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): August 16, 2021

DAY ONE BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40431**	**83-2415215**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

395 Oyster Point Blvd., Suite 217
South San Francisco, CA **94080**
(Address of principal executive offices) **(Zip Code)**

(650) 484-0899
(Registrant's telephone number, including area code)

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 Per Share	**DAWN**	**The Nasdaq Stock Market LLC (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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 Arrangements of Certain Officers.

Appointment of New Director

On August 16, 2021, upon the recommendation of the Nominating and Governance Committee (the "***Governance Committee***") of the Board of Directors (the "***Board***") of Day One Biopharmaceuticals, Inc. (the "***Company***"), the Board increased the size of the Board to eight directors and appointed Scott Garland as a Class II director, effective immediately (the "***Effective Date***").

In connection with his appointment as a non-employee director of the Board, and in accordance with the Company's current compensation policy for non-employee directors (the "***Compensation Policy***"), the Board granted Mr. Garland a stock option to purchase shares of the Company's common stock with an aggregate value of $645,000, calculated in accordance with the Compensation Policy (the "***Initial Grant***"). The Initial Grant shall vest monthly over three years, beginning on the one-month anniversary of the Effective Date, subject, however, to Mr. Garland's continued service on the Board on each vesting date.

Pursuant to the Compensation Policy, on the date of each annual meeting of the Company's stockholders, each non-employee director who is serving on the Board prior to, and will continue to serve on the Board following, such meeting is entitled to an annual stock option grant for shares of the Company's common stock with an aggregate value of $322,000 (the "***Annual Grant***"), calculated in accordance with the Compensation Policy. Mr. Garland will be eligible for Annual Grants, provided, that, he satisfies the requirements set forth in the Compensation Policy, including the service requirements.

The Initial Grant and any Annual Grants awarded to Mr. Garland will be issued under the Company's 2021 Equity Incentive Plan and will accelerate in full upon a change of control. Mr. Garland will also be entitled to the applicable annual cash retainer paid to non-employee directors under the Compensation Policy.

The Company has entered into its standard form of indemnification agreement with Mr. Garland. 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 (File No. 333-255754) filed with the Securities and Exchange Commission on May 26, 2021 and incorporated by reference herein.

There are no arrangements or understandings between Mr. Garland and any other persons, pursuant to which Mr. Garland was selected as a member of the Board. There are also no family relationships among any of the Company's other directors or executive officers and Mr. Garland. Mr. Garland does not have any other 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 August 17, 2021, the Company issued a press release announcing the appointment disclosed above. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 7.01, including Exhibit 99.1 to this report, shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statement and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Day One Biopharmaceuticals, Inc. regarding the appointment of a new director, dated August 17, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

DAY ONE BIOPHARMACEUTICALS, INC.

Date: August 17, 2021

By: /s/ Charles N. York II, M.B.A.
Name: Charles N. York II, M.B.A.
Title: Chief Operating Officer and Chief Financial Officer

Day One Appoints Scott Garland to Board of Directors

SOUTH SAN FRANCISCO, CA, August 17, 2021 – Day One Biopharmaceuticals (Nasdaq: DAWN), a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for patients of all ages with genomically defined cancers, today announced the appointment of Scott Garland to the Company's board of directors. Mr. Garland is a 30-year veteran of the biopharmaceutical industry with deep commercial and executive leadership experience.

"We are very pleased to welcome Scott to our board of directors at this important stage in Day One's evolution," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Having led the launch of multiple new medicines, Scott's commercial expertise will be invaluable as we advance our pivotal Phase 2 FIREFLY-1 clinical trial of DAY101 in pediatric patients with progressive low-grade glioma and prepare to initiate additional clinical trials."

Mr. Garland is the chief executive officer of PACT Pharma, an immuno-oncology company focused on developing neoantigen targeted T-cell therapies for solid tumors. Prior to PACT, Mr. Garland served as president and chief executive officer of Portola Pharmaceuticals, where he led the company through the commercial launch of Andexxa® and a successful acquisition by Alexion. Before joining Portola, Mr. Garland was at Relypsa, where he served as chief commercial officer, and then as president of the U.S. organization after Relypsa's acquisition by Vifor Pharma. Prior to Relypsa, Mr. Garland was chief commercial officer at Exelixis where he led the launch of cabozantinib. Mr. Garland has held numerous other commercial leadership roles at Genentech, Amgen and Merck, including leading the commercial franchises for two multi-billion dollar therapies – Avastin® and Rituxan®. He also serves as a board member for Calithera Biosciences. Mr. Garland received a Bachelor of Science degree from California Polytechnic State University-San Luis Obispo and a master's degree in Business Administration from the Fuqua School of Business at Duke University.

"I am proud to join Day One's board of directors and share in the Company's mission of advancing promising new targeted cancer therapies for children and patients of all ages," said Mr. Garland. "Day One's product pipeline, led by DAY101, holds great potential for patients and I look forward to working with the Company's talented board and management team to help prepare for potential commercialization."

About DAY101

DAY101 is an investigational, oral, brain-penetrant, highly-selective type II pan-RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway. Studies have shown DAY101 has high brain distribution and exposure in comparison to other MAPK pathway inhibitors, thus potentially benefiting patients with primary brain tumors or brain metastases of solid tumors. DAY101 is a type II RAF inhibitor found to selectively inhibit both monomeric and dimeric RAF kinase, which may broaden its potential clinical application to treat an array of RAF-altered tumors.

DAY101 has been studied in over 250 patients, and as a monotherapy demonstrated good tolerability and encouraging anti-tumor activity in pediatric and adult populations with specific MAPK pathway-alterations. In November 2020, Day One announced preliminary results from PNOC014, an ongoing Phase 1 Pacific Pediatric Neuro-Oncology Consortium (PNOC) network study with DAY101 sponsored by the Dana-Farber Cancer Institute. Preliminary results demonstrated that of the eight relapsed pediatric low-grade glioma (pLGG) patients in the study with RAF fusions, two patients achieved a complete response by Response Assessment for Neuro-Oncology (RANO), three had a partial response, two achieved prolonged stable disease, and one experienced progressive disease. DAY101 also demonstrated a tolerable safety profile with the most common side effects being skin rash and hair color changes.

DAY101 has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with pLGG harboring an activating RAF alteration who require systemic therapy and who have either progressed following prior treatment or who have no satisfactory alternative treatment options. The FDA has also granted Rare Pediatric Disease Designation to DAY101 for the treatment of low-grade gliomas harboring an activating RAF alteration that disproportionately affects children. In addition, DAY101 has received Orphan Drug designation from the FDA for the treatment of malignant glioma and orphan designation from the European Commission for the treatment of glioma.

Day One is conducting a pivotal Phase 2 trial (FIREFLY-1) of DAY101 in pediatric, adolescent and young adult patients with pLGG. Day One also plans to study DAY101 alone or in combination with other agents that target key signaling nodes in the MAPK pathway, such as the Company's MEK inhibitor pimasertib, in patient populations where various RAS and RAF alterations are believed to play an important role in driving disease.

About Day One Biopharmaceuticals

Day One Biopharmaceuticals is a clinical-stage biopharmaceutical company dedicated to developing and commercializing targeted therapies for patients of all ages with genomically defined cancers. Day One was founded to address a critical unmet need: children with cancer are being left behind in a cancer drug development revolution. Our name was inspired by the "The Day One Talk"[1] that physicians have with patients and their families about an initial cancer diagnosis and treatment plan. We aim to re-envision cancer drug development and redefine what's possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important emerging cancer treatments. The Company's lead product candidate, DAY101, is an oral, highly-selective type II pan-RAF kinase inhibitor, and is being evaluated in a pivotal Phase 2 clinical trial (FIREFLY-1) in pediatric, adolescent and young adult patients with recurrent or progressive low-grade glioma (pLGG). The Company's pipeline also includes the investigational agent pimasertib, a clinical-stage, oral, small molecule found to selectively inhibit mitogen-activated protein kinase kinases 1 and 2 (MEK). Through Day One and its collaborators, cancer drug development comes of age. Day One is based in South San Francisco. For more information, please visit www.dayonebio.com.

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: Day One’s plans to develop cancer therapies, expectations from current clinical trials, the execution of the Phase 2 clinical trial for DAY101 as designed, any expectations about safety, efficacy, timing and ability to complete clinical trials and to obtain regulatory approvals for DAY101 and other candidates in development, and the ability of DAY101 to treat pLGG or related indications.

Statements including words such as “believe,” “plan,” “continue,” “expect,” “will,” “develop,” “signal,” “potential,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One’s ability to develop, obtain regulatory approval for or commercialize any product candidate, Day One’s ability to protect intellectual property, the potential impact of the COVID-19 pandemic and the sufficiency of Day One’s cash, cash equivalents and investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

[1] Jennifer W. Mack and Holcombe E. Grier; Journal of Clinical Oncology 2004 22:3, 563-566

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