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):
November 13, 2020

Prevail Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38939**	**82-2129632**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

430 East 29th Street, Suite 1520	
New York, New York	**10016**
(Address of principal executive offices)	**(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 2.02. Results of Operations and Financial Condition.

On November 13, 2020, Prevail Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020 and certain other business updates. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information furnished pursuant to Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, 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, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, 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.

Exhibit No.	Description
99.1	Press Release dated November 13, 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: November 13, 2020

Prevail Therapeutics Reports Third Quarter 2020 Financial Results and Business Highlights

Patient Dosing Continues in the Phase 1/2 PROPEL Trial of PR001 for Parkinson's Disease with GBA1 Mutations

Phase 1/2 PROVIDE Trial of PR001 for Type 2 Gaucher Disease and Phase 1/2 PROCLAIM Trial of PR006 for Frontotemporal Dementia with GRN Mutations Expected to Initiate Enrollment in Fourth Quarter of 2020

PR001 Receives U.S. FDA Fast Track Designation for Neuronopathic Gaucher Disease

NEW YORK, November 13, 2020 -- Prevail Therapeutics Inc. (Nasdaq: PRVL), a biotechnology company developing potentially disease-modifying AAV-based gene therapies for patients with neurodegenerative diseases, today reviewed recent clinical and business updates and reported financial results for the third quarter ended September 30, 2020.

"We're pleased to be making significant progress across our pipeline as we seek to develop urgently needed disease-modifying gene therapy treatments for patients with neurodegenerative diseases," said Asa Abeliovich, M.D., Ph.D., Founder and Chief Executive Officer of Prevail. "We are encouraged by the continuation of patient dosing in our Phase 1/2 PROPEL trial of PR001 for Parkinson's disease with *GBA1* mutations, and we are excited to advance our PROVIDE and PROCLAIM clinical trials for Type 2 Gaucher disease and frontotemporal dementia with *GRN* mutations, respectively, this year."

Recent Business Updates

Patient Dosing Continues in Phase 1/2 PROPEL Trial of PR001 for Parkinson's disease with *GBA1* mutations (PD-GBA): Enrollment in the Phase 1/2 PROPEL clinical trial for PD-GBA has resumed following implementation of modifications to the clinical protocol. As previously announced, Prevail elected to modify the immunosuppression regimen in the clinical protocol for PROPEL and has adapted the trial design to be open-label. The Company expects to provide the next biomarker and safety analysis on a subset of patients in the PROPEL trial by mid-2021.

Phase 1/2 PROVIDE Trial Expected to Initiate Enrollment in Fourth Quarter of 2020: Initiation of patient enrollment remains on track for the fourth quarter of 2020 for the Phase 1/2 PROVIDE clinical trial of PR001 for Type 2 Gaucher disease. The optimized immunosuppression regimen used in the amended PROPEL trial will also be implemented in the PROVIDE trial. The Company currently anticipates it will provide the next update on PR001 biomarker and safety data for neuronopathic Gaucher disease (nGD) in 2021.

Phase 1/2 PROCLAIM Trial Expected to Initiate Enrollment in Fourth Quarter of 2020: Initiation of patient enrollment remains on track for the fourth quarter of 2020 for the Phase 1/2 PROCLAIM clinical trial of PR006 for frontotemporal dementia with *GRN* mutations (FTD-GRN). The optimized immunosuppression regimen used in the amended PROPEL trial will also be implemented in the PROCLAIM trial. The Company currently anticipates it will provide a biomarker and safety analysis on a subset of patients in the PROCLAIM trial in 2021.

PR001 Granted U.S. FDA Fast Track Designation for nGD: The U.S. Food and Drug Administration (FDA) granted Fast Track designation for PR001 for the treatment of nGD. The FDA previously granted PR001 Rare Pediatric Disease designation for the treatment of nGD, and Orphan Drug designation for the treatment of patients with Gaucher disease. In addition, the FDA has granted Fast Track designation for PR001 for the treatment of PD-GBA.

Strengthened Leadership with Board Appointment: Prevail has appointed William H. Carson, M.D., to its Board of Directors. 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. Before joining Otsuka, he held several roles in the CNS Research and Development department at Bristol Myers Squibb. 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 a Distinguished Fellow of the American Psychiatric Association, the National Medical Association and the Executive Leadership Council. 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.

Favorable Decision Received in Alector Arbitration: Prevail announced a favorable decision in the arbitration proceeding brought in 2019 by Alector Inc. against Prevail's Founder and Chief Executive Officer, Asa Abeliovich, M.D., Ph.D. The arbitrator rejected Alector's claims against Dr. Abeliovich that Alector confidential information was used in connection with his work on behalf of Prevail and that Alector had rights to Prevail's patents and patent applications. The arbitrator found that Dr. Abeliovich did not breach his confidentiality obligations to Alector under his consulting agreement. Prevail was not a party to this arbitration.

Third Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were $114.3 million as of September 30, 2020, as compared to $131.2 million and $168.1 million as of June 30, 2020 and December 31, 2019, respectively. The Company continues to anticipate that its cash runway will extend into the first half of 2022.

- **R&D Expenses:** R&D expenses were $12.3 million for the third quarter of 2020 compared to $16.8 million for the third quarter in 2019. The decrease was primarily due to a decrease of $3.9 million in external manufacturing costs due to the timing of production of clinical and preclinical supply, a decrease of $1.5 million in direct clinical trial costs, and a decrease of $0.5 million related to external preclinical studies. These decreases were partially offset by an increase of $1.4 million in employee-related costs, resulting from an increase in research and development employees hired to execute the development of our clinical-stage product candidates and preclinical pipeline.

- **G&A Expenses:** G&A expenses were $6.3 million for the third quarter of 2020, compared to $4.5 million for the third quarter of 2019. The increase was primarily due to a $1.3 million increase in employee related costs, resulting from an increase in general and administrative employees to support our expanded operations and establish capabilities to operate as a public company, a $0.8 million increase in legal fees, offset by a decrease of $0.2 million in other professional

services and facilities cost.

- **Net Loss:** Net loss was $18.6 million, or $0.55 loss per share, for the third quarter of 2020, compared to $20.3 million, or $0.62 loss per share, for the third quarter of 2019.

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 (nGD); 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 the potential for Prevail's gene therapy candidates to modify the course of neurodegenerative diseases; the anticipated timing of Prevail's clinical trials of PR001 in PD-GBA and in Type 2 Gaucher disease and Prevail's clinical trial of PR006 in FTD-GRN; the expected timing of reporting of additional interim data for a subset of patients from the PROPEL trial; and expectations regarding Prevail's cash runway. 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; 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 our 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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the SEC, 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.

Prevail Therapeutics Inc.
Statements of Operations
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating Expenses:				
Research and development	$ 12,321	$ 16,836	$ 36,681	$ 37,202
General and administrative	6,303	4,452	23,373	10,050
Total operating loss	(18,624)	(21,288)	(60,054)	(47,252)
Other income	—	—	210	—
Interest income, net	37	989	582	1,905
Total other income	37	989	792	1,905
Net loss	$ (18,587)	$ (20,299)	$ (59,262)	$ (45,347)
Other comprehensive income	5	—	4	—
Comprehensive loss	$ (18,582)	$ (20,299)	$ (59,258)	$ (45,347)
Net loss per share, basic and diluted	$ (0.55)	$ (0.62)	$ (1.77)	$ (1.68)
Weighted average shares outstanding, basic and diluted	33,636,651	32,864,156	33,457,768	26,950,854

Prevail Therapeutics Inc.
Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 81,732	$ 168,051
Investments	9,755	—
Prepaid expenses and other current assets	4,839	6,410
Total current assets	96,326	174,461
Property and equipment, net	2,746	2,549
Investments	22,861	—
Operating lease right-of-use assets	9,023	10,001
Other long-term assets	3,068	—
Restricted cash	91	91
TOTAL ASSETS	$ 134,115	$ 187,102
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,597	$ 5,162
Accrued expenses and other current liabilities	8,651	5,330
Operating lease liabilities	1,500	1,341
Total current liabilities	12,748	11,833
Long-term operating lease liabilities	8,787	9,927
TOTAL LIABILITIES	21,535	21,760
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; no shares issued as of September 30, 2020 and December 31, 2019, respectively	—	—
Common stock - $0.0001 par value, 200,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively, 34,245,433 and 34,138,750 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	255,937	249,441
Accumulated deficit	(143,364)	(84,102)
Accumulated other comprehensive income	4	—
Total stockholders' equity	112,580	165,342
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 134,115	$ 187,102

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