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): January 27, 2023

GreenLight Biosciences Holdings, PBC

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39894**	**85-1914700**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Boston Avenue Suite 3100 Medford, Massachusetts	**02155**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 616-8188

(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	GRNA	The Nasdaq Stock Market LLC
Warrants, each exercisable for one share of Common Stock for $11.50 per share	GRNAW	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 7.01 Regulation FD Disclosure

On February 1, 2023, GreenLight Biosciences Holdings, PBC (the "Company" or "GreenLight") issued a press release entitled "GreenLight Biosciences receives approval to initiate Phase I/II clinical trial of Covid-19 mRNA vaccine candidate."

The information in this Item 7.01, including Exhibit 99.1 to this Current Report on Form 8-K, 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On January 27, 2023, the Company received regulatory approval from the Rwanda Food and Drugs Authority to start a Phase I/II clinical trial of its vaccine candidate against Covid-19 as a booster to previously vaccinated individuals. Preparations for the trial are now underway.

GreenLight's mRNA vaccine candidate, GLB-COV2-043, contains mRNA, encoding the SARS-CoV-2 full-length spike protein from the Wuhan strain, formulated in a lipid nanoparticle. This vaccine candidate is part of GreenLight's broader Covid-19 strategy, which includes the development of a universal Covid-19 vaccine with broader and more durable protection. Pending positive safety and immunogenicity results from this Phase I/II clinical trial, GreenLight will look to continue development in Africa on potential next-generation Covid-19 vaccine candidates.

The Phase I/II study is designed to assess safety and immunogenicity as measured by humoral and cellular immune-response endpoints. Enrollment will be open to eligible adults who have received a 2-dose priming course of the mRNA BNT162b2/Comirnaty vaccine or a 2-dose priming and a third injection (i.e. as a booster) of the same mRNA vaccine. Participants will be evaluated in four cohorts, with the GreenLight vaccine candidate being administered in 15 microgram, 30 microgram, 60 microgram and 90 microgram doses, respectively. Each cohort will include 10 participants receiving the GreenLight vaccine candidate.

Forward-Looking Statements

Certain statements in this Current Report on Form 8-K may constitute "forward-looking statements" for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, including those relating to the success, timing of and costs associated with our clinical trials, including estimates regarding when patients will be enrolled, when data will be report for ongoing clinical trials, and timing to commence future clinical trials, the success, cost and timing of our research and development activities in our plant and human health programs, the acceptance of RNA-based technologies by regulators and the public, our ability to raise and productively deploy capital and the rate at which we can successfully bring products to market, our projected cash runway and our ability to obtain funding for our operations when needed. Forward-looking statements include statements relating to our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors included in our Quarterly Reports on Form 10-Q, periodic filings on Form 8-K, and any of our future filings with the SEC. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by current macroeconomic conditions and the ongoing COVID-19 pandemic and there may be additional risks that we consider immaterial, or which are unknown. It is not possible to predict or identify all such risks. Our forward-looking statements only speak as of the date they are made, and we do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by GreenLight Biosciences Holdings, PBC on February 1, 2023
104	Cover Page Interactive Date File (embedded within the Inline XBRL document)

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.

GREENLIGHT BIOSCIENCES HOLDINGS, PBC

Date: February 1, 2023

By: /s/ David Kennedy
David Kennedy
General Counsel

GreenLight Biosciences receives approval to initiate Phase I/II clinical trial of Covid-19 mRNA vaccine candidate

- The Rwanda FDA has given regulatory approval to GreenLight to start a Phase I/II clinical trial of its Covid-19 vaccine candidate in Rwanda
- This phase I/II clinical trial is the first step in GreenLight's integrated strategy of bringing a universal Covid-19 mRNA vaccine to market globally.
- By initiating this first-in-human clinical study in Rwanda, GreenLight is demonstrating its commitment to partner with the people of Africa in bringing advanced health technologies to the continent

Kigali, Rwanda and Lexington, MA February 1, 2022 — GreenLight Biosciences (Nasdaq: GRNA), a public benefit corporation striving to deliver on the full potential of RNA to address some of the world's toughest problems in human health and agriculture, today announced that it has received regulatory approval from the Rwanda Food and Drugs Authority (Rwanda FDA) to start a Phase I/II clinical trial of its vaccine candidate against Covid-19 as a booster to previously vaccinated individuals. Preparations for the trial are underway.

Mark Dybul, chair of GreenLight's Human Health Scientific Advisory Board, and former executive director of the Global Fund to Fight AIDS, Tuberculosis and Malaria, said:

"Covid-19 continues to be a significant global health issue. Efforts to develop novel vaccines that are longer-lasting and effective against a broad spectrum of variants are necessary to minimize the risk of disease resurgence or dangerous mutations of the SARS-CoV-2 virus. It is especially important to develop vaccines that are globally affordable and scalable. GreenLight's efforts to initiate this clinical study in Rwanda show the company's commitment to support Africa's goal of affordable vaccine self-sufficiency.

Andrey Zarur, GreenLight's CEO, said:

"This clinical trial marks the necessary first step toward developing an integrated, universal strategy against Covid-19. Our previously announced collaboration with the U.S. National Institutes of Health to develop a universal Covid-19 vaccine, and our previously reported scalable mRNA manufacturing process, will enable us to address this disease in a more effective manner."

"We are delighted to receive approval from the Rwanda Food and Drugs Authority to start our Covid-19 mRNA vaccine candidate trial. Approval to begin clinical trials in humans, from a national regulatory authority, is a significant milestone for GreenLight's human health business. This demonstrates our commitment of supporting vaccine and therapeutics accessibility for low- and middle-income countries.

We share the Rwandan government's vision that everybody should have access to the best healthcare. A Phase I/II trial of our Covid-19 vaccine candidate is just the start. Rwanda is at the forefront of bringing end-to-end research and development to Africa. We look forward to deepening our partnership so that we can play our part, and help Africa become self-sufficient in vaccines."

In addition to its mRNA Covid-19 vaccine candidate, GreenLight is developing mRNA vaccines against other infectious diseases, such as shingles (in collaboration with Serum Institute of India Pvt. Ltd.), and cancer (in collaboration with EpiVax Therapeutics), as well as RNA-based therapies against genetic disorders, such as sickle-cell disease. Further details of the Covid-19 vaccine candidate study can be found at: https://www.clinicaltrials.gov/ct2/show/NCT05602961.

Notes to editors

1. GreenLight's mRNA vaccine candidate, GLB-COV2-043, contains mRNA, encoding the SARS-CoV-2 full-length spike protein from the Wuhan strain, formulated in a lipid nanoparticle. This vaccine candidate is part of GreenLight's broader Covid-19 strategy, which includes the development of a universal Covid-19 vaccine with broader and more durable protection. Pending positive safety and immunogenicity results from this Phase I/II clinical trial, GreenLight will look to continue development in Africa on potential next-generation Covid-19 vaccine candidates.
2. The Phase I/II study is designed to assess safety and immunogenicity as measured by humoral and cellular immune-response endpoints. Enrollment will be open to eligible adults who have received a 2-dose priming course of the mRNA BNT162b2/Comirnaty vaccine or a 2-dose priming and a third injection (i.e. as a booster) of the same mRNA vaccine.

Participants will be evaluated in four cohorts, with the GreenLight vaccine candidate being administered in 15 microgram, 30 microgram, 60 microgram and 90 microgram doses, respectively. Each cohort will include 10 participants receiving the GreenLight vaccine candidate.

3. Further details on GreenLight's pipeline and plans can be found at investors.greenlightbio.com.
4. Platform Life Sciences, in collaboration with GreenLight and leading clinical investigators in Rwanda, will conduct the trial.

About GreenLight Biosciences

Founded in 2008, GreenLight aims to address some of the world's biggest problems by delivering on the full potential of RNA for human health and agriculture. In human health, this includes messenger RNA vaccines and therapeutics. In agriculture, this includes RNA to protect honeybees and a range of crops. The company's breakthrough cell-free RNA platform, which is protected by numerous patents, allows for cost-effective production of RNA. GreenLight's human health product candidates are in the pre-clinical stage, and its product candidates for the agriculture market are in the early stages of development or regulatory review. GreenLight is a public benefit corporation that trades under the ticker GRNA on Nasdaq. For more information, including our latest investor presentation and other materials, please visit https://www.greenlightbiosciences.com/.

Availability of Other Information About GreenLight Biosciences

Investors and others should note that we communicate with our investors and the public using our website (www.greenlightbiosciences.com), the investor relations website (https://investors.greenlightbio.com/), and on social media (Twitter and LinkedIn), including but not limited to investor presentations and investor fact sheets, U.S. Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that GreenLight posts on these channels and websites could be deemed to be material information. As a result, GreenLight encourages investors, the media, and others interested in GreenLight to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on GreenLight's investor relations website and may include additional social media channels. The contents of GreenLight's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Forward Looking Statements

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or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. For additional information on GreenLight and potential risks associated with investing, please see our public filings at https://investors.greenlightbio.com/financial-information/sec-filings.

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