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: Yvan-Claude Pierre Courtney M.W. Tygesson Cooley LLP 110 N. Wacker, Suite 4200 Chicago, Illinois 60606 (312) 881-6500

Approximate date of commencement of proposed sale to the public	From time to time after the effective date of this Registration Statemen	ıt.
If the only securities being registered on this Form are being offe following box. \Box	red pursuant to dividend or interest reinvestment plans, please check the	j
If any of the securities being registered on this Form are to be off Act of 1933, other than securities offered only in connection with divid	ered on a delayed or continuous basis pursuant to Rule 415 under the Selend or interest reinvestment plans, check the following box. \Box	ecurities
If this Form is filed to register additional securities for an offerin box and list the Securities Act registration statement number of the ear	g pursuant to Rule 462(b) under the Securities Act, please check the follier effective registration statement for the same offering. \Box	lowing
If this Form is a post-effective amendment filed pursuant to Rule Act registration statement number of the earlier effective registration s	462(c) under the Securities Act, check the following box and list the Securities at the same offering. \square	curities
	tion I.D. or a post-effective amendment thereto that shall become effective	tive upo
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	ed filer, an accelerated filer, a non-accelerated filer, a smaller reporting accelerated filer," "accelerated filer," "smaller reporting company" and	ĺ
Large accelerated filer □	Accelerated filer	
Non-accelerated filer ⊠	Smaller reporting company	\times
	Emerging growth company	
If an emerging growth company, indicate by check mark if the re-	gistrant has elected not to use the extended transition period for comply	ing with
any new or revised financial accounting standards provided pursuant to	Section 13(a) of the Exchange 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.

Subject to completion, Preliminary Prospectus dated August 14, 2023



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 9, 2023, the last reported sale price of our Common Stock on The Nasdaq Capital Market was \$1.64 per share.

Investing in these securities involves certain risks. See "Risk Factors" on page $\underline{5}$ 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.

TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	<u>1</u>
PROSPECTUS SUMMARY	<u>2</u>
THE OFFERING	<u>4</u>
RISK FACTORS	<u>5</u>
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	<u>6</u>
<u>USE OF PROCEEDS</u>	<u>7</u>
SELLING STOCKHOLDER	<u>8</u>
PLAN OF DISTRIBUTION	<u>9</u>
<u>LEGAL MATTERS</u>	<u>11</u>
<u>EXPERTS</u>	<u>11</u>
WHERE YOU CAN FIND ADDITIONAL INFORMATION	<u>11</u>
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	<u>11</u>
PART II INFORMATION NOT REQUIRED IN PROSPECTUS	<u>II-1</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

ONS-5010 subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA \geq 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 \geq 10 letters of vision and 68.5% (p = 0.0116) of ONS-5010 subjects gaining \geq 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

Common Stock offered by the Selling Stockholder

515,755 shares of Common Stock, issuable upon the exercise of the Placement Agent Warrants.

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 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."

Risk FactorsInvesting 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.

Nasdaq Capital Market Symbol

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."

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

^{*} Represents beneficial ownership of less than one percent.

^{(1) &}quot;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 <u>February 14, 2023</u>, <u>May 15, 2023</u>, and <u>August 14, 2023</u> 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 <u>April 29, 2016</u>, as amended on <u>May 11, 2016</u>, including any further amendments thereto
or reports filed for the purposes of updating this description, including <u>Exhibit 4.1 of the 2022 Form</u>
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

, 2023

PART II INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an estimate of the fees and expenses payable by the registrant in connection with the issuance and distribution of the securities being registered. All amounts shown are estimated except for the SEC registration fee.

SEC registration fee	\$	93
Legal fees and expenses	\$30,	.000
Accounting fees and expenses	\$12,	000
Miscellaneous	\$ 2,	,000
Total	\$44,	093

Item 15. Indemnification of Officers and Directors

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 amended and 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, or the Securities Act, 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. Exhibits.

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

Exhibit Number	Description
3.1	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).
3.2	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).
3.3	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).

Exhibit Number	Description
3.4	Certificate of Amendment of 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 26, 2021).
3.5	Certificate of Amendment of 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 30, 2023)
3.6	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).
4.1	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 December 23, 2022).
5.1	Opinion of Cooley LLP
10.1	Letter Agreement, dated December 22, 2022 by and between the Company and M.S. Howells & Co. (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2022).
23.1	Consent of KPMG LLP, independent registered public accounting firm.
23.2	Consent of Cooley LLP (including in Exhibit 5.1).
24.1	Power of Attorney (see signature page to this registration statement).
107	Filing Fee Table

Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (a) 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 of 1933;
 - (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 Commission 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 Registration Fee" table in the effective registration statement; and
 - (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)(i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 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.

- (b) That, for the purpose of determining any liability under the Securities Act of 1933, 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.
- (c) 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.

- (d) That, for the purpose of determining liability under the Securities Act of 1933 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 of 1933 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 that 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.
- (e) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (f) That, for the purpose of determining liability of the registrant under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.
- (g) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Trust Indenture Act.
- (h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Securities and Exchange Commission 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 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 Chicago, Illinois, on August 14, 2023.

OUTLOOK THERAPEUTICS, INC.

By: /s/ C. Russell Trenary III

Name: C. Russell Trenary III

Title: 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, their true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for them and in their 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

Signature	Title	Date
/s/ Ralph H. Thurman Ralph H. Thurman	Executive Chairman	August 14, 2023
/s/ C. Russell Trenary III C. Russell Trenary III	President, Chief Executive Officer and Director (Principal Executive Officer)	August 14, 2023
/s/ Lawrence A. Kenyon Lawrence A. Kenyon	Chief Financial Officer, Treasurer, Secretary and Director (<i>Principal Financial and Accounting Officer</i>)	August 14, 2023
/s/ Gerd Auffarth Gerd Auffarth	Director	August 14, 2023
/s/ Yezan Haddadin Yezan Haddadin	Director	August 14, 2023
/s/ Kurt J. Hilzinger Kurt J. Hilzinger	Director	August 14, 2023

Signature	Title	Date
/s/ Julian Gangolli Julian Gangolli	Director	August 14, 2023
/s/ Andong Huang Andong Huang	Director	August 14, 2023
/s/ Faisal G. Sukhtian Faisal G. Sukhtian	Director	August 14, 2023
/s/ Julia A. Haller Julia A. Haller	Director	August 14, 2023



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

August 14, 2023

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 of a Registration Statement on Form S-3 (the "*Registration Statement*") with the Securities and Exchange Commission (the "*Commission*") covering the resale by a certain selling stockholder of up to 515,755 shares (the "*Shares*") of the Company's common stock, par value \$0.01 per share ("*Common Stock*"), issuable upon the exercise of certain warrants (the "*Warrants*"). The Warrants were issued to M.S. Howells & Co. (the "*Placement Agent*"), pursuant to a letter agreement (the "*Engagement Letter*"), dated December 22, 2022, between the Company and the Placement Agent.

In connection with this opinion, we have examined and relied upon the Registration Statement and related prospectus, the Company's certificate of incorporation and bylaws, each as currently in effect, the Engagement Letter, the Warrants and such other documents, records, certificates, memoranda and other 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 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 atter 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 Shares, we express no opinion to the extent that future issuances of securities of the Company, adjustments to outstanding securities of the Company and/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 the exercise price of the Warrants will not be adjusted to an amount below the par value per share of the Common Stock.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares issuable upon conversion or exercise of the Warrants, when issued 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



Outlook Therapeutics, Inc. August 14, 2023 Page Two

We hereby consent to the reference to our firm under the caption "Legal Matters" in the prospectus included in the Registration Statement 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 of 1933, as amended, or the rules and regulations of the Commission thereunder.

Very truly yours,

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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 29, 2022, 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 August 14, 2023

Calculation of Filing Fee Tables

S-3 (Form Type)

Outlook Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

			Fee		Proposed			
			Calculation		Maximum			
			or Carry	Amount	Offering	Aggregate		Amount of
	Security	Security Class	Forward	Registered	Price Per	Offering		Registration
	Type	Title	Rule	(1)	Unit	Price(3)	Fee Rate	Fee
Fees to Be Paid		Common stock,						
		par value \$0.01		515,755				
	Equity	per share	Rule 457(c)	(2)	\$1.63	\$840,680.65	0.0001102	\$92.64
		Total Offerin	g Amounts			\$840,680.65		\$92.64
	Total Fees Previously Paid						_	
	Total Fee Offsets						_	
		Net Fe	e Due					\$92.64

- (1) Represents the shares of common stock, \$0.01 par value per share (the "Common Stock"), of Outlook Therapeutics, Inc. (the "Registrant") that will be offered for resale by the selling stockholders pursuant to the registration statement to which this exhibit is attached. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the shares being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable as a result of stock splits, stock dividends or similar transactions with respect to the shares being registered hereunder.
- (2) Consists of an aggregate of 515,755 shares of the Registrant's Common Stock issuable upon the exercise of placement agent warrants.
- (3) This estimate is made pursuant to Rule 457(c) of the Securities Act solely for purposes of calculating the registration fee. The price per share and aggregate offering price are based upon the average of the high and low prices of the Registrant's common stock on August 8, 2023, as reported on The Nasdaq Capital Market.