

**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): September 9, 2020

Prevail Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-38939
(Commission
File Number)

82-2129632
(I.R.S. Employer
Identification No.)

430 East 29th Street, Suite 1520
New York, New York
(Address of principal executive offices)

10016
(Zip Code)

Registrant's telephone number, including area code: (917) 336-9310

(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, par value \$0.0001 per share	PRVL	The Nasdaq Stock Market LLC

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

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 Arrangement of Certain Officers.

Appointment of William H. Carson, M.D.

The board of directors (the “Board”) of Prevail Therapeutics Inc. (the “Company”) appointed William H. Carson, M.D. to serve as a director of the Company, effective September 9, 2020. Dr. Carson’s term will expire at the Company’s 2021 annual meeting of stockholders.

Dr. Carson, age 61, has served as Chairman of Otsuka Pharmaceutical Development & Commercialization, Inc. (“OPDC”) since January 2020 and previously served as President and Chief Executive Officer of OPDC from 2010 to January 2020. Dr. Carson joined Otsuka America Pharmaceutical, Inc. in 2002 as Vice President, CNS/Aripiprazole, eventually serving as Vice President, Global Clinical Development and then Senior Vice President, Global Clinical Development at OPDC prior to his elevation to President and Chief Executive Officer, overseeing the development of Otsuka-discovered compounds. Prior to joining Otsuka, from 1998 to 2002, Dr. Carson was Group Director in Neuroscience Clinical Research and Development at Bristol Myers Squibb, or BMS. Earlier in his career, Dr. Carson was an Associate Professor and Director of the Inpatient and Partial Hospital Program at the Medical University of South Carolina. In addition to serving as Chairman of OPDC, Dr. Carson serves as a member of the board of directors of Excision BioTherapeutics, a private biotechnology company, and Internet 2, a not-for-profit organization. He is also Board Chair Emeritus of the Sphinx Organization, a not-for-profit organization advocating for parity and inclusion in the arts. Dr. Carson received an A.B. in History and Science from Harvard University and earned an M.D. from Case Western Reserve University.

There is no arrangement or understanding between Dr. Carson and any other person pursuant to which he was selected as a director of the Company, and there is no family relationship between Dr. Carson and any of the Company’s other directors or executive officers. Dr. Carson does not have a material interest in any transaction that is required to be disclosed under Item 404(a) of Regulation S-K.

Dr. Carson will be compensated in accordance with the Company’s amended and restated non-employee director compensation policy. Pursuant to this policy, Dr. Carson will be entitled to receive a \$38,750 annual retainer for his service on the Board. In addition, pursuant to this policy, on September 9, 2020, Dr. Carson was granted an initial option grant to purchase 34,000 shares of the Company’s common stock at an exercise price of \$11.11 per share, the closing price of the Company’s common stock as reported by The Nasdaq Global Select Market on that date. This option vests in equal monthly installments over a 36-month period. In addition, pursuant to the Company’s amended and restated non-employee director compensation policy, Dr. Carson will be eligible for an annual option grant to purchase 17,000 shares of the Company’s common stock, which will be granted in connection with the Company’s Annual Meeting of Stockholders each year. Dr. Carson has also entered into the Company’s standard indemnity agreement, the form of which was previously filed by the Company as Exhibit 10.5 to the Company’s Registration Statement on Form S-1 (File No. 333-231754), initially filed with the Securities and Exchange Commission on May 24, 2019.

Item 7.01 Regulation FD Disclosure.

On September 10, 2020, the Company issued a press release announcing the appointment of Dr. Carson to the Board.

A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated September 10, 2020.

SIGNATURES

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.

PREVAIL THERAPEUTICS INC.

By: /s/ Brett Kaplan, M.D.

Brett Kaplan, M.D.

Chief Financial Officer

Dated: September 10, 2020

Prevail Therapeutics Announces Appointment of William H. Carson, M.D., to Board of Directors

NEW YORK, Sept. 10, 2020 (GLOBE NEWSWIRE) — Prevail Therapeutics Inc. (Nasdaq: PRVL), a biotechnology company developing potentially disease-modifying AAV-based gene therapies for patients with neurodegenerative diseases, today announced the appointment of William H. Carson, M.D., to its Board of Directors.

“Bill knows how to drive the development of innovative treatments — including drugs for a wide range of diseases that affect the brain — from concept to commercialization,” said Francois Nader, M.D., Non-Executive Chairman of Prevail’s Board of Directors. “We are thrilled that he will bring that expertise to bear at Prevail as we continue to develop gene therapies for patients suffering from devastating neurodegenerative diseases, including Parkinson’s disease, frontotemporal dementia and Gaucher disease.”

Dr. Carson was most recently the President and CEO of Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC), leading the development and regulatory approvals of Otsuka’s global compounds including Abilify Maintena®, Rexulti®, Samsca® and Jynarque®. He also oversaw the approval of Abilify MyCite®, the first FDA-approved digital medicine. Dr. Carson joined Otsuka as Vice President of the Princeton Aripiprazole Unit in 2002, establishing the company’s presence there. Before joining Otsuka, he rose through the ranks in the CNS Research and Development department at Bristol-Myers Squibb. Prior to joining the pharmaceutical industry, Dr. Carson, a board-certified psychiatrist, was an Associate Professor in the Department of Psychiatry and Behavioral Sciences at the Medical University of South Carolina.

Dr. Carson currently serves as Chairman of the Board of Directors of OPDC, and is also the Chairman of the Board of the Sozosei Foundation, a newly established Otsuka charitable organization with a main focus on decriminalization of mental illness. He is a Board Member of Excision Biotherapeutics and Trustee of the non-profit Internet2. He is Board Chair Emeritus of the Sphinx Organization, which advocates for parity and inclusion in the arts. Dr. Carson holds an A.B. Degree from Harvard College and a M.D. degree from Case Western Reserve University. He is a Distinguished Fellow of the American Psychiatric Association, the National Medical Association and the Executive Leadership Council. Dr. Carson was named to *Savoy Magazine*’s 2018 list of the Top 100 Most Influential Blacks in Corporate America.

“Dr. Carson is an outstanding and important addition to our Board of Directors,” said Asa Abeliovich, M.D., Ph.D., Founder and Chief Executive Officer of Prevail. “I know that he will bring both deep medical expertise and compassion for patients to the role, as well as his stellar track record of advancing therapies through clinical development, FDA approval and commercialization.”

“I am honored to join Prevail at this exciting time for the company,” said Dr. Carson. “Prevail’s programs are moving forward quickly, and promising data are beginning to emerge. I am looking forward to helping the company continue to advance its mission of developing potentially disease-modifying treatments for patients with neurodegenerative disorders.”

About Prevail Therapeutics

Prevail is a gene therapy company leveraging breakthroughs in human genetics with the goal of developing and commercializing disease-modifying AAV-based gene therapies for patients with

neurodegenerative diseases. The Company is developing PR001 for patients with Parkinson's disease with GBA1 mutations (PD-GBA) and neuronopathic Gaucher disease; PR006 for patients with frontotemporal dementia with GRN mutations (FTD-GRN); and PR004 for patients with certain synucleinopathies.

Prevail was founded by Dr. Asa Abeliovich in 2017, through a collaborative effort with The Silverstein Foundation for Parkinson's with GBA and OrbiMed, and is headquartered in New York, NY.

Forward-Looking Statements Related to Prevail

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning Prevail's ability to develop potentially disease-modifying treatments for patients with neurodegenerative disorders. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Prevail's novel approach to gene therapy makes it difficult to predict the time, cost and potential success of product candidate development or regulatory approval; initial data or other preliminary analyses or results of early clinical trials may not be predictive of final trial results or of the results of later clinical trials; Prevail's gene therapy programs may not meet safety and efficacy levels needed to support ongoing clinical development or regulatory approval; the regulatory landscape for gene therapy is rigorous, complex, uncertain and subject to change; the fact that gene therapies are novel, complex and difficult to manufacture; and risks relating to the impact on Prevail's business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in Prevail's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020, filed with the SEC on August 11, 2020, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Prevail undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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