
**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)

485 Route 1 South
Building F, Suite 320
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
Outlook Therapeutics, Inc.
485 Route 1 South
Building F, Suite 320
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 MARCH 25, 2024

PROSPECTUS



21,428,556 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 21,428,556 shares of our common stock, which consists of (i) 8,571,423 shares of our common stock held by the selling stockholders and (ii) 12,857,133 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our common stock held by the selling stockholders, all of which were issued by us at the closing of our a private placement on March 18, 2024.

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 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 March 22, 2024, the last reported sale price of our common stock was \$8.63 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 _____, 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 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;
- 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 Placement (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 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. The formal review process of the MAA by the EMA’s Committee for Medicinal Products for Human Use, or CHMP, is now underway with an estimated decision date expected in the first half of calendar year 2024. 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).

The Private Placement

On January 22, 2024, we entered into a securities purchase agreement, or the Securities Purchase Agreement, with the institutional and accredited investors named therein, or the Investors, pursuant to which we agreed to issue and sell to the Investors, and the Investors agreed to purchase, in a private placement, or the Private Placement, an aggregate of \$60 million in shares, or the Shares, of our common stock and, for each Share issued in the Private Placement, Investors 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.

In addition, on January 22, 2024, we entered into a securities purchase agreement, or the Syntone Purchase Agreement, with Syntone Ventures, LLC, or Syntone, an existing investor affiliated with Andong Huang, one of our directors, pursuant to which Syntone agreed to purchase \$5 million of shares of common stock, or the Syntone Shares, and, for each Syntone Share issued under the Syntone 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 Securities Purchase Agreement and the Warrants, or the Syntone Private Placement. The closing of the Syntone Private Placement remains subject to receipt of certain regulatory approvals.

The closing of the Private Placement, or the Closing, occurred on March 18, 2024, following the satisfaction of the closing conditions set forth in the Securities Purchase Agreement, including the approval by the Company's stockholders of certain matters relating to the Private Placement. In accordance with the Securities Purchase Agreement, we issued an aggregate of 8,571,423 Shares and accompanying Warrants to purchase 12,857,133 shares of common stock. The purchase price per Share and accompanying Warrant was \$7.00 (which is equal to \$0.35 per Share 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 Securities Purchase Agreement, as adjusted for a 1-for-20 reverse stock split effected on March 14, 2024).

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 March 18, 2029. A holder of Warrants may not exercise the Warrant if the holder, together with its affiliates, would beneficially own more than a specified percentage of the outstanding common stock (4.99%, 9.99% or 19.99%, as applicable), immediately after giving effect to such exercise, which may be increased or decreased at the holders' option (not to exceed 19.99%), effective 61 days after written notice to us.

In addition, we may require the holders 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 the holders to exercise up to 20% of the aggregate number of Warrants issued to such 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.

At the Closing, we received gross proceeds of \$60 million, and may receive up to an additional \$99 million of gross proceeds upon cash exercise of the Warrants, in each case before deducting placement agent fees and offering expenses.

We intend to use the net proceeds from the 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 Securities Purchase Agreement and the Syntone Purchase Agreement. GMS Ventures and Investments, affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, purchased Securities for an aggregate purchase price of approximately \$16.1 million. Syntone, affiliated with Andong Huang, a director of the Company, expects to purchase Securities for an aggregate purchase price of approximately \$5 million.

In connection with the Private Placement, we entered into a registration rights agreement, or the Registration Rights Agreement, with the selling stockholders named in this prospectus pursuant to which we agreed to prepare and file, within five days following the Closing, one or more registration statements with the SEC to register for resale the Securities held by the selling stockholders. We have granted the selling stockholders customary indemnification rights in connection with any registration statement filed pursuant to the Registration Rights Agreement. The selling stockholders have also granted us customary indemnification rights in connection with any registration statement filed pursuant to the Registration Rights Agreement.

For more information regarding the 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 stockholders	21,428,556 shares, consisting of (i) 8,571,423 shares of our common stock held by the selling stockholders and (ii) 12,857,133 shares of our common stock issuable upon the exercise of the 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 covered by this prospectus. We will, however, receive the net proceeds of any 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 21,428,556 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 stockholders of any of the common stock 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 stockholders for offer and resale, we are referring to the Shares that have been issued to the selling stockholders and the shares of common stock issuable upon exercise of the Warrants issued in the Private Placement 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, 2023, 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 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 stockholders pursuant to this prospectus. Upon any exercise of the Warrants for cash, the applicable 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 all 12,857,133 Warrants are exercised on a cash basis, we will receive proceeds of approximately \$99 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 March 18, 2029.

We may require the holders 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 holders to exercise up to 20% of the aggregate number of Warrants issued to such 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 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 (i) issued to the selling stockholders in the Private Placement and (ii) issuable to the selling stockholders upon exercise of the Warrants issued in the Private Placement. For additional information regarding the issuance of the Shares and Warrants, see the section “Prospectus Summary—Private Placement” above. We are registering the resale of shares of common stock issued to the selling stockholders and issuable upon exercise of the Warrants in order to permit the selling stockholders to offer the shares for resale from time to time. Except for the ownership of the Shares and the 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 Shares and Warrants, as of March 18, 2024, assuming exercise of the Warrants held by the selling stockholders on that date, without regard to any limitations on exercises, unless otherwise indicated. 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 21,584,256 shares of common stock outstanding as of March 18, 2024. 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 Registration Rights Agreement, this prospectus generally covers the resale of the sum of (i) the number of Shares issued to the selling stockholders in the Private Placement and (ii) the maximum number of shares of common stock issuable upon exercise of the Warrants issued in the 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, a selling stockholder may not exercise the 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 Warrant). The number of shares in the second and fifth columns do not reflect this limitation, unless otherwise indicated below. 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
Entities affiliated with Great Point Partners LLC (1) <i>165 Mason Street, 3rd Floor, Greenwich, CT 06830</i>	3,718,750	15.6%	3,700,000	18,750	*
GMS Ventures & Investments (2) <i>Zahran Street, 7th Circle Zahran Plaza Building, 4th Floor P.O. Box 142904, Amman, Jordan 11844</i>	9,266,645	37.0%	5,764,285	3,502,360	16.2%
Altium Growth Fund, LP (3) <i>152 W 57th Street, 20th Floor, New York, NY 10019</i>	1,428,570	6.4%	1,428,570	–	–
ArcherOak Holdings, LLC (4) <i>176 Taconic Road, Greenwich, CT 06831</i>	418,569	1.9%	178,570	239,999	1.1%
Armistice Capital, LLC (5) <i>510 Madison Avenue, 7th Floor, New York, NY 10022</i>	1,785,712	7.9%	1,785,712	–	–
BrightForge Management, LLC (6) <i>1515 N 1200 E, Lehi, UT 84043</i>	53,570	*	53,570	–	–

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
Entities affiliated with Caligan Partners (7) 515 Madison Avenue, 8th Floor, New York, NY 10022	1,250,000	5.6%	1,250,000	–	–
Gravitas Capital LP (8) 34 Shrewsbury Avenue, Red Bank, NJ 07701	330,355	1.5%	330,355	–	–
Sarosca Farm LLC (9) 100 West Putnam - Slagle House, Greenwich, CT 06830	366,187	1.7%	339,285	26,902	*
Schonfeld Global Master Fund L.P. (10) 590 Madison Avenue, 23rd Floor, New York, NY 10022	714,285	3.2%	714,285	–	–
Entities affiliated with SDS Capital (11) 1010 W 10th Street, Suite 302, Austin TX 78703	349,212	1.6%	348,212	1,000	*
Entities affiliated with Sphera (12) 4 Yitzhak Sadeh, Entrance A, 29th Floor, Tel Aviv 6777520, Israel	1,458,192	6.5%	1,428,570	29,622	
Tang Capital Partners, LP (13) 4747 Executive Drive, Suite 210 San Diego, CA 92121	2,271,345	9.99%	2,500,000	119,412	*
Velan Capital Master Fund LP (14) 100 North Main Street, Suite 301, Alpharetta, Georgia 30009	1,250,000	5.6%	1,250,000	–	–
Woodline Master Fund LP (15) 4 Embarcadero Center, Suite 3450, San Francisco, CA 94111	357,142	1.6%	357,142	–	–

* Represents beneficial ownership of less than one percent.

- (1) Consists (i) 2,052,750 shares of common stock held by Biomedical Value Fund, L.P. (“BMVF”), of which (a) 10,350 are shares of common stock held prior to the Private Placement, (b) 816,960 are shares of common stock purchased in the Private Placement and (c) 1,225,440 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement, (ii) 1,413,125 shares of common stock held by Biomedical Offshore Value Fund, Ltd. (“BMOV”) of which (a) 7,125 are shares of common stock held prior to the Private Placement, (b) 562,400 are shares of common stock purchased in the Private Placement and (c) 843,600 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement and (iii) 252,875 shares of common stock held by Cheyne Select Master Fund ICAV – Cheyne Global Equity Fund (“CGEF” and together with BMVF and BMOV, the “GPP Entities”), of which (a) 1,275 are shares of common stock held prior to the Private Placement, (b) 100,640 are shares of common stock purchased in the Private Placement and (c) 150,960 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Great Point Partners LLC (“GPP LLC”) is the investment manager of BMVF and BMOV and the sub-advisor to CGEF, and by virtue of such status may be deemed to be the beneficial owner of the securities held by the GPP Entities. Each of Dr. Jeffrey R. Jay, M.D., as Senior Managing Member of GPP LLC, and Mr. Ortav Yehudai, as Managing Director of GPP LLC, has voting and investment power with respect to securities held by the GPP Entities, and therefore may be deemed to be the beneficial owner of the securities held by the GPP Entities. Notwithstanding the above, GPP LLC, Dr. Jay and Mr. Yehudai disclaim beneficial ownership of the securities held by the GPP Entities except to the extent of their respective pecuniary interests. The shares of common stock issuable upon exercise of the Warrants held by each of the GPP Entities are subject to a beneficial ownership limitation of 9.99%.
- (2) Consists of 9,266,645 shares of common stock held by GMS Ventures & Investments, of which (a) 3,502,360 are shares of common stock held prior to the Private Placement, (b) 2,305,714 are shares of common stock purchased in the Private Placement and (c) 3,458,571 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. 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 Act.
- (3) Consists of 1,428,570 shares of common stock held by Altium Growth Fund, LP (“Altium Growth”), of which (a) 571,428 are shares of common stock purchased in the Private Placement and (b) 857,142 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Altium Capital Management, LP, the investment manager of Altium Growth, has voting and investment power over these securities. Jacob Gottlieb is the managing member of Altium Capital Growth GP, LLC, which is the general partner of Altium Growth. Jacob Gottlieb disclaims beneficial ownership over these securities. The shares of common stock issuable upon exercise of the Warrants held by Altium are subject to a beneficial ownership limitation of 4.99%.
- (4) Consists of 178,569 shares of common stock held by ArcherOak Holdings, LLC (“ArcherOak”), of which (a) 71,428 are shares of common stock purchased in the Private Placement and (b) 107,142 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Also includes 239,999 shares of common stock held prior to the Private Placement by Brian Cohn. Brian Cohn, Managing Member of ArcherOak, has voting and dispositive power over the shares of common stock owned by ArcherOak, and may therefore be deemed to be the beneficial owner of the shares purchased by ArcherOak in the Private Placement. The shares of common stock issuable upon exercise of the Warrants held by ArcherOak are subject to a beneficial ownership limitation of 19.99%.

- (5) Consists of 1,785,712 shares of common stock held by Armistice Capital Master Fund Ltd. a Cayman Islands exempted company (the “Master Fund”), of which (a) 714,285 are shares of common stock purchased in the Private Placement and (b) 1,071,427 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. 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 Warrants held by Armistice Capital are subject to a beneficial ownership limitation of 4.99%.
- (6) Consists of 53,570 shares of common stock held by BrightForge Management, LLC (“BrightForge”), of which (a) 21,428 are shares of common stock purchased in the Private Placement and (b) 32,142 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. The shares of common stock issuable upon exercise of the Warrants held by BrightForge are subject to a beneficial ownership limitation of 19.99%.
- (7) Consists of 1,250,000 shares of common stock held by Caligan Partners Master Fund LP, a Cayman Islands limited partnership (the “Caligan Fund”), and certain accounts (the “Caligan Accounts”) managed by Caligan Partners LP, a Delaware limited partnership (“Caligan”), of which (a) 500,000 are shares of common stock purchased in the Private Placement and (b) 750,000 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Caligan and David Johnson, the Managing Partner of Caligan and the Managing Member of Caligan Partners GP LLC (the general partner of Caligan), beneficially own the securities reported herein that are held by the Caligan Fund and the Caligan Accounts. The shares of common stock issuable upon exercise of the Warrants held by each of the Caligan Fund and the Caligan Accounts are subject to a beneficial ownership limitation of 4.99%.
- (8) Consists of 330,355 shares of common stock held by Gravitass Capital LP (“Gravitass”), of which (a) 132,142 are shares of common stock purchased in the Private Placement and (b) 198,213 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. The shares of common stock issuable upon exercise of the Warrants held by Gravitass are subject to a beneficial ownership limitation of 19.99%.
- (9) Consists of 366,187 shares of common stock held by Sarosca Farm LLC (“Sarosca”), of which (a) 26,902 are shares of common stock held prior to the Private Placement, (b) 135,714 are shares of common stock purchased in the Private Placement and (c) 203,571 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. 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 his pecuniary interest. The shares of common stock issuable upon exercise of the Warrants held by Sarosca are subject to a beneficial ownership limitation of 19.99%.
- (10) Consists of 714,285 shares of common stock held by Schonfeld Global Master Fund L.P. (“Schonfeld”), of which (a) 285,714 are shares of common stock purchased in the Private Placement and (b) 428,571 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. The shares of common stock issuable upon exercise of the Warrants held by Schonfeld are subject to a beneficial ownership limitation of 9.99%.
- (11) Consists of (i) 312,500 shares of common stock held by SDS Capital Partners II, LLC (“SDS”), of which (a) 125,000 are shares of common stock purchased in the Private Placement and (b) 187,500 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement and (ii) 36,712 shares of common stock held by SIRA Investments, LLC (“SIRA”), of which (a) 1,000 are shares of common stock held prior to the Private Placement, (b) 14,285 are shares of common stock purchased in the Private Placement and (c) 21,427 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Steve Derby and Simon Derby, Managing Members of SDS, may be deemed to have voting and investment power over the securities held by SDS. Simon Derby, Managing Member of SIRA, may be deemed to have voting and investment power over the securities held by SIRA. The shares of common stock issuable upon exercise of the Warrants held by each of SDS and SIRA are subject to a beneficial ownership limitation of 19.99%.
- (12) Consists of (i) 1,237,983 shares of common stock held by Sphera Biotech Master Fund LP (“Sphera Biotech”), of which (a) 23,698 are shares of common stock held prior to the Private Placement, (b) 485,714 are shares of common stock purchased in the Private Placement and (c) 728,571 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement and (ii) 220,209 shares of common stock held by Sphera Global Healthcare Master Fund (“Sphera Global” and together with Sphera Biotech, the “Sphera Funds”), of which (a) 5,924 are shares of common stock held prior to the Private Placement, (b) 85,714 are shares of common stock purchased in the Private Placement and (c) 128,571 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. 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 Warrants held by each of the Sphera Funds are subject to a beneficial ownership limitation of 9.99%.
- (13) Consists of (a) 119,412 shares of common stock held prior to the Private Placement, (b) 1,000,000 shares of common stock purchased in the Private Placement and (c) 1,151,933 shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. The shares of common stock issuable upon exercise of the Warrants held by Tang are subject to a beneficial ownership limitation of 9.99%. The “Shares of Common Stock Beneficially Owned prior to this Offering” exclude an aggregate of 348,067 shares issuable upon the exercise of the Warrants described above, which are not currently exercisable due to the beneficial ownership limitation of 9.99%. Kevin Tang is the sole manager of Tang Capital Management, LLC, which is the general partner of Tang Capital Partners, LP. Kevin Tang has a pecuniary interest in the shares beneficially held by Tang Capital Partners, LP.

- (14) Consists of 1,250,000 shares of common stock held by Velan Capital Master Fund, LP (“Velan Capital”), of which (a) 500,000 are shares of common stock purchased in the Private Placement and (b) 750,000 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Velan Capital Holdings LLC (“Velan GP”), as the general partner of Velan Capital, may be deemed to beneficially own the shares beneficially owned by Velan Capital. Velan Capital Investment Management LP (“Velan IM GP”), as the investment manager of Velan Capital, may be deemed to beneficially own the shares held by Velan Capital. Velan Capital Management LLC (“Velan IM GP”), as the general partner of Velan Capital, may be deemed to beneficially own the shares held by Velan Capital. Balaji Venkataraman, as a Managing Member of each of Velan GP and Velan IM GP, may be deemed to beneficially own the shares held by Velan Capital. Adam Morgan, as a Managing Member of each of Velan GP and Velan IM GP, may be deemed to beneficially own the shares held by Velan Capital. The shares of common stock issuable upon exercise of the Warrants held by Velan Capital are subject to a beneficial ownership limitation of 19.99%.
- (15) Consists of 357,142 shares of common stock held by Woodline Master Fund LP (“Woodline”), of which (a) 142,857 are shares of common stock purchased in the Private Placement and (b) 214,285 are shares of common stock issuable upon exercise of Warrants purchased in the Private Placement. Woodline Partners LP serves as the investment manager of Woodline Fund and may be deemed to be the beneficial owner of the shares. Woodline Partners LP disclaims any beneficial ownership of these shares. The shares of common stock issuable upon exercise of the Warrants held by Woodline are subject to a beneficial ownership limitation of 4.99%.

Certain Relationships and Related Party Transactions

As discussed in greater detail above under the section “Prospectus Summary—Private Placement,” on January 22, 2024, we entered into the Securities Purchase Agreement and Registration Rights Agreement with the selling stockholders pursuant to which, on March 18, 2024, we sold Shares and 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 Private Placement, GMS Ventures and Investments, affiliated with Yezan Haddadin and Faisal G. Sukhtian, directors of the Company, purchased Securities for an aggregate purchase price of approximately \$16.1 million. On January 22, 2024, we entered into the Syntone Purchase Agreement with Syntone, affiliated with Andong Huang, a director of the Company, whereby Syntone agreed to purchase shares of common stock and accompanying warrants for an aggregate purchase price of approximately \$5.0 million. The closing of the Syntone Private Placement remains subject to receipt of certain regulatory approvals. 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, 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](#), and [March 18, 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.

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	\$	22,994
Legal Fees and Expenses	\$	100,000
Accounting Fees and Expenses	\$	30,000
Miscellaneous	\$	25,000
Total	\$	177,994

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
3.1	<u>Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).</u>
3.2	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on December 6, 2018).</u>
3.3	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 18, 2019).</u>
3.4	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 26, 2021).</u>
3.5	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 30, 2023, as subsequently amended).</u>
3.6	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 7, 2024).</u>
3.7	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 18, 2024).</u>
3.8	<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>
4.1	<u>Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed with the SEC on January 24, 2024).</u>
4.2	<u>Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to the registrant's current report on Form 8-K filed with the SEC on January 24, 2024).</u>
4.3	<u>Form of Warrant (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K filed with the SEC on January 24, 2024).</u>
5.1	<u>Opinion of Cooley LLP.</u>
23.1	<u>Consent of independent registered public accounting firm.</u>
23.2	<u>Consent of Cooley LLP (included in legal opinion filed as Exhibit 5.1).</u>
24.1	<u>Power of Attorney (included on signature page).</u>
107	<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 March 25, 2024.

OUTLOOK THERAPEUTICS, INC.

By: /s/ C. Russell Trenary III
C. Russell Trenary III
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints C. Russell Trenary III and 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/ C. Russell Trenary III</u> C. Russell Trenary III	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 25, 2024
<u>/s/ Lawrence A. Kenyon</u> Lawrence A. Kenyon	Chief Financial Officer, Treasurer, Secretary and Director <i>(Principal Financial and Accounting Officer)</i>	March 25, 2024
<u>/s/ Ralph H. Thurman</u> Ralph H. Thurman	Executive Chairman	March 25, 2024
<u>/s/ Gerd Auffarth</u> Gerd Auffarth	Director	March 25, 2024
<u>/s/ Yezan Haddadin</u> Yezan Haddadin	Director	March 25, 2024
<u>/s/ Julia A. Haller</u> Julia A. Haller	Director	March 25, 2024
<u>/s/ Kurt J. Hilzinger</u> Kurt J. Hilzinger	Director	March 25, 2024
<u>/s/ Julian Gangolli</u> Julian Gangolli	Director	March 25, 2024

/s/ Andong Huang
Andong Huang

Director

March 25, 2024

/s/ Faisal G. Sukhtian
Faisal G. Sukhtian

Director

March 25, 2024



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

March 25, 2024

Outlook Therapeutics, Inc.
485 Route 1 South
Building F, Suite 320
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 21,428,556 shares of the common stock, \$0.01 par value (the "**Common Stock**"), of the Company consisting of (a) 8,571,423 (the "**Shares**") outstanding shares of Common Stock and (b) up to 12,857,133 shares of Common Stock (the "**Warrant Shares**") issuable upon the exercise of outstanding warrants (the "**Warrants**"). The Shares and the Warrants were issued by the Company pursuant to that certain Securities Purchase Agreement (the "**Purchase Agreement**") dated as of January 22, 2024.

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, the Purchase Agreement, 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 (i) the Shares are validly issued, fully paid and nonassessable, and (ii) 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 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 22, 2023, 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

March 25, 2024

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)	21,428,556	\$7.27	\$155,785,602	0.00014760	\$22,994
	Total Offering Amounts					\$155,785,602		\$22,994
	Total Fees Previously Paid							—
	Total Fee Offsets							—
	Net Fee Due							\$22,994

- (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 (i) 8,571,423 shares of common stock of the Registrant held by the selling stockholders and (ii) 12,857,133 shares of common stock of the Registrant issuable upon the exercise of 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 March 21, 2024.
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