

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

Amendment No. 2
To
FORM S-1
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)

2836
(Primary Standard Industrial
Classification Code Number)

38-3982704
(I.R.S. Employer Identification No.)

**7 Clarke Drive
Cranbury, New Jersey 08512
(609) 619-3990**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Lawrence A. Kenyon
President, Chief Executive Officer and Chief Financial Officer
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that 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 Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 19, 2019

PROSPECTUS

7,062,146 Shares



Common Stock

We are offering \$50.0 million of our shares of common stock in this offering.

Our common stock is listed on The Nasdaq Capital Market, or Nasdaq, under the symbol "OTLK." On March 18, 2019, the last reported sale price of our common stock on Nasdaq was \$7.08 per share. The public offering price per share will be determined between us, the underwriters and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the recent market price used throughout this prospectus may not be indicative of the actual public offering price.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 5.

We are an "emerging growth company" under the federal securities laws and are subject to reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Price to the public	\$	\$
Underwriting discount ⁽¹⁾	\$	\$
Proceeds to us (before expenses)	\$	\$

(1) See "Underwriting" beginning on page 24 for additional information regarding the compensation payable to the underwriters.

We have also granted an option to the underwriters to purchase up to 1,059,321 additional shares on the same terms and conditions set forth above from us within 30 days after the date of this prospectus to cover over-allotments.

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

Delivery of the shares of common stock is expected to be made on or about _____, 2019.

Sole Book-Running Manager

Oppenheimer & Co.

Co-Manager

Aegis Capital Corp.

The date of this prospectus is _____, 2019

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

Our name “Outlook Therapeutics,” the Outlook Therapeutics logo and other trademarks or service marks of Outlook Therapeutics, Inc. appearing in this prospectus are the property of Outlook Therapeutics, Inc. Other trademarks, service marks or trade names appearing in this prospectus 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 summary highlights information contained elsewhere or incorporated by reference in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, especially the section titled “Risk Factors” and our consolidated financial statements and related notes included elsewhere or incorporated by reference in this prospectus and under similar titles in documents that we incorporate by reference to this prospectus, before making an investment decision. Except as otherwise indicated or unless the context otherwise requires, references to “company,” “we,” “us,” “our” or “Outlook Therapeutics,” refer to Outlook Therapeutics, Inc. and its consolidated subsidiaries.

Company Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing ONS-5010, a complex, technically challenging and commercially attractive monoclonal antibody, or mAb, for various ophthalmic indications. Our goal is to launch ONS-5010 as the first, and only, approved bevacizumab in the United States, Europe, Japan and other markets for the treatment of wet age related macular degeneration, or wet AMD, diabetic macular edema, or DME, and branch retinal vein occlusion, or BRVO.

ONS-5010 is an innovative mAb therapeutic product candidate currently enrolling patients in a Phase 3 clinical trial (ONS-5010-001) in Australia designed to serve as the first of two adequate and well controlled clinical trials evaluating ONS-5010 against ranibizumab (Lucentis) for wet AMD. Enrollment in ONS-5010-001 is approximately 75% complete. The second of the two Phase 3 clinical trials (ONS-5010-002) has been initiated in Australia and is expected to begin enrolling patients in Australia and New Zealand in March 2019. We submitted an investigational new drug, or IND, application with the U.S. Food and Drug Administration, or FDA, in the first quarter of calendar year 2019, and expect to begin enrolling patients in the U.S. portion of ONS-5010-002 in April 2019. The ONS-5010-002 study is expected to enroll a total of at least 180 patients. Our ONS-5010 clinical program was reviewed at a successful end-of-Phase 2 meeting with the FDA conducted in 2018. We currently plan to meet with European regulatory agencies in the second quarter of 2019, and other foreign regulatory agencies in the second half of 2019. If the program is successful, it will support our plans to submit for regulatory approval in multiple markets in 2020 including the United States, Europe and Japan. Because there are no approved bevacizumab products for the treatment of retinal diseases in such major markets, we are developing ONS-5010 as an innovative therapy and not using the biosimilar drug development pathway. If approved, we believe ONS-5010 has potential to mitigate risks associated with off-label use of Avastin or other drugs. Off-label use of Avastin is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

Separately, we have licensed the emerging markets rights to third parties for development in those markets for two biosimilar product candidates: ONS-3010, a biosimilar to adalimumab (Humira), and ONS-1045, a biosimilar to bevacizumab (Avastin). We do not plan to further advance ONS-3010 and ONS-1045 in major markets, including the United States. At this time, ONS-5010 is our only product candidate in active development.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled “Risk Factors” herein and in the documents incorporated by reference herein.

Additional Information

For additional information related to our business and operations, please refer to the reports incorporated herein by reference, including our Annual Report on Form 10-K for the year ended September 30, 2018 as filed with the SEC on December 18, 2018, our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018 as filed with the SEC on February 14, 2018 and our Current Reports on Form 8-K as filed with the SEC, as described in the section titled “Incorporation of Documents by Reference.”

Implications of Being an Emerging Growth Company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and we may remain an emerging company for up to five years from the closing of our IPO in May 2016. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

Our Corporate Information

We initially incorporated in January 2010 in New Jersey as Oncobiologics, Inc., and in October 2015, we reincorporated in Delaware by merging with and into a Delaware corporation. In November 2018, we changed our name to Outlook Therapeutics, Inc. Our headquarters are located at 7 Clarke Drive, Cranbury, New Jersey, 08512, and our telephone number at that location is (609) 619-3990. Our website address is www.outlooktherapeutics.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this prospectus.

The Offering

Common stock offered by us	7,062,146 shares (8,121,467 shares if the underwriters exercise their over-allotment option in full) (assuming the sale of \$50.0 million of our shares of common stock at an assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019)
Common stock to be outstanding after this offering	18,821,168 shares (assuming the sale of \$50.0 million of our shares of common stock at an assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019)
Use of proceeds	<p>We intend to use the net proceeds from this offering, together with our existing cash resources as follows:</p> <ul style="list-style-type: none"> • approximately \$30.0 million to fund the Phase 3 clinical trials of ONS-5010 for wet AMD, DME and BRVO; • up to approximately \$8.6 million to repay outstanding principal and accrued interest on our 5% senior secured notes due June 2019 as required by the terms of a November 2018 amendment, which notes are currently convertible at the option of the holders and have an aggregate outstanding principal and accrued interest balance of approximately \$8.6 million as of the date of this prospectus; and • the remainder for general corporate purposes and funding our working capital needs. <p>Based on our planned use of the net proceeds from this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to enable us to complete our Phase 3 clinical trial of ONS-5010 for wet AMD, but we will require additional capital to complete the regulatory approval process and commercialize ONS-5010 for wet AMD, and complete the Phase 3 clinical trials for ONS-5010 in other indications. See “Use of Proceeds.”</p>
Risk Factors	An investment in our common stock involves a high degree of risk. See the section titled “Risk Factors” beginning on page 5 of this prospectus and the similarly titled sections in the documents incorporated by reference into this prospectus.
Nasdaq Capital Market symbol	“OTLK”
	<p>The number of shares of common stock outstanding after the offering is based on 11,759,022 shares of common stock outstanding as of December 31, 2018 on pro forma basis consisting of (i) 10,636,473 shares of common stock outstanding as of December 31, 2018, (ii) the issuance of an aggregate of 1,072,156 shares of common stock in January and February 2019 to BioLexis Pte. Ltd., or BioLexis, pursuant to our November 2018 private placement, and (iii) the issuance of an aggregate of 50,393 shares of common stock in February and March 2019 upon conversion of an aggregate \$0.5 million principal amount of our senior secured notes; and excludes, as of that date, the following:</p> <ul style="list-style-type: none"> • 16,136 shares of common stock issuable upon the exercise of outstanding performance-based stock unit awards, or PSUs, whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of \$49.99;

- 7,457 shares of common stock issuable upon vesting of outstanding restricted stock unit awards, or RSUs, granted under our 2015 Equity Incentive Plan, or the 2015 Plan, with a weighted-average grant date fair value of \$155.28;
- 386,247 shares of common stock issuable upon exercise of outstanding stock options granted under the 2015 Plan with a weighted-average exercise price of \$7.16, plus an additional 350,000 shares issuable upon exercise of stock options granted under the 2015 Plan on February 19, 2019;
- 490,767 shares of common stock reserved for future issuance under the 2015 Plan (1,126,136 after the reduction of 350,000 shares for stock options granted under the 2015 Plan on February 19, 2019), plus an additional 319,094 shares reserved for future issuance as of January 1, 2019, as well as any future automatic increases in the number of shares of common stock reserved for future issuance under the 2015 Plan;
- 68,145 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, or the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP;
- 5,661,015 shares of common stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of \$8.11 per share;
- 955,927 shares of common stock issuable upon the conversion of outstanding senior secured notes having an aggregate principal amount of \$8.6 million as of March 19, 2019;
- 145,221 shares of common stock issuable upon conversion of outstanding principal and accrued interest on unsecured notes having an aggregate principal amount of \$1.0 million as of March 19, 2019;
- 1,166,156 shares of common stock issuable upon conversion of the 61,708 outstanding shares of our Series A-1 Convertible preferred stock, as well as any future shares of common stock issuable upon conversion of additional shares of Series A-1 Convertible preferred stock that may be issued as payment-in-kind dividends thereon in accordance with their terms;

Except as otherwise indicated herein, all information in this prospectus, including the number of shares of common stock that will be outstanding after this offering, reflects:

- a 1-for-8 reverse stock split of our common stock effected March 15, 2019;
- the issuance of an aggregate of 1,072,156 shares of common stock in January and February 2019 to BioLexis Pte. Ltd., or BioLexis, pursuant to the November 2018 private placement;
- the issuance of an aggregate of 50,393 shares of common stock in February and March 2019 upon conversion of an aggregate \$0.5 million principal amount of senior secured notes;
- no exercise of outstanding options or warrants, or conversion of notes, or settlement of PSUs or RSUs in shares of stock, in each case listed above; and
- no exercise by the underwriters of their over-allotment option to purchase additional shares.

Abandoned Private Offering

Prior to the offering to which this prospectus relates, we commenced and abandoned a private offering in which we sought to raise up to approximately \$50.0 million in proceeds from the sale of securities to fund our Phase 3 clinical trials of ONS-5010 for wet AMD, DME and BRVO, to repay outstanding principal and accrued interest on our 5% senior secured notes and the remainder for working capital and general corporate purposes. The private placement was being contemplated in reliance upon the exemption from registration available under Rule 506 of Regulation D of the Securities Act of 1933, as amended, or the Securities Act. The private offering was made solely to persons or entities whom we and Oppenheimer & Co. Inc., in its capacity as placement agent, believed to be “accredited investors,” as such term is defined in Regulation D under the Securities Act. We abandoned the private offering on or about February 20, 2019 and all offering activity in connection therewith was terminated. We did not accept any offers to buy or indications of interest in the private offering. This prospectus supersedes any offering materials used in the private offering.

Risk Factors

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties discussed under the heading “Risk Factors” contained in our Annual Report on Form 10-K for the year ended September 30, 2018 as filed with the SEC, and as incorporated by reference herein, and as the same may be amended, supplemented or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference herein. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Please also read carefully the section below titled “Special Note Regarding Forward-Looking Statements.”

Risks Related to this Offering and Ownership of Our Securities

If you purchase securities in this offering, you will suffer immediate dilution of your investment. You will experience further dilution if we issue additional equity securities in future financing transactions.

Because the public offering price per share of our common stock is higher than the net tangible book value per share of our common stock, you will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Investors purchasing shares of common stock in this offering will incur immediate dilution of approximately \$5.65 per share, assuming the sale of \$50.0 million of shares of our common stock at an assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019. In addition, we have a significant number of stock options and warrants outstanding, as well as outstanding preferred stock and senior secured notes that are convertible into shares of our common stock. To the extent that such outstanding securities are exercised or converted into shares of our common stock, investors purchasing our common stock in this offering may experience further dilution.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders or result in downward pressure on the price of our common stock. See the section titled “Dilution” for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

Our management will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in investment-grade, interest-bearing securities. These investments may not yield a favorable return to our securityholders.

Our independent registered public accounting firm has indicated that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern.

As described in their audit report, our auditors have included an explanatory paragraph that states that we have incurred recurring losses and negative cash flows from operations and have an accumulated deficit at September 30, 2018 of \$216.3 million, \$13.5 million of senior secured notes that may become due in fiscal 2019 and \$4.6 million of unsecured indebtedness, \$1.0 million of which is due on demand, and \$3.6 million of which matured December 22, 2018. These matters raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot continue as a viable entity, our securityholders may lose some or all of their investment in our company. As of December 31, 2018, we had an accumulated deficit of

\$229.7 million, and indebtedness that included \$10.4 million of senior secured notes that may become due in fiscal 2019 and \$4.6 million of unsecured notes, all of which was due on demand as of such date.

BioLexis has beneficial ownership of a significant percentage of our common stock, has the right to designate a majority of our board of directors, and is able to exert significant control over matters subject to stockholder approval, preventing new investors from influencing significant corporate decisions.

BioLexis beneficially owns 14,045,320 shares of our common stock as of February 15, 2019, which includes 1,166,156 shares of common stock issuable upon conversion of 61,708 shares of Series A-1 Convertible preferred stock and 4,657,852 shares of common stock issuable upon exercise of outstanding warrants. Accordingly, BioLexis currently beneficially owns approximately 80.1% of our common stock and controls approximately 72.9% of our outstanding voting power. The Series A-1 Convertible preferred stock accrues quarterly dividends at a rate of 10.0%, which are payable at our option in additional shares of voting Series A-1 Convertible preferred stock. Under an investor rights agreement, as amended, with BioLexis, BioLexis also currently has the power to designate a majority of our board of directors, and four of our eight board members were designated by BioLexis. BioLexis' interests may not coincide with the interests of other securityholders. BioLexis has the ability to influence our company through both its ownership position and control of our board of directors, which may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may believe are in your best interest as one of our securityholders.

Special Note Regarding Forward-Looking Statements

This prospectus and the documents incorporated by reference contain forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus and the documents incorporated by reference, 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 forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “potential,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” contained in our Annual Report on Form 10-K for the year ended September 30, 2018 as filed with the SEC and incorporated by reference herein, as the same may be amended, supplemented or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus, regarding, among other things:

- the timing and the success of the design of the clinical trials and planned clinical trials of our lead product candidate, ONS-5010;
- 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 if we successfully complete clinical trials;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved, for commercial use;
- our ability to fund our working capital requirements;
- the rate and degree of market acceptance of our current and future product candidates;
- 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; and
- the factors that may impact our financial results.

These risks are not exhaustive. Other sections of this prospectus or the documents incorporated by reference may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus or to conform these statements to actual results or to changes in our expectations.

You should carefully read this prospectus, together with the information incorporated herein by reference as described under the heading “Incorporation of Documents by Reference,” and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Use of Proceeds

We estimate that the net proceeds from this offering will be approximately \$46.2 million (or approximately \$53.2 million if the underwriters exercise their over-allotment option in full), assuming the sale of \$50.0 million of shares of our common stock at a public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019, after deducting the underwriting discount and estimated offering expenses payable by us.

A \$0.25 increase (decrease) in the assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019, would increase (decrease) the net proceeds to us from this offering by approximately \$1.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discount and estimated offering expenses payable by us. We may also increase (decrease) the number of shares we are offering. An increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering by approximately \$6.6 million, assuming the assumed public offering price stays the same, and after deducting the underwriting discount.

We intend to use the net proceeds from this offering, together with our existing cash resources as follows:

- approximately \$30.0 million to fund the Phase 3 clinical trials of ONS-5010 for wet AMD, DME and BRVO;
- up to approximately \$8.6 million to repay outstanding principal and accrued interest on our 5% senior secured notes due June 2019 as required by the terms of a November 2018 amendment, which notes are currently convertible at the option of the holders and have an aggregate outstanding principal and accrued interest balance of approximately \$8.6 million as of the date of this prospectus; and
- the remainder for general corporate purposes and funding our working capital needs.

Based on our planned use of the net proceeds from this offering and our existing cash resources, we estimate that such funds will be sufficient to enable us to complete our Phase 3 clinical trial of ONS-5010 for wet AMD, but we will require additional capital to complete the regulatory approval process and commercialize ONS-5010 for wet AMD, and complete the Phase 3 clinical trials for ONS-5010 in other indications.

However, due to the uncertainties inherent in the product development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions and the amount of cash obtained through current and any future collaborations.

We anticipate that our existing cash and the net proceeds from this offering will be sufficient to fund our planned operations until September 2020. We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes. Pending the use of the proceeds from this offering as described above, we intend to invest the net proceeds in interest-bearing investment-grade securities or government securities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our outstanding senior secured notes restrict our ability to pay dividends. The terms of our Series A-1 Convertible preferred stock may also act to limit our ability to pay dividends as we may not declare or pay any dividends on our common stock unless we also concurrently declare and set aside for payment or distribution, as applicable, participating dividends for our Series A-1 Convertible preferred stock.

Capitalization

The following table sets forth our cash and capitalization as of December 31, 2018 on:

- an actual basis;
- a pro forma basis to reflect (i) the issuance of an aggregate of 1,072,156 shares of common stock to BioLexis for \$8.0 million of cash proceeds in January and February 2019, (ii) the issuance of an aggregate of 50,393 shares of common stock upon conversion of \$0.5 million aggregate principal amount of senior secured notes in February and March 2019; and (iii) the cash repayment of approximately \$1.5 million of aggregate principal amount and accrued interest on our senior secured notes in February 2019; and
- a pro forma as adjusted basis to give effect to (i) the assumed sale of 7,062,146 shares of common stock in this offering at an assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019, and after deducting the underwriting discount and estimated offering expenses payable by us, and (ii) the assumed repayment of up to approximately \$8.6 million outstanding principal and accrued interest on our 5% senior secured notes due June 2019, net of \$1.3 million of unamortized debt issuance costs.

You should read this table together with our consolidated financial statements and the related notes and the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended September 30, 2018 and our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018, each of which are filed with the SEC and incorporated by reference herein.

	As of December 31, 2018		
	Actual	Pro Forma	Pro Forma As Adjusted ⁽¹⁾
Cash	\$ 227,716	\$ 6,722,170	\$ 44,352,876 ⁽²⁾
Debt obligations, current and long term	13,814,108	11,928,533	4,755,988 ⁽³⁾
Convertible preferred stock:			
Series A-1 convertible preferred stock, par value \$0.01 per share; 200,000 shares authorized, 61,708 shares issued and outstanding actual, pro forma and pro forma as adjusted	4,884,924	4,884,924	4,884,924
Stockholders’ equity (deficit):			
Common stock, par value \$0.01 per share; 200,000,000 shares authorized and 10,636,473 shares issued and outstanding, actual; 11,759,022 shares issued and outstanding, pro forma; and 18,821,168 shares issued and outstanding, pro forma as adjusted	106,365	117,590	188,212
Additional paid-in capital	203,237,836	211,628,579	257,747,957
Accumulated deficit	(229,698,465)	(229,698,465)	(230,986,091) ⁽⁴⁾
Total stockholders’ equity (deficit)	(26,354,264)	(17,952,296)	26,950,078
Total capitalization	\$ (7,655,232)	\$ (1,138,839)	\$ 36,590,990

(1) A \$0.25 increase (decrease) in the assumed public offering price per share would increase (decrease) the pro forma as adjusted amount of cash, total stockholders’ equity and total capitalization by approximately \$1.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discount and estimated offering expenses payable by us. We may also increase (decrease) the number of shares we are offering. An increase (decrease) of 1.0 million in the number of shares offered by us would increase (decrease) the pro forma as adjusted amount of cash, total stockholders’ equity and total capitalization by approximately \$6.6 million, assuming the assumed public offering price remains the same, and after deducting the underwriting discount.

(2) Reflects repayment of \$8.6 million of principal and \$0.1 million of accrued interest on our senior secured notes.

(3) Reflects repayment of up to approximately \$8.6 million of principal and accrued interest on our 5% senior secured notes, net of \$1.3 million unamortized debt issuance costs.

(4) Adjusted to reflect \$1.3 million write-off of unamortized debt issuance costs.

The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined between us and the underwriters at pricing.

The table above is based on 11,759,022 shares of common stock outstanding as of December 31, 2018 on pro forma basis consisting of (i) 10,636,473 shares of common stock outstanding as of December 31, 2018, (ii) the issuance of an aggregate of 1,072,156 shares of common stock in January and February 2019 to BioLexis pursuant to our November 2018 private placement, and (iii) the issuance of an aggregate of 50,393 shares of common stock in February and March 2019 upon conversion of an aggregate \$0.5 million principal amount of our senior secured notes; and excludes the following:

- 16,136 shares of common stock issuable upon the exercise of outstanding performance-based stock unit awards, or PSUs, whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of \$49.99;
- 7,457 shares of common stock issuable upon vesting of outstanding restricted stock unit awards, or RSUs, granted under the 2015 Plan with a weighted average grant date fair value of \$155.28;
- 386,247 shares of common stock issuable upon exercise of outstanding stock options granted under the 2015 Plan with a weighted-average exercise price of \$7.16, plus an additional 350,000 shares issuable upon exercise of stock options granted under the 2015 Plan on February 19, 2019;
- 490,767 shares of common stock reserved for future issuance under the 2015 Plan (140,767 after the reduction of 350,000 shares for stock options granted under the 2015 Plan on February 19, 2019), plus an additional 319,094 shares reserved for future issuance as of January 1, 2019, as well as any future automatic increases in the number of shares of common stock reserved for future issuance under the 2015 Plan;
- 68,145 shares of common stock reserved for future issuance under the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP;
- 5,661,015 shares of common stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of \$8.11 per share;
- 955,927 shares of common stock issuable upon the conversion of outstanding senior secured notes having an aggregate principal amount of \$8.6 million as of March 19, 2019;
- 145,221 shares of common stock issuable upon conversion of outstanding principal and accrued interest on unsecured notes having an aggregate principal amount of \$1.0 million as of March 19, 2019;
- 1,166,156 shares of common stock issuable upon conversion of the 61,708 outstanding shares of our Series A-1 Convertible preferred stock, as well as any future shares of common stock issuable upon conversion of additional shares of Series A-1 Convertible preferred stock that may be issued as payment-in-kind dividends thereon in accordance with their terms.

Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our pro forma net tangible book deficit as of December 31, 2018 was \$18.0 million, or \$(1.53) per share of our common stock, based on the total number of shares of our common stock outstanding as of December 31, 2018. Pro forma net tangible book deficit per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of December 31, 2018, after giving effect to (i) the issuance of an aggregate of 1,072,156 shares of common stock to BioLexis for \$8.0 million in January and February 2019, (ii) the issuance of an aggregate of 50,393 shares of common stock upon conversion of \$0.5 million aggregate principal amount of senior secured notes in February and March 2019; and (iii) the cash repayment of approximately \$1.5 million of aggregate principal amount and accrued interest on our senior secured notes in February 2019;

After giving effect to (i) the issuance and assumed sale of 7,062,146 shares of our common stock in this offering at an assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019, and after deducting the underwriting discount and estimated offering expenses payable by us, and (ii) the assumed repayment of up to approximately \$8.6 million outstanding principal and accrued interest on our 5% senior secured notes due June 2019, net of \$1.3 million of unamortized debt issuance costs, our pro forma as adjusted net tangible book value as of December 31, 2018 would have been \$27.0 million, or \$1.43 per share. This represents an immediate increase in pro forma net tangible book value per share of \$2.96 to existing stockholders and immediate dilution of \$5.65 per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share	\$7.08
Pro forma net tangible book deficit per share	\$(1.53)
Increase in pro forma net tangible book value per share attributable to new investors	<u>2.96</u>
Pro forma as adjusted net tangible book value per share after this offering	<u>1.43</u>
Dilution per share to new investors	<u>\$5.65</u>

A \$0.25 increase (decrease) in the assumed public offering price of \$7.08 per share, the last reported sale price of our common stock on Nasdaq on March 18, 2019, would increase (decrease) our pro forma as adjusted net tangible book value after this offering by \$0.09 per share, and the dilution to new investors purchasing shares in this offering by \$0.16 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us. We may also increase (decrease) the number of shares we are offering. An increase (decrease) of 1.0 million shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value by \$0.26 (\$0.29) per share and the dilution to new investors purchasing shares in this offering by \$0.26 (\$0.29) per share, assuming that the assumed public offering price remains the same, and after deducting the underwriting discount. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the underwriters at pricing.

Further, if the underwriters exercise their option to purchase an additional 1,059,321 shares of common stock in full, our pro forma as adjusted net tangible book value after this offering would have been \$1.71 per share, representing an increase in our pro forma as adjusted net tangible book value of approximately \$3.24 per share to existing stockholders and immediate dilution of approximately \$5.37 per share to new investors purchasing shares in this offering.

The table and discussion above are based on 11,759,022 shares of common stock outstanding as of December 31, 2018 on pro forma basis consisting of (i) 10,636,473 shares of common stock outstanding as of December 31, 2018, (ii) the issuance of an aggregate of 1,072,156 shares of common stock in January

and February 2019 to BioLexis pursuant to our November 2018 private placement, and (iii) the issuance of an aggregate of 50,393 shares of common stock in February and March 2019 upon conversion of an aggregate \$0.5 million principal amount of our senior secured notes; and excludes the following:

- 16,136 shares of common stock issuable upon the exercise of outstanding performance-based stock unit awards, or PSUs, whose terms provide for settlement in shares of common stock or cash at our discretion, with a weighted-average exercise price of \$49.99;
- 7,457 shares of common stock issuable upon vesting of outstanding restricted stock unit awards, or RSUs, granted under the 2015 Plan with a weighted-average grant date fair value of \$155.28;
- 386,247 shares of common stock issuable upon exercise of outstanding stock options granted under the 2015 Plan with a weighted-average exercise price of \$7.16, plus an additional 350,000 shares issuable upon exercise of stock options granted under the 2015 Plan on February 19, 2019;
- 490,767 shares of common stock reserved for future issuance under the 2015 Plan (140,767 after the reduction of 350,000 shares for stock options granted under the 2015 Plan on February 19, 2019), plus an additional 319,094 shares reserved for future issuance as of January 1, 2019, as well as any future automatic increases in the number of shares of common stock reserved for future issuance under the 2015 Plan;
- 68,145 shares of common stock reserved for future issuance under the ESPP, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP;
- 5,661,015 shares of common stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of \$8.11 per share;
- 955,927 shares of common stock issuable upon the conversion of outstanding senior secured notes having an aggregate principal amount of \$8.6 million as of March 19, 2019;
- 145,221 shares of common stock issuable upon conversion of outstanding principal and accrued interest on unsecured notes having an aggregate principal amount of \$1.0 million as of March 19, 2019;
- 1,166,156 shares of common stock issuable upon conversion of the 61,708 outstanding shares of our Series A-1 Convertible preferred stock, as well as any future shares of common stock issuable upon conversion of additional shares of Series A-1 Convertible preferred stock that may be issued as payment-in-kind dividends thereon in accordance with their terms.

Description of Capital Stock

As of the date of this prospectus, our authorized capital stock consists of 200,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of preferred stock, par value \$0.01 per share.

The following summary description of our capital stock is based on the provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law. This information may not be complete in all respects and is qualified entirely by reference to the provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and the Delaware General Corporation Law. For information on how to obtain copies of our amended and restated certificate of incorporation and our amended and restated bylaws, see “Where You Can Find More Information.”

Common Stock

As of December 31, 2018, we had 11,759,022 shares of common stock outstanding on pro forma basis consisting of (i) 10,636,473 shares of common stock outstanding as of December 31, 2018, (ii) the issuance of an aggregate of 1,072,156 shares of common stock in January and February 2019 to BioLexis, pursuant to our November 2018 private placement, and (iii) the issuance of an aggregate of 50,393 shares of common stock in February and March 2019 upon conversion of an aggregate \$0.5 million principal amount of our senior secured notes.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of 66⅔% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. Our outstanding senior secured notes first issued beginning December 2016 restrict our ability to pay dividends.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the

voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control or other corporate action. In June 2018, our Board designated 200,000 shares as "Series A-1 Convertible preferred stock." As of December 31, 2018, there were 61,708 shares of our Series A-1 Convertible preferred stock issued and outstanding.

Series A-1 Convertible Preferred Stock

As of December 31, 2018, 200,000 shares of Series A-1 Convertible preferred stock have been authorized for issuance, 61,708 of which were issued and outstanding. The shares of Series A-1 Convertible preferred stock have a stated value of \$100.00 per share and the 61,708 outstanding shares are currently convertible into approximately 1,166,156 shares of our common stock.

Dividends

The Series A-1 Convertible preferred stock accrue dividends at a rate of 10% per annum, compounded quarterly, payable quarterly at our option in cash or in kind in additional shares of Series A-1 Convertible preferred stock. The Series A-1 Convertible preferred stock are also entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of our common stock or other securities. The initial conversion rate is subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification or other recapitalization affecting our common stock.

Voting

The holders of the Series A-1 Convertible preferred stock have the right to vote on matters submitted to a vote of our stockholders on an as-converted basis. In addition, without the prior written consent of a majority of the outstanding shares of Series A-1 Convertible preferred stock, we may not take certain actions.

The terms of the Series A-1 Convertible preferred stock distinguish between certain liquidation events (such as a voluntary or involuntary liquidation, dissolution or winding up of our company) and "deemed" liquidation events (such as a sale of all or substantially all of our assets, various merger and reorganization transactions, being delisted from the Nasdaq and the occurrence of an event of default under the terms of the senior secured notes), in each case as defined in the Certificate of Designation. In the event of a liquidation (as defined in the Certificate of Designation) the liquidation preference payable equals the sum of (A) 550% of the stated value per share plus (B) (x) 550% of any accrued but unpaid preferred dividends (as defined in the Certificate of Designation) plus (y) any unpaid participating dividends (as defined in the Certificate of Designation). In the case of a deemed liquidation event (as defined in the Certificate of Designation), the multiplier is increased to 600%.

Conversion

The Series A-1 Convertible preferred stock is convertible at any time at the option of the holder based on the then applicable conversion rate. If conversion is in connection with a liquidation (as defined in the Certificate of Designation), the holder is entitled to receive 550% of the number of shares of common stock issuable based upon the then applicable conversion rate. In the event of a deemed liquidation event (as defined in the Certificate of Designation), the multiplier is increased to 600%.

Redemption

Additionally, the holder may require the Company to redeem the Series A-1 Convertible preferred stock in the event of deemed liquidation event for the sum of (A) 600% of the stated value per share plus (B) an amount equal to (x) 600% of any accrued, but unpaid, preferred dividends plus (y) any unpaid participating dividends, although such redemption may not be made without the consent of the senior secured noteholders if such notes are outstanding at the time of any such redemption.

Common Stock Equivalents

As of December 31, 2018, we had issued and outstanding 16,136 PSUs, 7,457 RSUs and 386,247 stock option awards under our equity incentive plans. At such date, we also had outstanding warrants to acquire

an aggregate of 5,661,015 shares of our common stock. In addition, as of December 31, 2018, we had 61,708 shares of our Series A-1 Convertible preferred stock issued and outstanding. We also had outstanding an aggregate \$10.4 million principal amount of senior secured notes, which are convertible into shares of our common stock at an initial conversion price of \$8.9539 per share and an aggregate \$1.0 million of unsecured notes, which are currently convertible into shares of our common stock at an initial conversion price of \$13.44 per share. In February and March 2019, we issued an aggregate of 50,393 shares of our common stock upon conversion of an aggregate of \$0.5 million principal amount of senior secured notes.

Stockholder Registration Rights

Certain holders of our securities, including certain holders of 5% of our capital stock, certain of our directors, and the holder of the Series A-1 Convertible preferred stock are entitled to certain rights with respect to registration of such securities under the Securities Act. These securities are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of registration rights agreements.

In general, the registration of shares of our common stock pursuant to the exercise of registration rights enables the holders to trade such shares without restriction under the Securities Act when the applicable registration statement is declared effective. We generally have agreed to pay the registration expenses for such registration statements, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares the holders may include. We must use commercially reasonable efforts to keep the registration statement effective until the earlier of the date on which all registrable securities covered by such registration statement have been sold, or at such time that the holders of the registrable securities can sell their shares under Rule 144 of the Securities Act during any three-month period.

Anti-Takeover Provisions of Delaware Law and Our Charter Documents

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder;
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation; and
- in general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as Amended

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws, as amended:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors is classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least a majority of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder’s notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions requires approval by the holders of at least 66 $\frac{2}{3}$ % of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions may make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could

also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws, as amended, provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable.

Listing

Our common stock and Series A warrants are listed on The Nasdaq Capital Market under the symbols "OTLK" and "OTLKW," respectively.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219.

Material U.S. Federal Income Tax Consequences to Non-U.S. Holders

The following is a summary of the material U.S. federal income tax consequences of the purchase, ownership and disposition of our common stock to Non-U.S. Holders (defined below), but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed or subject to differing interpretations, possibly with retroactive effect, so as to result in United States federal income tax consequences different from those set forth below. We have not sought and will not seek any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any United States state or local or any non-U.S. jurisdiction, estate or gift tax, the 3.8% Medicare tax on net investment income or any alternative minimum tax consequences. In addition, this discussion does not address tax considerations applicable to a Non-U.S. Holder's particular circumstances or to a Non-U.S. Holder that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- tax-exempt or government organizations;
- brokers of or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock;
- certain United States expatriates, citizens or former long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," synthetic security, other integrated investment, or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- real estate investment trusts or regulated investment companies;
- pension plans;
- partnerships, or other entities or arrangements treated as partnerships for United States federal income tax purposes, or investors in any such entities;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- integral parts or controlled entities of foreign sovereigns;
- tax-qualified retirement plans;
- controlled foreign corporations;
- persons subject to special tax accounting rules under Section 451(b) of the Code;
- passive foreign investment companies and corporations that accumulate earnings to avoid United States federal income tax; or
- persons that acquire our common stock as compensation for services.

In addition, if a partnership, including any entity or arrangement classified as a partnership for United States federal income tax purposes, holds our common stock, the tax treatment of a partner generally will depend on the status of the partner, the activities of the partnership, and certain determinations made at

the partner level. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors regarding the United States federal income tax consequences to them of the purchase, ownership, and disposition of our common stock.

You are urged to consult your tax advisor with respect to the application of the United States federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any United States state or local or any non-United States or other taxing jurisdiction or under any applicable tax treaty.

Definition of a Non-U.S. Holder

For purposes of this summary, a “Non-U.S. Holder” is any beneficial owner of our common stock that is not a “U.S. person,” and is not a partnership, or an entity disregarded from its owner, each for U.S. federal income tax purposes. A U.S. person is any person that, for United States federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to United States federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

Distributions

As discussed in the section titled “Market Price and Dividend Information — Dividend Policy,” we do not anticipate paying any dividends on our capital stock in the foreseeable future. If we make cash distributions on our common stock, those payments will constitute dividends for United States income tax purposes to the extent we have current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a tax-free return of capital and will first reduce a Non-U.S. Holder’s basis in our common stock, but not below zero. Any excess will be treated as gain realized upon a sale or other disposition and will be treated as described below under the “— Gain on Sale or Other Disposition of Common Stock” section. Any such distributions would be subject to the discussions below regarding back-up withholding and Foreign Account Tax Compliance Act, or FATCA.

Subject to the discussion below on effectively connected income, any dividend paid to a Non-U.S. Holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. To receive a reduced treaty rate, a Non-U.S. Holder must provide us or our agent with an IRS Form W-8BEN, IRS Form W-8-BEN-E or another appropriate version of IRS Form W-8, or a successor form (generally including a United States taxpayer identification number) which must be updated periodically, and which, in each case, must certify qualification for the reduced rate. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder’s conduct of a United States trade or business within the United States (and are attributable to the Non-U.S. Holder’s permanent establishment in the United States, if required by an applicable income tax treaty), generally are exempt from the (gross basis) withholding tax described above. To obtain this exemption from withholding tax, the Non-U.S. Holder must provide the applicable withholding agent with an IRS Form W-8ECI or successor form or other applicable IRS Form W-8 certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States. Such effectively connected dividends, if not eligible for relief under a tax treaty, would not be subject to a withholding tax,

but would be taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits and if, in addition, the Non-U.S. Holder is a corporation, may also be subject to a branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may be able to obtain a refund of any excess amounts currently withheld if you timely file an appropriate claim for refund with the IRS.

Gain on Sale or Other Disposition of Common Stock

Subject to the discussion below regarding backup withholding and FATCA, a Non-U.S. Holder generally will not be required to pay United States federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and is attributable to the Non-U.S. Holder's permanent establishment in the United States, if required by an applicable income tax treaty), in which case the Non-U.S. Holder will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and for a Non-U.S. Holder that is a corporation, such Non-U.S. Holder may be subject to the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items;
- the Non-U.S. Holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met, in which case the Non-U.S. Holder will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States) provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to the losses (subject to applicable income tax or other treaties); or
- our common stock constitutes a U.S. real property interest by reason of our status as a "U.S. real property holding corporation" for U.S. federal income tax purposes, or a USRPHC, at any time within the shorter of the five-year period preceding the disposition or the Non-U.S. Holder's holding period for our common stock. Generally, a corporation is a USRPHC if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business (all as determined for U.S. federal income tax purposes). We believe we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to United States federal income tax as long as our common stock is "regularly traded" (as defined by applicable U.S. Treasury Regulations) on an established securities market and such Non-U.S. Holder does not, actually or constructively, hold more than five percent (5%) of our common stock at any time during the applicable period that is specified in the Code. If the foregoing exception does not apply, such Non-U.S. Holder's proceeds received on the disposition of shares will generally be subject to withholding at a rate of 15% and such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Backup Withholding and Information Reporting

Generally, we must file information returns annually to the IRS in connection with any dividends on our common stock paid to a Non-U.S. Holder, regardless of whether any tax was actually withheld. A similar report will be sent to the Non-U.S. Holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in the Non-U.S. Holder's country of residence.

Payments of dividends or of proceeds on the disposition of stock made to a Non-U.S. Holder may be subject to additional information reporting and backup withholding at a current rate of 24% unless such Non-U.S. Holder establishes an exemption, for example by properly certifying its non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E, IRS Form W-8ECI, or another appropriate version of IRS Form W-8 (or a successor form). Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that a holder is a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act

FATCA imposes withholding tax on certain types of payments made to foreign financial institutions and certain other non-United States entities. The legislation imposes a 30% withholding tax on dividends on or after January 1, 2019, and subject to the discussion of the proposed U.S. Treasury Regulations below, the gross proceeds from the sale or other disposition of, our common stock paid to a “foreign financial institution” or to certain “non-financial foreign entities” (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by “specified United States persons” or “United States-owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. If the country in which a payee is resident has entered into an “intergovernmental agreement” with the United States regarding FATCA, that agreement may permit the payee to report to that country rather than to the U.S. Department of the Treasury.

The U.S. Department of the Treasury recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or disposition of our common stock. In its preamble to the proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued.

Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock, and the possible impact of these rules on the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax under FATCA.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

Underwriting

We entered into an underwriting agreement with the underwriters listed below on _____, 2019.

Oppenheimer & Co. Inc. is acting as the sole book-running manager and representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of shares of our common stock by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of shares, but is not responsible for the commitment of any other underwriter to purchase shares. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares set forth opposite its name below:

Underwriter	Number of Shares
Oppenheimer & Co. Inc.	
Aegis Capital Corporation	
Total	

The underwriters have agreed to purchase all of the shares offered by this prospectus (other than those covered by the over-allotment option described below) if any are purchased. Under the underwriting agreement, if an underwriter defaults in its commitment to purchase shares, the commitments of non-defaulting underwriters may be increased or the underwriting agreement may be terminated, depending on the circumstances.

The shares of common stock offered hereby are expected to be ready for delivery on or about _____, 2019 against payment in immediately available funds.

The underwriters are offering the shares subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose to offer the shares directly to the public at the public offering price set forth on the cover page of this prospectus. In addition, the representative may offer some of the shares to other securities dealers at such price less a concession of \$ _____ per share. After the shares are released for sale to the public, the representative may change the offering price and other selling terms at various times.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus, permits the underwriters to purchase a maximum of _____ additional shares from us to cover over-allotments. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to public will be \$ _____ and the total proceeds to us, before expenses, will be \$ _____. The underwriters have severally agreed that, to the extent the over-allotment option is exercised, they will each purchase a number of additional shares proportionate to the underwriter's initial amount reflected in the foregoing table.

The following table provides information regarding the amount of the discount to be paid to the underwriters by us, before expenses. These amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option.

	Per Share	Total Without Exercise of Over-Allotment Option	Total With Full Exercise of Over-Allotment Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds to us (before expenses)	\$	\$	\$

We estimate that our total expenses of the offering, excluding the estimated underwriting discount, will be approximately \$560,000, which includes \$150,000 of fees and expenses for which we have agreed to reimburse the underwriters.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We and our executive officers and directors have agreed to a 90-day “lock-up” with respect to shares of our common stock and other securities beneficially owned, including securities that are convertible into, or exchangeable or exercisable for, shares of our common stock. Subject to certain exceptions, for a period of 90 days following the date of this prospectus, we and our executive officers and directors may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Oppenheimer & Co. Inc.

Rules of the Securities and Exchange Commission may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions — The representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.
- Over-allotments and syndicate covering transactions — The underwriters may sell more shares of our common stock in connection with this offering than the number of shares than they have committed to purchase. This overallotment creates a short position for the underwriters. This short sales position may involve either “covered” short sales or “naked” short sales. Covered short sales are short sales made in an amount not greater than the underwriters’ over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.
- Penalty bids — If the representative purchases shares in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.
- Passive market making — Market makers in the shares who are underwriters or prospective underwriters may make bids for or purchases of shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.
- Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.
- Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. These transactions may occur on the Nasdaq Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Electronic Delivery of Preliminary Prospectus: A preliminary prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The preliminary prospectus in electronic format will be identical to the paper version of such preliminary prospectus. Other than the preliminary prospectus in electronic format, the information on any underwriter’s website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

The underwriters and their affiliates have provided in the past and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and our affiliates in the ordinary course of their business, for which they may receive customary fees and commissions. In addition, from time to time, the underwriters and their affiliates may effect transactions for their own account or the accounts of customers, and hold on behalf of itself or its customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Oppenheimer & Co. Inc. acted as sole financial advisor in connection with our debt restructuring in November 2018, for which Oppenheimer & Co. Inc. received fees totaling \$750,000 and reimbursement of expenses in the amount of \$583.84. Until September 20, 2019, Oppenheimer & Co. Inc. will have a right of first refusal to act as our exclusive financial advisor in connection with any acquisition or other effort by us to obtain control, directly or indirectly and whether in one or a series of transactions, of all or a significant portion of the assets or securities of a third party, or the sale or other transfer by us, whether in one or a series of transactions, of assets or securities, or any extraordinary corporate transaction, regardless of the form or structure of such transaction. We had also engaged Oppenheimer & Co. Inc. to act as our sole placement agent in connection with a proposed private placement of our securities. We have terminated this private placement as of February 20, 2019.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of our securities described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares of our securities shall require us or the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and our securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

We and the underwriters have not authorized and do not authorize the making of any offer of our securities through any financial intermediary on our or their behalf, other than offers made by the underwriters with a view to the final placement of our securities as contemplated in this prospectus. Accordingly, no purchaser of our securities, other than the underwriters, is authorized to make any further offer of our securities on behalf of us or the underwriters.

Notice to Prospective Investors in the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a relevant person).

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Canada

This document constitutes an “exempt offering document” as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities described herein (the “Securities”). No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the Securities and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts (“NI 33-105”). Pursuant to section 3A.3 of NI 33-105, this document is exempt from the requirement to provide investors with certain conflicts of interest disclosure pertaining to “connected issuer” and/or “related issuer” relationships as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement to prepare and file a prospectus under applicable Canadian securities laws. Any resale of Securities acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the Securities outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the securities will be deemed to have represented to the issuer and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an “accredited investor” as such term is defined in section 1.1 of National Instrument 45-106 Prospectus Exemptions (“NI 45-106”) or, in Ontario, as such term is defined in section 73.3(1) of the Securities Act (Ontario); and (iii) is a “permitted client” as such term is defined in section 1.1 of National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the securities or with respect to the eligibility of the securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an “eligible foreign security” as such term is defined in Ontario Securities Commission Rule 45-501 Ontario Prospectus and

Registration Exemptions and in Multilateral Instrument 45-107 Listing Representation and Statutory Rights of Action Disclosure Exemptions, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a “misrepresentation” as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the Securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu’il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d’achat ou tout avis) soient rédigés en anglais seulement.*

Notice to Prospective Investors in Australia

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act) in relation to our securities has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia you confirm and warrant that you are either:

- a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;
- a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the company under section 708(12) of the Corporations Act; or
- a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and
- you warrant and agree that you will not offer any of our securities for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to our securities described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. These securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to our securities has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of our securities to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restreint d'investisseurs), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

Our securities may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

Notice to Prospective Investors in Chile

Our securities are not registered in the Securities Registry (Registro de Valores) or subject to the control of the Chilean Securities and Exchange Commission (Superintendencia de Valores y Seguros de Chile). This prospectus and other offering materials relating to the offer of the securities do not constitute a public offer of, or an invitation to subscribe for or purchase, the shares in the Republic of Chile, other than to individually identified purchasers pursuant to a private offering within the meaning of Article 4 of the Chilean Securities Market Act (Ley de Mercado de Valores) (an offer that is not “addressed to the public at large or to a certain sector or specific group of the public”).

Notice to Prospective Investors in Hong Kong

Our securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to our securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to our securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in the State of Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase securities under the Israeli Securities Law, 5728-1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the “Addressed Investors”); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728-1968, subject to certain conditions (the “Qualified Investors”). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728-1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our securities to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728-1968. In particular, we may request, as a condition to be offered securities, that Qualified Investors will each represent, warrant and certify to us and/or to anyone

acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728-1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the securities that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728-1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728-1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

Notice to Prospective Investors in Japan

Our securities offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. Our securities have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our securities may not be circulated or distributed, nor may our securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where our securities are subscribed or purchased under Section 275 of the SFA by a relevant party which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of our securities and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired our securities pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of our securities and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

Legal Matters

The validity of the issuance of our securities offered in this prospectus will be passed upon for us by Cooley LLP. Lowenstein Sandler LLP, New York, New York, is acting as counsel for the underwriters in connection with this offering.

Experts

The consolidated financial statements of Outlook Therapeutics, Inc. as of September 30, 2018 and 2017, and for the years then ended, have been incorporated by reference in this prospectus 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, 2018 consolidated financial statements contains an explanatory paragraph that states that the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit at September 30, 2018 of \$216.3 million, \$13.5 million of senior secured notes that may become due in fiscal 2019 and \$4.6 million of unsecured indebtedness, \$1.0 million of which is due on demand, and \$3.6 million of which matures December 22, 2018, that raise substantial doubt about the Company's 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

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock being offered by this prospectus. 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, we refer you to the registration statement and the exhibits filed as a part of the registration statement. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC, including Outlook Therapeutics. The SEC's Internet site can be found at www.sec.gov. We maintain a website at www.outlooktherapeutics.com. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus, and you should not consider it part of this prospectus.

Incorporation of Documents 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, 2018, filed with the SEC on December 18, 2018;
- our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018, filed with the SEC on February 14, 2019;
- our Current Reports on Form 8-K, filed with the SEC on October 26, 2018, October 30, 2018, November 9, 2018, December 6, 2018, December 18, 2018, January 22, 2019, March 5, 2019 and March 18, 2019, 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.

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, 7 Clarke Drive, Cranbury, New Jersey 08512. 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.

7,062,146 Shares



Common Stock

PROSPECTUS

, 2019

Sole Book-Running Manager

Oppenheimer & Co.

Co-Manager

Aegis Capital Corp.

PART II

Information not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than the underwriting discount, all which will be paid by the Registrant. All amounts are estimates except the Securities and Exchange Commission, or SEC, registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

	Amount
SEC registration fee	\$ 6,969
FINRA filing fee	8,625
Accountant's fees and expenses	100,000
Legal fees and expenses	400,000
Transfer agent's fees and expenses	5,000
Printing and engraving expenses	30,000
Miscellaneous	9,406
Total expenses	\$560,000

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws, each as amended, which limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws, as amended, provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our bylaws are not exclusive.

Our amended and restated certificate of incorporation and bylaws, each as amended, which are filed as Exhibits 3.1 and 3.4, provide for the indemnification provisions described above and elsewhere herein. We have entered into separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. In addition, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following is a summary of all securities that we have sold within the past three years without registration under the Securities Act of 1933, as amended, or the "Securities Act".

The following list sets forth information as to all securities we have sold since the preceding three years up to the date of this document, which were not registered under the Securities Act.

- (1) From January 2016 through May 2016, we granted 3,802 RSUs under our 2015 Equity Incentive Plan.
- (2) In May 2016, we issued certain of the accredited investors party to that certain investors' rights agreement dated March 10, 2014, as amended, three-year warrants to purchase an aggregate of 190,033 shares of our common stock at \$0.01 per share. We have issued an aggregate of 88,787 shares upon exercise of such warrants for aggregate gross proceeds of \$3,355.
- (3) In May 2016, concurrent with the closing of our IPO, we sold to an accredited investor in a concurrent private placement 104,166 shares of our common stock, 416,666 of our Series A warrants and 416,666 of our Series B warrants, for an aggregate purchase price of approximately \$5.0 million. The underwriters of our IPO served as placement agents for the private placement and received a placement agent fee of approximately \$350,000.
- (4) In December 2016, we entered into a Note and Warrant Purchase Agreement, which we amended in April 2017 with the accredited investors named therein providing for the issuance and sale of up to \$15.0 million of senior secured promissory notes, which bear interest at a rate of 5% per year and initially mature December 22, 2017, and warrants to acquire up to an aggregate 495,625 shares of our common stock at an initial exercise price of \$24.00 per share, which initially had a five-year term. In October 2017, we exchanged \$1.5 million of these notes for 1.5 million shares of our Series B Convertible preferred stock. All Series B Convertible preferred stock subsequently converted into shares of our common stock in accordance with their terms and are no longer outstanding. We have subsequently amended the terms of the senior secured notes and warrants issued in connection therewith, most recently in November 2018, extending the maturity of the notes date up to December 2019, and providing for conversion into shares of our common stock at \$8.9539 per share, and reducing the exercise price of the warrants to \$12.00 per share and extending expiration date by three years. Through March 19, 2019, we have issued an aggregate of 50,393 shares of our common stock upon conversion of such notes.
- (5) In March 2017, we entered into a Purchase Agreement with the accredited investor named therein providing for the issuance and sale of up to \$15.4 million of shares of our common stock, and up to an additional 28,301 shares of common stock as a commitment fee. In April and May 2017, the accredited purchaser purchased an additional 37,500 shares of common stock for total proceeds of \$659,790.
- (6) In September 2017, we entered into a Purchase Agreement with the accredited investor named therein providing for, between September and October 2017, the issuance and sale of an aggregate of

250,000 shares of our Series A Convertible preferred stock and warrants to acquire 2,093,750 shares of our common stock at an exercise price of \$7.20 per share, which have an eight year term, for an aggregate purchase price of \$25.0 million. All shares of Series A Convertible preferred stock have converted into shares of our common stock and/or been exchanged for Series A-1 Convertible preferred stock. Prior to conversion and/or exchange, we issued an additional aggregate 11,045 shares of Series A Convertible preferred stock as quarterly dividends thereon in accordance with its terms.

- (7) In May 2018, we entered into a Purchase Agreement with the accredited investor named therein, providing for, between May and June 2018, the issuance and sale of an aggregate of 1,594,345 shares of common stock and common stock warrants to purchase 2,564,102 shares of common stock at an exercise price of \$7.80 per share, which have an eight year term, for an aggregate purchase price of approximately \$15.0 million.
- (8) In July 2018, we exchanged all 58,735 outstanding shares of our Series A Convertible preferred stock for 58,735 shares of newly-created Series A-1 Convertible preferred stock, which Series A-1 Convertible preferred stock earns 10% quarterly dividends. Accordingly, we issued 1,468 additional shares on September 30, 2018, and 1,505 additional shares on December 31, 2018, in each case, as dividends thereon.
- (9) In November 2018, we entered into a Purchase Agreement with the accredited investor named therein, pursuant to which we issued and sold an aggregate of 2,680,390 shares of our common stock at \$7.46 per share, for aggregate gross proceeds of \$20.0 million.

We claimed exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraphs (2)-(9) by virtue of Section 3(a)(9), 4(a)(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which we relied on Section 4(a)(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. We claimed such exemption on the basis that (i) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (ii) appropriate legends were affixed to the stock certificates issued in such transactions.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraph (1) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701

Item 16. Exhibits and Financial Statement Schedules

a) Exhibits.

Exhibit No.	Description
1.1+	Form of Underwriting Agreement
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 Designation of Series A-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 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 December 6, 2018).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on March 18, 2019).

<u>Exhibit No.</u>	<u>Description</u>
<u>3.5</u>	<u>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 May 19, 2016).</u>
<u>3.6</u>	<u>Amendment to the Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K filed with the SEC on November 29, 2016).</u>
5.1+	Opinion of Cooley LLP
<u>10.1</u>	<u>2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.2</u>	<u>Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).</u>
<u>10.3</u>	<u>2015 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's current report on Form 8-K filed with the SEC on September 24, 2018).</u>
<u>10.4</u>	<u>Forms of agreements and award grant notices for 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.5</u>	<u>2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 12, 2016).</u>
<u>10.6</u>	<u>Form of Indemnity Agreement, by and between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.7</u>	<u>Employment Agreement between the Registrant and Pankaj Mohan, Ph.D. dated February 22, 2016 (incorporated by reference to Exhibit 10.25 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).</u>
<u>10.8</u>	<u>Separation Agreement and Release by and between the Registrant and Pankaj Mohan, Ph.D., dated July 2, 2018 (incorporated by reference to Exhibit 10.5 to the Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2018).</u>
<u>10.9</u>	<u>Consulting Agreement and Release by and between the Registrant and Pankaj Mohan, Ph.D., dated July 2, 2018 (incorporated by reference to Exhibit 10.6 to the Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2018).</u>
<u>10.10</u>	<u>Executive Employment Agreement between the Registrant and Lawrence A. Kenyon, dated October 22, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on October 26, 2018).</u>
<u>10.11</u>	<u>Employment Agreement between the Registrant and Kenneth Bahrt, M.D., dated February 22, 2016 (incorporated by reference to Exhibit 10.26 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).</u>
<u>10.12</u>	<u>Separation Agreement and Release by and between the Registrant and Stephen J. McAndrew, Ph.D., effective as of November 26, 2018 (incorporated by reference to Exhibit 10.12 to the Registrant's annual report on Form 10-K filed with the SEC on December 18, 2018).</u>
<u>10.13†</u>	<u>Research License Agreement by and between the Registrant and Selexis SA, effective as of October 3, 2011, as amended by Amendment No. 1 dated as of October 9, 2014 (incorporated by reference to Exhibit 10.13 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 26, 2016).</u>
<u>10.14†</u>	<u>ONS-3010 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>

<u>Exhibit No.</u>	<u>Description</u>
<u>10.15†</u>	<u>ONS-1045 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.16†</u>	<u>ONS-1050 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.16 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.17</u>	<u>Joint Participation Agreement by and between the Registrant and Zhejiang Huahai Pharmaceutical Co., Ltd., effective as of May 6, 2013, as amended by that Amendment No. 1 and Mutual Termination Agreement re: Joint Participation Agreement, dated December 23, 2014 (incorporated by reference to Exhibit 10.17 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.18†</u>	<u>Strategic Partnership Agreement by and between the Registrant and MTTR, LLC, effective as of February 15, 2018, as amended by the Letter Addendum dated March 2, 2018 (incorporated by reference to Exhibit 10.18 to the Registrant's annual report on Form 10-K filed with the SEC on December 18, 2018).</u>
<u>10.19</u>	<u>Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of March 18, 2011 (incorporated by reference to Exhibit 10.18 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.20</u>	<u>First Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of December 2013 (incorporated by reference to Exhibit 10.19 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.21</u>	<u>Second Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of July 18, 2014 (incorporated by reference to Exhibit 10.20 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.22</u>	<u>Third Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of January 16, 2015 (incorporated by reference to Exhibit 10.21 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.23</u>	<u>Fourth Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of February 9, 2015 (incorporated by reference to Exhibit 10.22 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.24</u>	<u>Fifth Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of September 26, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).</u>
<u>10.25</u>	<u>Sixth Amendment to Lease Agreement by and between the Registrant and Cedar Brook 7 Corporate Center, LP, dated as of February 1, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 7, 2018).</u>
<u>10.26</u>	<u>Lease Termination Agreement by and between the Registrant and Cedar Brook East Corporate Center, LP, dated as of August 28, 2018 (incorporated by reference to Exhibit 10.26 to the Registrant's annual report on Form 10-K filed with the SEC on December 18, 2018).</u>
<u>10.27</u>	<u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.30 to the Registrant's registration statement on Form S-1 (File No. 333-209011) filed with the SEC on May 11, 2016).</u>

<u>Exhibit No.</u>	<u>Description</u>
<u>10.28</u>	<u>Securities Purchase Agreement between the Registrant and Sabby Healthcare Master Fund Ltd., dated May 11, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 19, 2016).</u>
<u>10.29</u>	<u>Warrant Agreement by and between the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent dated May 18, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on June 27, 2016).</u>
<u>10.30</u>	<u>Amendment to the Warrant Agreement dated May 18, 2016 by the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated February 6, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 6, 2017).</u>
<u>10.31</u>	<u>Amendment #2 to the Warrant Agreement dated May 18, 2016 by and between the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated February 9, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 9, 2018).</u>
<u>10.32</u>	<u>Amendment #3 to the Warrant Agreement dated May 18, 2016 by and between the Registrant and American Stock Transfer & Trust Company LLC, as Warrant Agent, dated January 22, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on January 22, 2019).</u>
<u>10.33</u>	<u>Form of Series A warrant certificate (included in Exhibit A to Exhibit 10.29).</u>
<u>10.34</u>	<u>Note and Warrant Purchase Agreement by and between the Registrant and the Purchasers named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).</u>
<u>10.35</u>	<u>First Amendment to Note and Warrant Purchase Agreement by and the Registrant and the Noteholders named therein, dated April 13, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on April 17, 2017).</u>
<u>10.36</u>	<u>Note, Warrant and Registration Rights Amendment and Waiver, dated September 7, 2017 (incorporated by reference to Exhibit 10.9 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).</u>
<u>10.37</u>	<u>Second Note and Warrant Amendment and Waiver, dated November 5, 2018 (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).</u>
<u>10.38</u>	<u>Form of Senior Secured Promissory Note (included as Exhibit A to the Note and Warrant Purchase Agreement filed as Exhibit 10.34).</u>
<u>10.39</u>	<u>Form of Warrant (included as Exhibit B to the Note and Warrant Purchase Agreement filed as Exhibit 10.34).</u>
<u>10.40</u>	<u>Security Agreement by and between the Registrant and the Secured Parties named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).</u>
<u>10.41</u>	<u>Intellectual Property Security Agreement by and between the Registrant and the Secured Parties named therein dated December 22, 2016 (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K filed with the SEC on December 23, 2016).</u>
<u>10.42</u>	<u>Registration Rights Agreement by and among the Registrant and the Investors named therein, dated February 3, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on February 3, 2017).</u>
<u>10.43</u>	<u>Purchase and Exchange Agreement by and between the Registrant and the Noteholders named therein, dated September 7, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).</u>
<u>10.44</u>	<u>Purchase Agreement by and between the Registrant and Lincoln Park Capital Fund, LLC, dated March 8, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on March 9, 2017).</u>

Exhibit No.	Description
10.45	Registration Rights Agreement by and between the Registrant and Lincoln Park Capital Fund, LLC, dated March 8, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on March 9, 2017).
10.46	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated September 7, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.47	Form of Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.48	Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated September 11, 2017 (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K filed with the SEC on September 11, 2017).
10.49	Amendment to Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated May 11, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).
10.50	Second Amendment to Investor Rights Agreement by and between the Registrant, and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated July 18, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).
10.51	Third Amendment to Investor Rights Agreement by and between the Registrant and BioLexis Pte. Ltd., dated November 5, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
10.52	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated May 11, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).
10.53	Form of Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K filed with the SEC on May 15, 2018).
10.54	Term Sheet, Convertible Preferred Equity Investment in the Registrant by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated June 20, 2018 (incorporated by reference to Exhibit 10.4 to the Registrant's quarterly report on Form 10-Q filed with the SEC on August 14, 2018).
10.55	Exchange Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated July 18, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on July 19, 2018).
10.56	Purchase Agreement by and between the Registrant and BioLexis Pte. Ltd. (formerly GMS Tenshi Holdings Pte. Limited), dated November 5, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K filed with the SEC on November 9, 2018).
23.1*	Consent of independent registered public accounting firm.
23.2+	Consent of Cooley LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page to the original filing of this registration statement).

* Filed herewith

† Confidential treatment has been granted for certain information contained in this document pursuant to an order of the SEC. Such information (indicated by asterisks) has been omitted and been filed separately with the SEC.

+ To be filed by amendment.

b) Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (1) That, for purposes of determining any liability 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.
- (2) To deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to securityholders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.
- (3) 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 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 Act and will be governed by the final adjudication of such issue.
- (4) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (5) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 2 to registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Cranbury, New Jersey, on March 19, 2019.

OUTLOOK THERAPEUTICS, INC.

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon
*President, Chief Executive Officer and Chief
Financial Officer*

Pursuant to the requirements of the Securities Act of 1933, this Amendment No.2 to the registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signatures	Title	Date
*	Executive Chairman	March 19, 2019
Ralph H. Thurman		
/s/ Lawrence A. Kenyon	President and Chief Executive Officer, Chief Financial Officer, Treasurer, Secretary and Director <i>(Principal Executive, Financial and Accounting Officer)</i>	March 19, 2019
Lawrence A. Kenyon		
*	Director	March 19, 2019
Yezan Haddadin		
*	Director	March 19, 2019
Kurt J. Hilzinger		
*	Director	March 19, 2019
Pankaj Mohan, Ph.D.		
*	Director	March 19, 2019
Faisal G. Sukhtian		
*	Director	March 19, 2019
Joe Thomas		
*	Director	March 19, 2019
Joerg Windisch, Ph.D.		
* By: /s/ Lawrence A. Kenyon		
Lawrence A. Kenyon		
Attorney-in-Fact		

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Outlook Therapeutics, Inc.:

We consent to the use of our report incorporated by reference herein and to the reference to our firm under the heading “Experts” in the prospectus.

Our report dated December 18, 2018 contains an explanatory paragraph that states that Outlook Therapeutics, Inc. has incurred recurring losses and negative cash flows from operations and has an accumulated deficit at September 30, 2018 of \$216.3 million, \$13.5 million of senior secured notes that may become due in fiscal 2019 and \$4.6 million of unsecured indebtedness, \$1.0 million of which is due on demand, and \$3.6 million of which matures December 22, 2018, 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 this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 19, 2019
