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): October 15, 2026

Crescent Biopharma, Inc.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-36177**	**06-1686563**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
300 Fifth Avenue Waltham, MA		**02451**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's telephone number, including area code: (617) 430-5595

Not applicable
(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 (*see* General Instruction A.2. below):

☐ 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
Ordinary Shares, $0.001 par value per share	**CBIO**	**The Nasdaq Capital 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 8.01 Other Events.

On October 15, 2026, Crescent Biopharma, Inc. (“Crescent” or the “Company”) issued a press release announcing clinical pipeline updates, including (i) enrolling patients in cohorts combining CR-001, a PD-1 x VEGF bispecific antibody, plus standard of care chemotherapy regimens in its global Phase 1/2 ASCEND trial, (ii) the initiation of additional antibody-drug conjugates (“ADCs”) combination studies with CR-001, (iii) anticipated initiation of the Phase 1/2 APOLLO trial of CR-002, a topoisomerase inhibitor ADC targeting PD-L1, and (iv) the expected timing of clinical data readouts.

Clinical Execution Progress in ASCEND, a Global Phase 1/2 Trial of CR-001

In the global Phase 1/2 ASCEND of CR-001 as a monotherapy, the Company has completed dose escalation and enrolled participants across several tumor types at clinical sites in the United States, Europe and South Korea. The Company is on track to report initial monotherapy data from ASCEND in the first quarter of 2027, including preliminary antitumor response as measured by overall response rate (“ORR”) from a first-line non-small cell lung cancer (“NSCLC”) cohort of up to 12 patients and the safety, tolerability, pharmacokinetic and pharmacodynamic data from more than 125 treatment-naive and previously-treated patients across multiple solid tumor types.

Enrollment has also commenced in the standard of care chemotherapy combination expansion cohorts of ASCEND. The Company is targeting various tumor types and chemotherapy regimens for evaluation, including the types below, with initial data anticipated in mid-2027:

- First-line (1L) NSCLC: CR-001 + paclitaxel and carboplatin (squamous) or pemetrexed and carboplatin (non-squamous)
- 1L mismatch repair proficient (“pMMR”) / microsatellite stable (“MSS”) colorectal cancer (“CRC”): CR-001 + mFOLFOX6
- Third-line (3L) CRC: CR-001 + trifluridine and tipiracil
- 1L biliary tract cancer: CR-001 + gemcitabine and cisplatin
- 1L pMMR endometrial cancer CR-001 + carboplatin and paclitaxel
- 1L programmed cell death ligand ("PD-L1") - expressing gastric/gastroesophageal junction (“GEJ”) cancer: CR-001 + capecitabine and oxaliplatin
- Second-line (2L) PD-L1-expressing gastric/GEJ cancer: CR-001 + paclitaxel

Pending results and further interactions with regulators, the Company plans to initiate the first of multiple Phase 3 trials of CR-001 in early 2028.

Kelun-Biotech Combination Studies

In partnership with the Company, Kelun-Biotech Biopharmaceutical Co., Ltd. (“Kelun-Biotech”), is conducting the following clinical trials in China to evaluate CR-001 (also known as SKB118) in combination with sacituzumab tirumotecan (“sac-TMT”), a TROP2-directed ADC, with additional ADC combination studies planned:

- A Phase 2 trial of CR-001 (SKB118) and sac-TMT in participants with locally advanced or metastatic NSCLC is ongoing with initial data expected in mid-2027;
- A Phase 2 trial of CR-001 (SKB118) and sac-TMT is enrolling participants with advanced solid tumors;
- A Phase 2 trial of CR-001 (SKB118) in combination with sac-TMT is initiating in EGFR-mutant locally advanced or metastatic non-squamous NSCLC who have failed epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI) therapy; and
- A Phase 1/2 trial of CR-001 (SKB118) in combination with CR-003 (also known as SKB105), an integrin-beta 6-directed ADC, is expected to commence in the first half of 2027.

ADC Pipeline

In October 2026, the Company’s topoisomerase inhibitor ADC targeting PD-L1, CR-002, received allowance to proceed under an Investigational New Drug Application from the U.S. Food and Drug Administration. The Company is on track to initiate the global Phase 1/2 APOLLO trial in the fourth quarter of 2026 in patients with advanced solid tumors, including NSCLC, head and neck squamous cell carcinoma, and various gastrointestinal and gynecological tumors. Initial data are expected in the second half of 2027.

Kelun-Biotech granted the Company exclusive rights to research, develop, and commercialize CR-003 (SKB105), an integrin-beta 6-targeted ADC, in the United States, Europe and all markets outside of Greater China. A Phase 1/2 trial of

CR-003 (SKB105) in participants with advanced solid tumors conducted by Kelun-Biotech in China is ongoing and proof-of-concept data are expected in the first quarter of 2027. The Company plans to leverage data generated in China to support the global clinical development of CR-003 (SKB105).

Forward-Looking Statements

Certain statements in this Current Report on Form 8-K, other than purely historical information, may constitute "forward-looking statements" within the meaning of the federal securities laws, including for purposes of the
"safe harbor" provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements relating to Crescent's expectations, beliefs, or strategies regarding the future of its pipeline and business including, without limitation: the timing and success of clinical data from the ASCEND monotherapy and combination trials of CR-001; the potential initiation and success of Phase 3 studies of CR-001; the timing and success of the Phase 2 combination trials for CR-001 and sac-TMT, including the potential initiation of additional ADC combination studies by Kelun-Biotech; the expected timing for initiation, trial design, indication selection, and initial clinical data for the global Phase 1/2 APOLLO trial of CR-002; the timing and success of clinical data from the Phase 1/2 trial of CR-003 as generated by Kelun-Biotech in China; the expected benefits or opportunities with respect to CR-001, CR-002, and CR-003, including the anticipated number of patients dosed across the portfolio; and the potential for CR-002 and CR-003 to act as single agents and in combination with CR-001. Forward-looking statements generally relate to future events or future financial or operating performance. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect 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 and involve a number of risks, uncertainties or other assumptions that may cause actual performance to be materially different from those expressed or implied by these forward-looking statements. Risks and uncertainties include, but are not limited to: the expected benefits of, and opportunities related to, the strategic partnership between Crescent and Kelun-Biotech may not be realized or may take longer to realize than anticipated; Crescent's limited operating history, including with respect to clinical trials; Crescent's historical losses and any future ability to generate revenue; Crescent's ability to raise capital to support its business plans; risks associated with clinical development and regulatory approval; risks related to Crescent's intellectual property; Crescent's reliance on third parties, including to help develop its product candidates, run its clinical trials, and manufacture its product candidates; significant disruptions of information technology systems or breaches of data security, litigation and regulatory risks; risks related to the current macroeconomic environment, including fluctuating interest rates, barriers to trade, changes to fiscal and monetary policy or government budget dynamics, geopolitical factors, including the ongoing conflicts in Iran and between Russia and Ukraine and the responses thereto, and supply chain disruptions, as well as those factors more fully described in Crescent's most recent filings with the Securities and Exchange Commission (including its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2026), and Crescent's other filings with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of Crescent's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Forward-looking statements in this Current Report on Form 8-K speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Except as required by law, Crescent does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CRESCENT BIOPHARMA, INC.

Date: October 15, 2026

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: Chief Executive Officer