock, consisting of (i) 800,000 shares of our common stock held by the selling stockholder that were issued by us in the May 2020 Private Placement (as adjusted for the Reverse Stock Split), (ii) 41,152 shares of our common stock held by the selling stockholder that were issued by us in the June 2020 Private Placement (as adjusted for the Reverse Stock Split), (iii) 150,000 shares of our common stock held by the selling stockholder that were issued by us in the 2021 Private Placement (as adjusted for the Reverse Stock Split) and (iv) the following securities held by the selling stockholder that were issued by us in the 2024 Private Placement: (a) 714,286 shares of our common stock and (b) 1,071,429 shares of our common stock issuable upon the exercise of the Warrants.
Terms of the offering	The 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 covered by this prospectus. We will, however, receive the net proceeds of any Warrants exercised for cash.
Risk factors	See "Risk Factors" on page 7 for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq symbol	"OTLK"

The selling stockholder named in this prospectus may offer and sell up to 2,776,867 shares of our common stock. 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 stockholder of any of the Shares covered by this prospectus. We will, however, receive the exercise price of $7.70 per share of any of the Warrants exercised for cash. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholder for offer and resale, we are referring to the Shares that have been issued to the selling stockholder and the shares of common stock issuable upon exercise of the Warrants as described above. When we refer to the selling stockholder in this prospectus, we are referring to Syntone Ventures LLC and, as applicable, its 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, 2023, as updated by our subsequent annual, quarterly and other reports and documents that are incorporated herein by reference in their entirety, as well 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 below 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 stockholder pursuant to this prospectus. Upon any exercise of the Warrants for cash, the selling stockholder would pay us the exercise price set forth in the Warrants.

Each Warrant has an exercise price equal to $7.70 per share, and if the Warrants are exercised in full on a cash basis, we will receive proceeds of approximately $8 million. We expect to use any such proceeds primarily to fund our clinical development programs and for working capital and other corporate and operational purposes. The Warrants are exercisable at any time after the Issue Date and expire on April 15, 2029.

We may require the holder to cash exercise the Warrants under certain circumstances as follows: (i) if the Stock Price Condition has been satisfied at any time after the NORSE EIGHT Announcement, upon the consent of a majority of the members of the Board, we may require the holder to exercise up to 20% of the aggregate number of Warrants issued to the holder on the Issue Date; and (ii) we may require up to the remainder of the Warrants be exercised (A) if the Stock Price Condition is satisfied at any time after we publicly announce approval from the FDA of the BLA for ONS-5010, upon the consent of a majority of the members of the Board or (B) if the Stock Price Condition is satisfied at any time after the NORSE EIGHT Announcement, upon the unanimous consent of the members of the Board present at duly called meeting.

The 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 Warrants, in which case the Warrants may be exercised on a cashless basis. If any of the 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 stockholder pursuant to this prospectus. Other than registration expenses, the selling stockholder will bear its own broker or similar commissions payable with respect to sales of shares of our common stock.

SELLING STOCKHOLDER

The shares of common stock being offered by the selling stockholder are those (i) issued to the selling stockholder in the Private Placements and (ii) issuable to the selling stockholder upon exercise of the Warrants issued in the 2024 Private Placement. For additional information regarding the issuance of the Shares and Warrants, see the section "Prospectus Summary—Private Placements" above. We are registering the resale of shares of common stock issued to the selling stockholder and issuable upon exercise of the Warrants in order to permit the selling stockholder to offer the shares for resale from time to time. A description of our relationship with the selling stockholder is provided below under "Certain Relationships and Related Party Transactions."

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 provides information regarding the beneficial ownership of the shares of common stock by Syntone, which information has been obtained from Syntone. The second column lists the number of shares of common stock beneficially owned by Syntone, based on its ownership of Shares and Warrants, as of April 15, 2024, assuming exercise of the Warrants held by Syntone on that date, without regard to any limitations on exercise. The Warrants are exercisable only for cash, except in limited circumstances, at any time after the Issue Date. The percentage of shares owned prior to and after the offering in the third and sixth columns are based on 23,298,495 shares of common stock outstanding as of April 15, 2024. The fourth column assumes the sale of all of the shares offered by the selling stockholder pursuant to this prospectus.

In accordance with the terms of the May 2020 Purchase Agreement and the Registration Rights Agreement, this prospectus generally covers the resale of the sum of (i) the number of Shares issued to the selling stockholder in the Private Placements and (ii) the maximum number of shares of common stock issuable upon exercise of the Warrants issued in the 2024 Private Placement. This maximum amount is determined as if the outstanding Warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, subject to adjustment as provided in the Registration Rights Agreement and without regard to any limitations on the exercise of the Warrants. Under the terms of the Warrants, Syntone may not exercise the Warrants to the extent such exercise would cause Syntone, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 19.99% 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 Warrant). The number of shares in the second and fifth columns do not reflect this limitation. Syntone may sell all, some or none of its shares in this offering. See the section "Plan of Distribution."

	Before Offering		After Offering		
Name and Address	**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**
Syntone Ventures LLC [(1)]	2,776,867	11.4%	2,776,867	–	–

(1) All shares are held directly by Syntone Ventures LLC, a Delaware limited liability company, or Syntone. Syntone LLC, a Delaware limited liability company, or the Manager, is the manager of Syntone, and is wholly-owned by Syntone Technologies Group Co. Ltd., a company organized in the People's Republic of China, or Syntone Technologies. The principal business address for each of Syntone and the Manager is 1517 Champlain Crest Way, Cary, NC 27513. The principal business address for Syntone Technologies is Beihuan Road East, Renqiu City, Heibei Province, People's Republic of China.

Certain Relationships and Related Party Transactions

As discussed in greater detail above under the section "Prospectus Summary—Private Placements," on January 22, 2024, we entered into the 2024 Purchase Agreement and Registration Rights Agreement with Syntone, pursuant to which, on April 15, 2024, we sold shares of common stock and Warrants to Syntone and agreed to file a registration statement to enable the resale of the shares of common stock covered by this prospectus. Syntone, affiliated with Andong Huang, a director of the Company, purchased shares of common stock and Warrants for an aggregate purchase price of approximately $5.0 million. On January 22, 2024, we also entered into the Concurrent Purchase Agreement with the institutional and accredited investors named therein, including GMS Ventures and Investments, an existing investor affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, whereby GMS Ventures and Investments purchased shares of common stock and accompanying warrants for an aggregate purchase price of approximately $16.1 million.

PLAN OF DISTRIBUTION

The selling stockholder and any of its 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. The 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 stockholder 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.

The 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 the selling stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the 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.

The 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).

The 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. The 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 the 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 stockholder 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 stockholder 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 the selling stockholder or any other person. We will make copies of this prospectus available to the selling stockholder and have informed the selling stockholder 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, 2023 and 2022, 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, 2023 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, 2023, filed with the SEC on December 22, 2023, or the 2023 Form 10-K, and amended on January 24, 2024;
- our Quarterly Report on Form 10-Q for the quarter ended December 31, 2023 filed with the SEC on February 14, 2024;
- our Current Reports on Form 8-K, filed with the SEC on October 20, 2023, November 2, 2023, December 6, 2023, January 24, 2024, March 7, 2024, March 18, 2024, March 26, 2024, April 2, 2024, April 12, 2024, April 15, 2024 and May 1, 2024, 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 2023 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, 485 Route 1 South, Building F, Suite 320, 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.