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): April 3, 2020

PASSAGE BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39231**	**82-2729751**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Two Commerce Square **2001 Market Street, 28th Floor** **Philadelphia, PA**	**19103**
(Address of principal executive offices)	**(Zip Code)**

(267) 866-0311
(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	PASG	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 ☒

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 7.01 Regulation FD Disclosure.

On April 3, 2020, Passage Bio, Inc. (the "***Company***") updated its corporate presentation. The corporate presentation is available on the Company's website in the Events & Presentations section at https://investors.passagebio.com/news-and-events/events-and-presentations.

The information furnished with this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

In light of recent developments relating to the coronavirus disease 2019 ("***COVID-19***") global pandemic, the Company is providing an update on the impact of COVID-19 on its operations.

Business Operations

The Company is continuing to proactively monitor and assess the current COVID-19 global pandemic. Since early March the Company has activated a management team taskforce to assess the potential impact on our business that may result from this rapidly evolving crisis and to avoid any unnecessary potential delays to our programs. At this time, all programs and research activities remain on track. The safety and well-being of employees, patients and partners is the Company's highest priority.

Financial Position

In March 2020, the Company closed its initial public offering, including exercise of the underwriters' option to purchase additional shares, resulting in total net proceeds of $232 million. Based on its current operating plan, the Company's expects its cash and cash equivalents as of Dec. 31, 2019, together with the proceeds from its initial public offering, will enable the Company to fund its operating expenses and capital expenditure requirements into 2023.

Risk Factor Update

The Company is also supplementing the risk factors previously disclosed in the Risk Factors section of its registration statement on Form S-1 (Registration No. 333-236214), initially filed with the Securities and Exchange Commission on February 3, 2020, as amended, to include the following risk factor in the section titled: "Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business":

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our preclinical development activities and planned clinical trials.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus, SARS-CoV-2, which causes coronavirus disease 2019, or COVID-19, surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. As a result of the COVID-19 outbreak, or similar pandemics, we may experience disruptions that could severely impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials, including:

- delays or disruptions in preclinical development activities, particularly at Penn, including non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies due to unforeseen circumstances in supply chain;
- interruption or delays in the operations of the U.S. Food and Drug Administration and comparable foreign regulatory agencies, which may impact timelines for regulatory submission, trial initiation and regulatory approval;
- interruption or delays in our CROs and collaborators meeting expected deadlines or complying with regulatory requirements related to preclinical development activities, preclinical studies and planned clinical trials;
- interruptions of, or delays in receiving, supplies of our product candidates from our CMOs, particularly at Paragon, due to staffing shortages, productions slowdowns or stoppages and disruptions in delivery systems;

- delays or difficulties in any planned clinical site initiation, including difficulties in obtaining IRB approvals, recruiting clinical site investigators and clinical site staff;

- delays or difficulties in enrolling patients in clinical trials;

- increased rates of patients withdrawing from any planned clinical trials following enrollment as a result of contracting COVID-19 or being forced to quarantine;

- diversion of healthcare resources away from the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including the diversion of hospitals serving as any potential clinical trial sites and hospital staff supporting the conduct of our planned clinical trials;

- interruption of planned key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and planned clinical study endpoints;

- limitations on employee or collaborator resources that would otherwise be focused on the conduct of our preclinical development activities, preclinical studies and planned clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions; and

- reduced ability to engage with the medical and investor communities due to the cancellation of conferences scheduled throughout the year.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct preclinical development activities, preclinical studies and planned clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

In addition, the trading prices for our common stock and other biopharmaceutical companies, as well as the broader equity and debt markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity. As a result, we may face difficulties raising capital when needed, and any such sales may be on unfavorable terms to us. Further, to the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials and will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Please also refer to the complete set of Risk Factors in the Company's registration statement on Form S-1 (Registration No. 333-236214), initially filed with the Securities and Exchange Commission on February 3, 2020, as amended, for additional risks and uncertainties facing the Company that may have a material adverse effect on the Company's business prospects, financial condition and results of operations.

Forward-Looking Statements

This Current Report on Form 8-K includes “forward-looking statements” within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995, including, but not limited to: our expectation about timing and execution of anticipated milestones, including our planned IND submissions and initiation of clinical trials; our expectations about our collaborators’ and partners’ ability to execute key initiatives; estimates regarding our cash forecasts; the expected impact of the COVID-19 pandemic on our operations; and the ability of our lead product candidates to treat the underlying causes of their respective target monogenic CNS disorders. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “potential,” “possible,” “will,” “would,” and other words and terms of similar meaning. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our ability to develop, obtain regulatory approval for and commercialize PBGM01, PBFT02, PBKR03 and future product candidates; the timing and results of preclinical studies and clinical trials; the risk that positive results in a preclinical study or clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events; failure to protect and enforce our intellectual property, and other proprietary rights; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; risks relating to technology failures or breaches; our dependence on collaborators and other third parties for the development of product candidates and other aspects of our business, which are outside of our full control; risks associated with current and potential delays, work stoppages, or supply chain disruptions caused by the coronavirus pandemic; risks associated with current and potential future healthcare reforms; risks relating to attracting and retaining key personnel; failure to comply with legal and regulatory requirements; risks relating to access to capital and credit markets; and the other risks and uncertainties that are described in the Risk Factors section of our most recent filings with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statements except as required by law.

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.

PASSAGE BIO, INC.

Date: April 3, 2020

By: /s/ Richard Morris
Richard Morris
Chief Financial Officer