



515,755 Shares of Common Stock

This prospectus relates to the offer and resale, from time to time, by the selling stockholder named under the heading “Selling Stockholder” in this prospectus, or its assigns (the “Selling Stockholder”) of up to 515,755 shares (the “Shares”) of our common stock, par value \$0.01 per share (“Common Stock”), issuable upon the exercise of placement agent warrants (the “Placement Agent Warrants”) issued to our placement agent, M.S. Howells & Co., pursuant to a letter agreement (the “Engagement Letter”), dated as of December 22, 2022, between us and M.S. Howells & Co. The Placement Agent Warrants were issued pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended (the “Securities Act”) provided in Section 4(a)(2) thereof and/or Rule 506 of Regulation D promulgated thereunder. We are registering the resale of the Shares of Common Stock underlying the Placement Agent Warrants covered by this prospectus pursuant to the registration rights granted to the Selling Stockholder pursuant to the Engagement Letter.

We will not receive any of the proceeds from the sale by the Selling Stockholder of the Common Stock pursuant to the Engagement Letter. Upon any exercise of the Placement Agent Warrants by payment of cash, however, we will receive the exercise price of the Placement Agent Warrants. We intend to use those proceeds, if any, for general corporate purposes.

Our registration of the Shares covered by this prospectus does not mean that the Selling Stockholder will offer or sell such Common Stock. The Selling Stockholder may sell the Shares covered by this prospectus in a number of different ways and at varying prices. For additional information on the possible methods of sale that may be used by the Selling Stockholder, you should refer to the section of this prospectus entitled “Plan of Distribution.” The Selling Stockholder may be deemed to be an “underwriter” within the meaning of the Securities Act, of the Shares that they are offering pursuant to this prospectus. The Selling Stockholder will bear all commissions and discounts, if any, attributable to its sales of the Shares hereunder. We will bear all costs, expenses and fees in connection with the registration of the Shares. We will not be paying any underwriting discounts or commissions in this offering.

A prospectus supplement may add, update, or change information contained in this prospectus. You should carefully read this prospectus, any applicable prospectus supplement, and the information incorporated by reference in this prospectus and any applicable prospectus supplement before you make your investment decision.

Our Common Stock is listed on The Nasdaq Capital Market under the trading symbol “OTLK.” On August 23, 2023, the last reported sale price of our Common Stock on The Nasdaq Capital Market was \$1.28 per share.

Investing in these securities involves certain risks. See “Risk Factors” on page 5 of this prospectus. See also “Risk Factors” in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.

Neither the Securities and Exchange Commission 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 August 25, 2023.

TABLE OF CONTENTS

	<u>Page</u>
<u>ABOUT THIS PROSPECTUS</u>	<u>1</u>
<u>PROSPECTUS SUMMARY</u>	<u>2</u>
<u>THE OFFERING</u>	<u>4</u>
<u>RISK FACTORS</u>	<u>5</u>
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>6</u>
<u>USE OF PROCEEDS</u>	<u>7</u>
<u>SELLING STOCKHOLDER</u>	<u>8</u>
<u>PLAN OF DISTRIBUTION</u>	<u>9</u>
<u>LEGAL MATTERS</u>	<u>11</u>
<u>EXPERTS</u>	<u>11</u>
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	<u>11</u>
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	<u>11</u>

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3, which we have filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration process, the Selling Stockholder may from time to time sell the Shares described in this prospectus in one or more offerings or otherwise as described under “Plan of Distribution.”

This prospectus may be supplemented from time to time by one or more prospectus supplements. Such prospectus supplements may also add, update or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you must rely on the information in the prospectus supplement. You should carefully read both this prospectus and any applicable prospectus supplement together with additional information described under the heading “Where You Can Find More Information” before deciding to invest in any Shares being offered.

Neither we nor the Selling Stockholder has authorized anyone to provide any information other than that contained or incorporated by reference in this prospectus or in any applicable prospectus supplement or any applicable free writing prospectus that we have authorized. If anyone provides, or has provided you, with different or inconsistent information, you should not rely on it. The Shares are not being offered in any jurisdiction where the offer is not permitted. You should not assume that the information contained in or incorporated by reference in this prospectus is accurate as of any date other than the respective dates of such document. Our business, financial condition, results of operations and prospects may have changed since those dates.

Unless the context otherwise indicates, references in this prospectus to, “Outlook,” “the Company,” “we,” “our,” or “us” mean Outlook Therapeutics, Inc. and its consolidated subsidiaries.

Our name “Outlook Therapeutics,” the Outlook Therapeutics logo, the Oncobiologics logo, LYTENAVA and other trademarks or service marks of Outlook Therapeutics, Inc. appearing in this prospectus and in any applicable prospectus supplement or any related free writing prospectus and the information incorporated by reference herein or therein are the property of Outlook Therapeutics, Inc. Other trademarks, service marks or trade names appearing in this prospectus, in any applicable prospectus supplement or free writing prospectus and the information incorporated by reference herein or therein are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

PROSPECTUS SUMMARY

This prospectus summary highlights certain information about us and selected information contained elsewhere in or incorporated by reference into this prospectus. This prospectus 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 the Company, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus and any applicable prospectus supplement or amendment, including the factors described under the heading “Risk Factors,” beginning on page 5 of this prospectus, as well as the information incorporated herein by reference, before making an investment decision.

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 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 potentially securing a strategic partner for the United Kingdom, Europe, Japan and other markets. If approved, we expect to receive 12 years of regulatory exclusivity in the United States and up to 10 years of regulatory 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. Following receipt of further correspondence from the FDA, we confirmed the additional information necessary to re-submit the BLA for ONS-5010 and resubmitted the BLA in August 2022. In October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. Additionally, 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 formal review process of the MAA by the EMA’s Committee for Medicinal Products for Human Use, or CHMP, has begun with an estimated decision date expected in 2024. ONS-5010 is our sole product candidate in active development.

Our BLA and MAA registration program 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 ($p = 0.0043$). 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 ($p = 0.05$) 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.

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.

Currently, the cancer drug Avastin (bevacizumab) is used off-label for the treatment of wet AMD and other retinal diseases such as DME and BRVO even though Avastin has not been approved by regulatory authorities for use in these diseases. In addition to our BLA submission in the United States, we have submitted an MAA for approval in Europe and plan to submit for regulatory approval in multiple other markets, including the United Kingdom and other major markets. Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted a standard BLA, and are not using the biosimilar drug 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. Off-label use of unapproved bevacizumab is currently estimated to account for approximately 50% of all wet AMD injections in the United States (approximately 3.5 million injections annually).

Private Placement

Pursuant to the Engagement Letter, we engaged M.S. Howells & Co. to act as placement agent with respect to certain accredited investors in a registered direct offering and agreed to issue to M.S. Howells & Co. the Placement Agent Warrants to purchase up to 515,755 shares of Common Stock, which will be exercisable commencing on December 28, 2023, at an exercise price of \$1.05 per share and will expire on December 28, 2025. None of the Shares issuable upon the exercise of the Placement Agent Warrants were initially registered under the Securities Act or any state securities laws, rather, we offered the securities in reliance on exemption from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof and Rule 506 of Regulation D under the Securities Act.

Corporate Information

We initially incorporated in January 2010 in New Jersey, in October 2015, we reincorporated in Delaware by merging with and into a Delaware corporation and 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 or any applicable prospectus supplement.

THE OFFERING

<i>Common Stock offered by the Selling Stockholder</i>	515,755 shares of Common Stock, issuable upon the exercise of the Placement Agent Warrants.
<i>Use of Proceeds</i>	We will not receive any of the proceeds from the sale of the Shares covered by this prospectus, except with respect to amounts received by us due to the exercise of any Placement Agent Warrants for cash. We intend to use the proceeds from the exercise of any Placement Agent Warrants for cash for support of our ONS-5010 development and commercialization, and working capital and general corporate purposes. See the section of this prospectus titled “Use of Proceeds.”
<i>Risk Factors</i>	Investing in our Common Stock involves a high degree of risk. For a discussion of factors to consider before deciding to invest in our Common Stock, you should carefully review and consider the “Risk Factors” section of this prospectus, as well as the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement or amendment.
<i>Nasdaq Capital Market Symbol</i>	OTLK

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. Before deciding whether to invest in our Common Stock, you should consider carefully the risks and uncertainties discussed in this section and under the sections titled “Risk Factors” contained in our most recent Annual Report on Form 10-K and in our subsequent Quarterly Reports on Form 10-Q for the quarterly periods ended subsequent to our filing of such Annual Report on Form 10-K, as well as any amendments or updates to our risk factors reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus, together with other information in this prospectus, the documents incorporated by reference, any prospectus supplement and any free writing prospectus that we may authorize. These risks and uncertainties are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us, or that we currently view as immaterial, may also impair our business. If any of the risks or uncertainties described in our SEC filings or any additional risks and uncertainties actually occur, our business, financial condition, results of operations and cash flow could be materially and adversely affected. In that case, the trading price of our Common Stock could decline and you might lose all or part of your investment. Please also read carefully the section titled “Special Note Regarding Forward-Looking Statements.”

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, and the documents incorporated by reference herein, contain, or will contain, “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. All statements, other than statements of historical facts contained in this prospectus, any applicable prospectus and the documents incorporated by reference herein and therein, 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,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “will,” the negative of terms like these or other comparable terminology. 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, and our expectations regarding our current cash resources;
- 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 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 any applicable prospectus supplement, in any free writing prospectuses we may authorize for use in connection with a specific offering, and in our most recent annual report on Form 10-K and in our subsequent Quarterly Reports on Form 10-Q for the quarterly periods ended subsequent to our filing of such Annual Report on Form 10-K, which are incorporated by reference into this prospectus in their entirety, as well as any amendments thereto reflected in subsequent filings with the SEC. Also, these 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 bearing out 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 herein and therein 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.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the Shares covered by this prospectus, except with respect to amounts received by us due to the exercise of the Placement Agent Warrants for cash. We intend to use the proceeds from the exercise of the Placement Agent Warrants for working capital and general corporate purposes, including in support of ONS-5010 development and commercialization.

SELLING STOCKHOLDER

The shares of Common Stock being offered by the Selling Stockholder are those issuable to the Selling Stockholder upon exercise of the Placement Agent Warrants. Pursuant to the Engagement Letter, in connection with a registered direct equity offering to certain institutional and accredited investors, we issued to M.S. Howells & Co., as placement agent, warrants to purchase up to an aggregate of 515,755 shares of Common Stock, which will be exercisable commencing on December 28, 2023, at an exercise price of \$1.05 per share and will expire on December 28, 2025.

The table below lists the Selling Stockholder and other information regarding the beneficial ownership of Common Stock by the Selling Stockholder. The second column lists the number of shares of Common Stock beneficially owned by the Selling Stockholder, based on its beneficial ownership of the Shares, as of August 11, 2023.

The information in the following table has been provided to us by or on behalf of the Selling Stockholder and the Selling Stockholder may have sold, transferred or otherwise disposed of all or a portion of their securities after the date on which they provided us with information regarding their securities. The Selling Stockholder may sell all, some or none of their Shares in this offering. See “Plan of Distribution.”

Selling Stockholders	Number of Shares Beneficially Owned Prior to this Offering ⁽¹⁾	Maximum Number of Shares to be Sold Pursuant in this Offering ⁽²⁾	Number of Shares Beneficially Owned After Offering	Percentage of Shares Owned After Offering
M.S. Howells & Co. ⁽³⁾	—	515,755	—	—%

* Represents beneficial ownership of less than one percent.

- (1) “Beneficial ownership” means that a person, directly or indirectly, has or shares voting or investment power with respect to a security or has the right to acquire such power within 60 days.
- (2) Assumes sale of all Shares covered by this prospectus and no further acquisitions of shares of Common Stock by the Selling Stockholder.
- (3) Consists of 515,755 shares of Common Stock issuable upon exercise of the Placement Agent Warrants. Mark S. Howells has the power to vote or dispose of the shares owned by M.S. Howells & Co. The Selling Stockholder’s address is 23350 North Pima Road, Scottsdale, Arizona 85255.

PLAN OF DISTRIBUTION

The Selling Stockholder, which includes any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their Shares covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the Common Stock is 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 the Shares:

- 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;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- 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 supplements to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholder may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholder may also 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 that we incur incident to the registration of the Shares covered by this prospectus.

The resale 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 resale 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 resale 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 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).

LEGAL MATTERS

The validity of the shares of Common Stock to be offered for resale by the Selling Stockholder under this prospectus will be passed upon for us by Cooley LLP, Chicago, Illinois.

EXPERTS

The consolidated financial statements of Outlook Therapeutics, Inc. as of September 30, 2022 and 2021, 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, 2022 consolidated financial statements contains an explanatory paragraph that states that we have 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.

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, 2022, filed with the SEC on December 29, 2022](#) and as [amended on January 24, 2023, or the 2022 Form 10-K](#);
- Our Quarterly Reports on Form 10-Q for the fiscal quarters ended December 31, 2022, March 31, 2023, and June 30, 2023 filed with the SEC on [February 14, 2023](#), [May 15, 2023](#), and [August 14, 2023](#) respectively;
- Our Current Reports and amendments thereto, as applicable, on Form 8-K filed with the SEC on [November 23, 2022](#), [December 22, 2022](#), [December 23, 2022](#), [March 30, 2023](#), [April 3, 2023](#) and [May 16, 2023](#), 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 2022 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, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the common stock made by this prospectus and will become a part of this prospectus from the date that such documents are filed with the SEC. 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.



515,755 Shares of Common Stock

PROSPECTUS

August 25, 2023
