# REPLY EXHIBIT 7

Reply Exhibit 7 – Synthetic Biologics, Inc. Form 10-Q filed November 10, 2020 (excerpts)

*Nejmeh v. Theriva Biologics, Inc.*, No. 3:26-cv-00705-ART-CSD (D. Nev.)

Source: SEC EDGAR, Accession No. 0001104659-20-123646.

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, DC 20549**

**FORM 10-Q**

(Mark One)
☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended September 30, 2020**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

**For the transition period from _____ to _____**

**Commission File Number: 001-12584**

# SYNTHETIC BIOLOGICS, INC.

*(Exact name of Registrant as Specified in Its Charter)*

| **Nevada** | **13-3808303** |
|---|---|
| *(State or Other Jurisdiction of Incorporation or Organization)* | *(I.R.S. Employer Identification No.)* |
| **9605 Medical Center Drive, Suite 270**<br>**Rockville, MD** | **20850** |
| *(Address of Principal Executive Offices)* | *(Zip Code)* |

**(301) 417-4364**
(*Registrant's Telephone Number, Including Area Code*)

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 | SYN | NYSE American |

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer, "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☐

Non-accelerated Filer ☒ Smaller Reporting Company ☒

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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of November 6, 2020, the registrant had 19,993,390 shares of common stock, $0.001 par value per share, outstanding.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents will not be sufficient to complete our planned Phase 3 clinical trial for SYN-004 or post-Phase 1 future clinical programs for SYN-020, which are expected to require significant cash expenditures. In addition, based on the anticipated significant cost of a Phase 3 clinical program in a broad indication for SYN-004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Our ability to raise capital through the sale of securities is currently limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on registration statement Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is $75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

***The COVID-19 global health crisis has impacted our planned operations, including our clinical studies***

In January 2020, the World Health Organization declared a global pandemic for the novel strain of coronavirus, COVID-19. Since then, the COVID-19 coronavirus has spread to multiple countries, including throughout the United States. We have experienced disruptions that have impacted our business and clinical trials and expect to experience additional disruptions as the pandemic continues, including:

- unwillingness of potential study participants to enroll in new clinical trials and/or visit healthcare facilities;
- postponement in clinical site initiation for our SYN-004 clinical study;
- postponement of the initiation of our SYN-020 single ascending dose (SAD) study
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical site visits by study participants and clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;