UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 9, 2022

Prelude Therapeutics Incorporated

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39527 (Commission File Number) 81-1384762 (IRS Employer Identification No.)

200 Powder Mill Road Wilmington, Delaware, 19803 (Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (302) 467-1280

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	PRLD	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company $extsf{ }$

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 13(a) of the Exchange Act.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(c)

On March 9, 2022, Prelude Therapeutics Incorporated, (the "*Company*") announced that the Board of Directors of the Company (the "*Board*") appointed Jane Huang, M.D., age 49, as the President and Chief Medical Officer of the Company, effective on or about April 4, 2022 (the "*Appointment Date*").

Prior to joining the Company, Dr. Huang served as Chief Medical Officer, Hematology of BeiGene, Ltd. ("*BeiGene*"), since September 2016. Prior to BeiGene, Dr. Huang served as the Vice President, Clinical Development at Acerta Pharma from April 2015 to September 2016. Previously, she worked at Genentech, Inc from 2005 to March 2015, serving most recently as Group Medical Director. Dr. Huang has served as a director for Protara Therapeutics, Inc. since June 2021, and she currently serves as an Adjunct Clinical Assistant Professor in Oncology at Stanford University, specializing in thoracic oncology. Dr. Huang received her Bachelor of Science degree in Biological Sciences from Stanford University in 1994 and her M.D. from University of Washington School of Medicine in 1998. She is board certified in hematology, oncology, and internal medicine, and she completed her residency in internal medicine and fellowships in hematology and oncology at Stanford University.

In connection with Dr. Huang's appointment as President and Chief Medical Officer, the Compensation Committee of the Board approved the Company's entry into an employment agreement (the "Employment Agreement") with Dr. Huang, which includes the following terms: (i) an initial annual base salary of \$525,000 per year (the "Initial Base Salary"), (ii) an annual discretionary bonus of up to 50% of the Initial Base Salary (the "Target Bonus"), (iii) a restricted stock unit (the "RSU Award") representing the opportunity to receive an aggregate of 150,000 shares of the Company's common stock ("Common Stock") with 1/4th of the shares underlying the RSU Award vesting on the one-year anniversary of the grant date, and 1/16th of the shares underlying the RSU Award vesting on a quarterly basis thereafter, among other benefits, and (iv) an option to purchase up to 460,000 shares of Company's Common Stock (the "Option Award") with 1/4th of the shares underlying the Option Award vesting and becoming exercisable on the one-year anniversary of the Appointment Date, and 1/48th of the shares underlying the Option Award vesting and becoming exercisable on a monthly basis thereafter. Additionally, in the event Dr. Huang experiences a termination of her employment without "Cause" or she resigns for "Good Reason" (each as defined in the Employment Agreement), provided that she executes and makes effective a release of claims against the Company and its affiliates, Dr. Huang will become entitled to (i) continued base salary for nine months, payable in accordance with the Company's standard payroll practices; (ii) premium payments for continued healthcare coverage for up to nine months and (iii) a prorated portion of the Target Bonus as in effect as of the date such termination. In the event Dr. Huang experiences a termination without "Cause" or she resigns for "Good Reason" during the 12-month period following a change in control, or the 3-month period prior to a change in control, then in lieu of the foregoing, Dr. Huang would become entitled to (a) continued base salary for 12 months, payable in accordance with the Company's standard payroll practices; (b) 100% of her annual target bonus; (c) premium payments for continued healthcare coverage for up to 12 months; and (d) 100% accelerated vesting her thenoutstanding equity awards.

The foregoing summary of the Employment Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the Employment Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal year ending March 31, 2022.

The Company expects to enter into its standard form of indemnification agreement for directors and executive officers with Dr. Huang. The form of the indemnification agreement was previously filed by the Company as Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 4, 2020 and incorporated by reference herein.

There are no arrangements or understandings between Dr. Huang and any other persons, pursuant to which she was appointed as President and Chief Medical Officer, no family relationships among any of the Company's directors or executive officers and Dr. Huang and she has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 7.01. Regulation FD Disclosure.

On March 9, 2022, the Company issued a press release announcing the appointment of Dr. Huang to the Company. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On March 9, 2022, the Company also issued a press release announcing a clinical update and new preclinical data it plans to present at the 2022 American Association for Cancer Research Annual Meeting. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

The furnishing of these materials is not intended to constitute a representation that such furnishing is required by Regulation FD or other securities laws, or that the materials include material investor information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information in the future.

The information in Item 7.01 of this Current Report, including Exhibit 99.1 and Exhibit 99.2, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*") or otherwise subject to the liabilities of that Section. The information in this Item 7.01 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, unless it is specifically incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release announcing the appointment of Jane Huang, dated March 9, 2022
99.2	Press Release announcing a clinical update and new preclinical data to be presented at the 2022 American Association for Cancer Research Annual Meeting, dated March 9, 2022
104	Inline XBRL for the cover page of this Current Report on Form 8-K.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 9, 2022

PRELUDE THERAPEUTICS INCORPORATED

By: <u>/s/ Laurent Chardonnet</u>

Laurent Chardonnet Chief Financial Officer



Jane Huang, M.D., Joins Prelude Therapeutics as President and Chief Medical Officer

Wilmington, DE – March 9, 2022 – Prelude Therapeutics Incorporated (Nasdaq: PRLD) a clinical-stage precision oncology company, today announced that Jane Huang, M.D., has been appointed to the newly created position of President and Chief Medical Officer, effective on April 4, 2022. Dr. Huang is currently Chief Medical Officer, Hematology, at BeiGene, Ltd., a global, science-driven biotechnology company developing oral small molecules and monoclonal antibodies for cancer.

"We are pleased to announce that Dr. Huang will be joining Prelude. Jane's deep experience in oncology drug development and her strategic leadership throughout the lifecycle of multiple products resulting in successful global regulatory approvals will be of great value to Prelude," stated Kris Vaddi, Ph.D., Chief Executive Officer of Prelude.

Dr. Vaddi added, "With multiple distinct precision oncology programs underway, our growing pipeline offers tremendous promise. I am confident in Jane's ability to build and lead high-performing cross-functional clinical development teams, and her strong relationships and recognized leadership within the cancer research community will be instrumental in achieving our goals to rapidly advance compounds through proof-of-concept and into potential registration trials."

"I am impressed by the strong execution of the Prelude R&D team and its ability to bring multiple proprietary and potentially best-in-class small molecule compounds forward. Their strategic selection of clinically relevant targets involved in many underserved cancers is equally impressive. This level of performance gives me confidence that Prelude is uniquely resourced to make a meaningful difference in the lives of cancer patients," stated Dr. Huang.

Most recently, Dr. Huang served as Chief Medical Officer of Hematology at BeiGene, Ltd. where she created a global development organization encompassing clinical pharmacology to global product safety and had strategic oversight of the development of five hematology medicines. During her tenure with BeiGene, she oversaw the approval of zanubrutinib in three diseases spanning more than 45 countries and was responsible for the first approval of tislelizumab in Hodgkin's lymphoma. Prior to joining BeiGene in 2016, Dr. Huang served as Vice President, Clinical Development at Acerta Pharma, where she oversaw global clinical development of the BTK inhibitor, acalabrutinib. Prior to this, she worked at Genentech, where she played a leading role in drug development programs for multiple therapies throughout all stages of development, including, Rituxan®, Avastin®, Kadcyla®, Venclexta® and Gazyva®. She is board certified in hematology, oncology, and internal medicine and is Adjunct Clinical Assistant Professor at Stanford University. Dr. Huang was recently named one of the 20 most influential women in biopharma R&D by Endpoints News.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. The Company's diverse pipeline is comprised of highly differentiated, potentially best-in-class proprietary small molecule compounds aimed at addressing clinically validated pathways for cancers with selectable underserved patients. Prelude's pipeline includes four candidates currently in clinical development: PRT543 and PRT811, highly selective, potent, orally bioavailable PRMT5 inhibitors; PRT1419, a potent, selective inhibitor of MCL1; and PRT2527, a potent and highly selective CDK9 inhibitor. Additionally, the Company is progressing two novel preclinical candidates, PRT3645, a brain penetrant CDK4/6 inhibitor; and a potential first-in-class SMARCA2/BRM protein degrader.



Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated discovery, preclinical and clinical development activities, timing of availability and announcements of clinical results, the timing of the expansion portion for its Phase 1 clinical trial for PRT543, PRT811 and PRT1419, the timing of IND-related activities for PRT2527 and PRT-SCA2, the potential benefits of Prelude's product candidates and platform and appointment of Jane Huang as Prelude's President and Chief Medical Officer. All statements other than statements of historical fact are statements that could be deemed forwardlooking statements. Although Prelude believes that the expectations reflected in such forward-looking statements are reasonable, Prelude cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause Prelude's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Prelude's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the impact of the COVID-19 pandemic on Prelude's business, clinical trial sites, supply chain and manufacturing facilities, Prelude's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, Prelude's ability to fund development activities and achieve development goals, Prelude's ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in documents Prelude files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Prelude undertakes no obligation to revise or update any forwardlooking statements to reflect events or circumstances after the date hereof.

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Prelude Therapeutics Provides Clinical Update and Announces Presentation of New Preclinical Data at the Upcoming 2022 AACR Annual Meeting

Announces strategic prioritization within lead programs targeting PRMT5 and MCL1

Describes new pipeline candidate, PRT3645, a highly brain penetrant CDK4/6 inhibitor; IND submission planned mid-2022

Advances PRT2527, a highly selective CDK9 inhibitor, with the goal of establishing a recommended Phase 2 dose in 2H/2022

Progresses its highly selective potential first-in-class SMARCA2/BRM degrader with IND submission planned by year-end 2022

Data from all of Prelude's portfolio programs to be presented at the upcoming AACR Annual Meeting

Wilmington, DE – March 9, 2022 – Prelude Therapeutics Inc. (Nasdaq: PRLD), a clinical-stage precision oncology company, today provided a clinical update on its diverse and growing pipeline and announced that new preclinical data have been accepted for presentation at the upcoming 2022 American Association for Cancer Research (AACR) Annual Meeting being held April 8-13 in New Orleans, Louisiana.

"Through disciplined and effective execution, Prelude made meaningful progress across all of our portfolio programs in 2021," said Kris Vaddi, Ph.D., Chief Executive Officer. "Because of these efforts, we now have five distinct precision oncology programs with four internally discovered molecules in clinical development. One of our key objectives in 2022 is to focus our development efforts and generate the clinical data necessary to prioritize these programs. For the PRMT5 program, which includes PRT543 and PRT811, we are concentrating our efforts on PRT811 because of its superior safety profile, higher level of target engagement, and unique brain penetrant properties. Our development efforts for PRT811 are focused on specific indications, including splicing mutated myeloid malignancies and solid tumors, including uveal melanoma, and IDH1 mutated high grade glioma. We anticipate reporting data from the ongoing dose expansion cohorts in 2H/2022."

"For our MCL1 program, in which we have both an oral and intravenous formulation for PRT1419 currently in clinical development, our priority is to advance the intravenous formulation in combination with venetoclax to rapidly establish proof-of-concept in myeloid malignancies. Provided this combination is well-tolerated, we believe PRT1419 has the potential to be a best-in-class MCL1 inhibitor. We look forward to reporting data from the combination study in 2H/2022."

Dr. Vaddi added, "We are particularly excited to announce the newest addition to our pipeline, PRT3645, a novel, highly brain penetrant CDK4/6 inhibitor. Despite the success of approved CDK4/6 inhibitors in HR+ breast cancer, their utility in breast cancer with brain metastasis and other CNS cancers remains limited because of their low brain penetration. We have also made significant progress in our SMARCA2/BRM protein degrader program and have identified highly selective, potential first-in-class lead molecules. An IND submission for PRT3645 is planned for mid-year, with a second IND submission for our SMARCA2/BRM candidate by year-end 2022."



Data from all of Prelude's portfolio programs will be presented at the upcoming AACR annual meeting, underscoring the strength of the Company's internal discovery engine to produce differentiated, optimal small molecule therapies for cancer patients in key areas of unmet need.

Clinical Update

PRMT5 (PRT543/PRT811)

PRMT5 plays essential roles in promoting cancer cell growth and survival. Overexpression of PRMT5 is associated with poor outcomes and decreased survival in several cancers. Prelude's PRMT5 program includes two lead compounds, PRT543 and PRT811.

Based on data from the ongoing Phase 1 dose expansion studies of both PRT543 and PRT811, Prelude is concentrating its further development efforts on PRT811 in biomarker-selected patients in specific cancer types. While the Company believes that both PRT811 and PRT543 are high quality, clinically active compounds, PRT811 was selected based on its superior safety profile, higher level of target engagement, and unique brain penetrant properties.

Specifically Prelude intends to:

- Focus clinical development in select patient populations where clinical activity has been observed, including splicing mutated myeloid malignancies and solid tumors, including uveal melanoma, and IDH1 mutated high grade gliomas
- Complete data analysis of the ongoing expansion cohort of adenoid cystic carcinoma (ACC) by mid-year to determine if further development is warranted
- Report data from the ongoing dose expansion cohorts in 2H/2022
- Determine appropriate development options for PRT811 based on emerging data from ongoing expansion cohorts

MCL1 (PRT1419): MCL1 is a member of the anti-apoptotic BCL2 family of proteins and has also been implicated in mediating resistance to chemotherapeutic agents and targeted therapies. PRT1419 is a potent, selective inhibitor of MCL1 currently in Phase 1 development as oral and intravenous (IV) formulations.

Based on the data to date, the Company plans to:

- Prioritize development of the IV formulation of PRT1419 which demonstrated a desirable pharmacokinetic, pharmacodynamic and safety profile with potential for differentiation from competitor compounds
- Initiate combination trial with venetoclax by mid-year, with the goal of establishing safety, clinical activity and a recommended Phase 2 dose by 2H/2022

CDK9 (PRT2527): CDK9 is a cyclin dependent kinase and an essential regulator of cancer-promoting transcriptional programs and an important driver in *Myc*-driven solid tumors and myeloid malignancies. PRT2527 is a potent and highly selective CDK9 inhibitor currently being evaluated in a Phase 1 dose escalation study in patients whose cancers are likely to be dependent on CDK9.

The key objective for PRT2527 in 2022 is to:

 Complete enrollment in the Phase 1 dose escalation study of PRT2527 with the goal of identifying a recommended Phase 2 dose by 2H/2022

CDK4/6 (PRT3645): CDK4 and CDK6 are validated targets in HR+ breast cancers. Approved CDK4/6 inhibitors have limited utility in breast cancers with brain metastases and other central nervous system (CNS) cancers, including glioblastoma multiforme (GBM). PRT3645 is a highly potent, selective and brain penetrant CDK4/6 inhibitor that demonstrated greater than 10x brain penetration compared to approved CDK4/6 agents in preclinical models. Prelude intends to develop PRT3645 in these underserved cancers.

For PRT3645, Prelude plans to:

• Complete investigational new drug (IND)-enabling studies, file IND and initiate Phase 1 in 2H/2022



SMARCA2/BRM Protein Degrader: SMARCA2 (BRM) and SMARCA4 (BRG1) are the core catalytic subunits of the SWI/SNF complexes that control gene transcription. When SMARCA4 is lost because of mutations, cancer cells become highly dependent on SMARCA2 for their survival. Prelude has identified a number of highly selective SMARCA2 degraders that have the potential to be first-in-class for SMARCA4-deleted cancers.

During 2022, Prelude intends to:

Complete IND-enabling studies and submit an IND application by year-end 2022

Summary of AACR Accepted Abstracts

Title: PRT2527, a novel highly selective cyclin-dependent kinase 9 (CDK9) inhibitor, is active in preclinical models of prostate cancer Abstract: 5471

Date and Time: Sunday, April 10, 2022, 8:30 am CT – 1:00 pm CT Session Title: Small Molecule Therapeutic Agents Presenter: Dr. Elisa Federici, Institute of Oncology Research, Università della Svizzera Italiana

• Conclusion: PRT2527 was evaluated in prostate cancer models to assess its effects on cell proliferation, stem-cell-like properties, and tumor growth. Collectively, the data demonstrate that PRT2527 had potent antitumor activity in multiple models of castration-sensitive and castration-resistant prostate cancer, inhibited *Myc* transcriptional activity and reduced tumor stem-like cells.

Title: Combination of the MCL1 inhibitor PRT1419 and SMARCA2 degrader PRT3789 shows combinatorial benefit in SMARCA4 deleted lung cancer Abstract: 420

Date and Time: Sunday, April 10, 2022, 1:30 pm CT – 5:00 pm CT Session Title: Protein Degraders and Proteasome Inhibitors Presenter: Norman Fultang, Prelude Therapeutics

Conclusion: The abstract highlights new preclinical data demonstrating synergistic benefit when PRT1419 was combined with the Company's
novel and selective SMARCA2 degrader, PRT3789, in SMARCA4 deleted lung cancer models. Potent synergistic interaction in SMARCA4
deleted cell lines was observed *in vitro*, whereas no additive benefit was seen in SMARCA4 WT lines. Combining PRT1419 and PRT3789 *in vivo*in cell line-derived xenograft models resulted in significant tumor growth inhibition, including tumor regressions.

Title: PRMT5 Inhibitor PRT543 Displays Potent Antitumor Activity in U2AF1S34F and RBM10LOF Spliceosome-Mutant Non-Small Cell Lung Cancer In Vitro and In Vivo

Abstract: 2159 Date and Time: Monday, April 11, 2022, 2:30 pm CT – 4:30 pm CT Session Title: Emerging New Anticancer Agents Presenter: Jack Carter, Prelude Therapeutics



Conclusion: The abstract highlights *in vitro* and *in vivo* activity of PRT543 in cancer cells harboring mutations in spliceosome factors such as U2AF1 and RBM10, which occur in ~5-10% of all NSCLC. Both U2AF1 and RBM10 mutant cell lines were significantly more sensitive to PRT543 compared to wild-type cell lines. PRT543 increased the effectiveness of chemotherapeutic agents both *in vitro* and *in vivo*. These results suggest PRMT5 inhibitors may be beneficial in cancers with these mutations.

Title: Brain Penetrant CDK4/6 Inhibitor PRT3645 Demonstrates Anti-tumor Activity and Enhances Survival in Glioblastoma and Breast Cancer Brain Metastasis Models

Abstract: 2300 Date and Time: Tuesday, April12, 2022, 9:00 am CT—12:30 pm CT Session Title: Cell Cycle Control and Cell Cycle Regulators as Therapeutic Targets Presenter: Ashish Juvekar, Prelude Therapeutics

• Conclusion: This abstract highlights data from multiple preclinical studies showing that PRT3645 exhibits the desired balance of potency, selectivity, and brain penetration compared to approved CDK4/6 inhibitors. *In vivo*, oral administration of PRT3645 was highly efficacious in orthotopic human breast cancer brain metastasis (BCBM) and GBM preclinical models and demonstrated a combinatorial benefit with hormonal therapy as well as HER2 kinase inhibition.

Title: Preclinical characterization of PRT3789, a potent and selective SMARCA2 targeted degrader Abstract: 3263 Date and Time: Tuesday, April 12, 2022, 1:30 pm CT – 5:00 pm CT Session Title: Epigenetic Targets Presenter: Michael Hulse, Prelude Therapeutics

• Conclusion: The abstract describes the characterization of PRT3789, one of Prelude's potent and selective SMARCA2 targeted degraders. Treatment with PRT3789 demonstrated robust inhibition of SMARCA4-deleted non-small cell lung cancer cell growth but not SMARCA4 WT cancer cells, both in vitro and in vivo at well-tolerated doses.

About Prelude Therapeutics

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timing of IND-related activities for PRT3645, SMARCA2 and SMARCA4, and the potential benefits of the Company's product candidates and platform. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the Company's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the impact of the COVID-19 pandemic on the Company's business, clinical trial sites, supply chain and manufacturing facilities, the Company's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the Company's ability to fund development activities and achieve development goals, the Company is ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in documents the Company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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