UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____ .**

Commission File Number 001-37348

Corbus Pharmaceuticals Holdings, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-4348039**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
500 River Ridge Drive Norwood, Massachusetts	**02062**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 963-0100

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	**CRBP**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $67.8 million, based on the closing price of the registrant's common stock on June 30, 2025.

As of March 6, 2026, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 17,736,464.

Documents incorporated by reference

None.

CORBUS PHARMACEUTICALS HOLDINGS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2025
TABLE OF CONTENTS

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as “may,” “can,” “anticipate,” “assume,” “should,” “indicate,” “would,” “believe,” “contemplate,” “expect,” “seek,” “estimate,” “continue,” “plan,” “point to,” “project,” “predict,” “could,” “intend,” “target,” “potential” and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our history of operating losses;
- our current and future capital requirements and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our product candidates and obtain approval from the U.S. Food and Drug Administration (the "FDA") or other regulatory agents in different jurisdictions;
- our ability to internally develop new product candidates, intellectual property, and other product candidates we may acquire and/or license;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- the potential impact of geopolitical events and their effects on our operations, including on our clinical development plans and timelines;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see “Risk Factors” for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

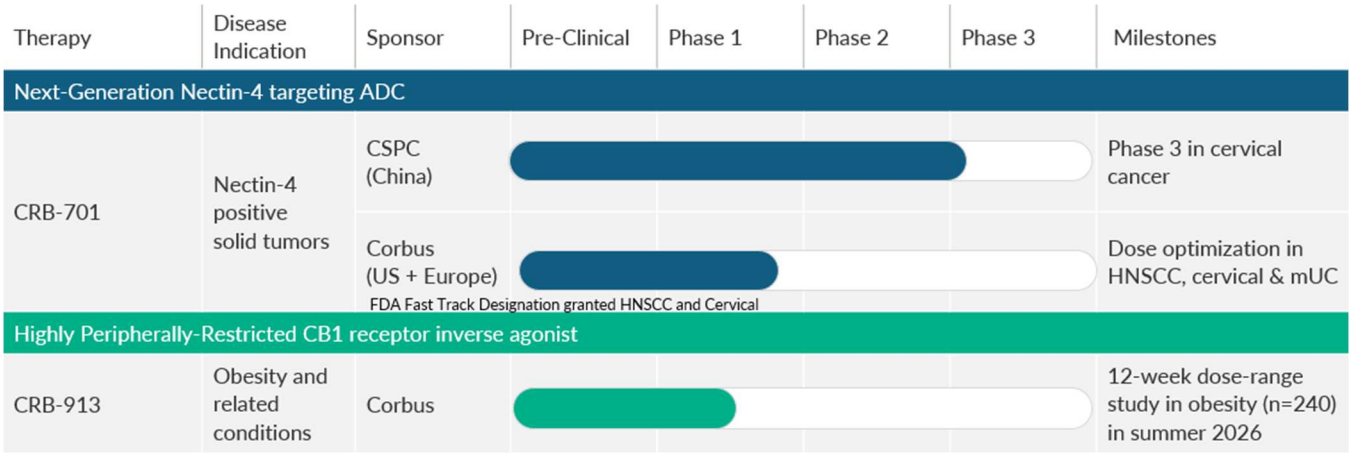
Item 1. BUSINESS

All references in this report to “Corbus,” the “Company,” “we,” “us,” or “our” mean Corbus Pharmaceuticals Holdings, Inc. and its subsidiaries unless we state otherwise, or the context otherwise indicates.

Overview

Corbus Pharmaceuticals Holdings, Inc. (the “Company” or “Corbus”) is a clinical stage company focused on promising new therapies in oncology and obesity and is committed to helping people defeat serious illness by bringing innovative scientific approaches to well-understood biological pathways. Corbus’ pipeline includes CRB-701, a next-generation antibody drug conjugate ("ADC") that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload of monomethyl auristatin E ("MMAE") and CRB-913, a highly peripherally restricted cannabinoid type-1 ("CB1") receptor inverse agonist for the treatment of obesity.

Our pipeline is as follows:



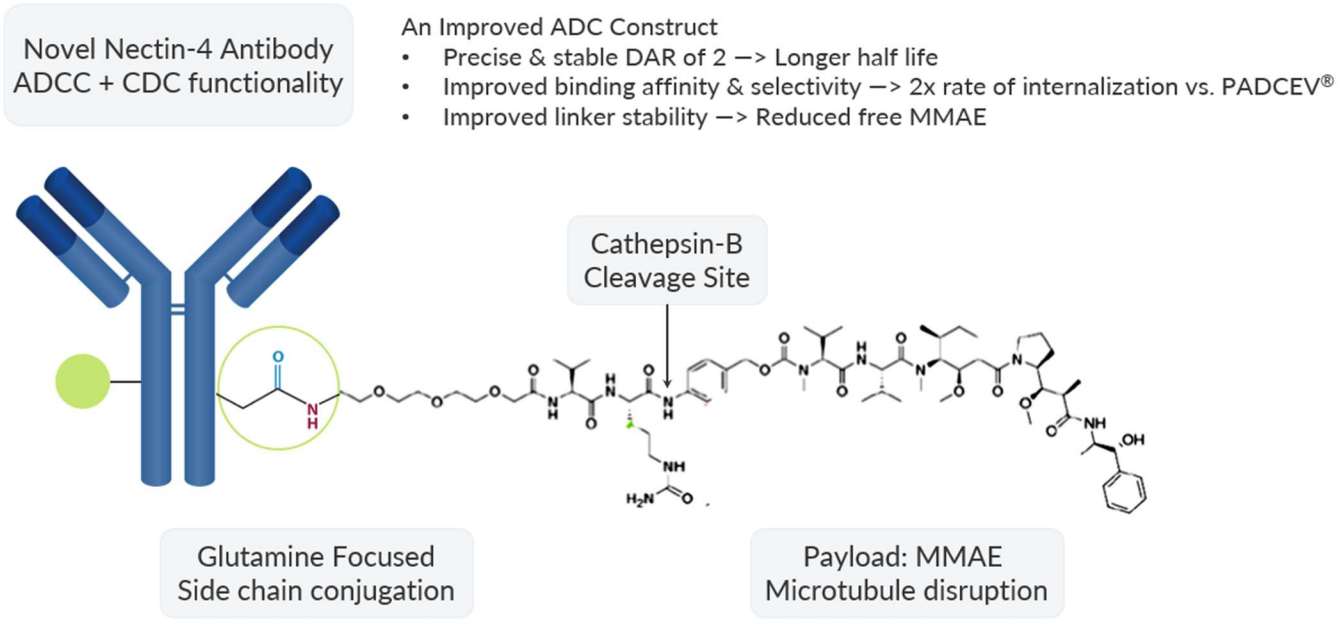
CRB-701

CRB-701 (SYS6002) is a novel clinical stage ADC that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload of MMAE. In February 2023, the Company obtained a license from CSPC Megalith Biopharmaceutical Co. Ltd. (“CSPC”), a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize the drug in the United States (“U.S.”), Canada, the European Union (including the European Free Trade Area), the United Kingdom (“U.K.”) and Australia. The Company is conducting a Phase 1/2 study in the U.S. and Europe (the "Western study") enrolling patients with advanced solid tumors associated with Nectin-4 expression. The dose expansion phase of the clinical trial is ongoing. In June 2025, the Company began dosing participants in the PD-1 combination arm with CRB-701 in combination with Keytruda® (pembrolizumab). The Company has received fast track designation for CRB-701 from the U.S. Food and Drug Administration (the "FDA") for the treatment of relapsed or refractory metastatic cervical cancer in December 2024 and in recurrent or metastatic head and neck squamous cell carcinoma (“HNSCC”) previously treated with platinum-based chemotherapy and an anti-PD(L)-1 therapy in September 2025. CRB-701 is currently being investigated by CSPC in a Phase 3 clinical trial in patients with cervical cancer in China (the "China study").

The targeting of Nectin-4 on cancer cells to release the cytotoxic payload MMAE is a clinically validated target as enfortumab vedotin ("EV" or "PADCEV®") has been approved for the treatment of metastatic urothelial cancer (“mUC”). PADCEV® toxicity and safety limitations include serious and potentially life-threatening skin reactions and peripheral neuropathy, which negatively impact tolerability and dose intensity.

CRB-701 is designed to be an improved next-generation site-specific Nectin-4 targeting ADC (Figure 1). The drug benefits from site-specific conjugation and novel linker technology to create a stable linker and enable homogeneous payload incorporation with a reproducible drug-to-antibody ration ("DAR") of 2. The linker technology attaches the MMAE cytotoxic payload to the monoclonal antibody and is designed to hold on to the ADC until it binds to Nectin-4 on the target cell. MMAE is then released upon internalization within the target cell. The targeted delivery of CRB-701 is designed to maximize delivery of MMAE while minimizing toxicity to healthy tissues. CRB-701's longer half-life and lower free plasma payload supports less frequent dosing. The complexity and cost of manufacturing CRB-701 has also been reduced by the drug's single enzyme and improved linker technology.

Figure 1: CRB-701 - Novel design



MMAE = Monomethyl auristatin E. **ADCC** = antibody-dependent cellular cytotoxicity. **CDC** = complement dependent cytotoxicity
Source(s): Modified image from Corbus data on file; Corbus data on file

On October 18, 2025, the Company announced data from its Phase 1/2 Western study that was presented at the 2025 European Society for Medical Oncology Congress ("ESMO25"). Data as of September 1, 2025 was presented from 167 patients, of whom 122[1] were evaluable for efficacy. The tumor types being investigated were HNSCC (n=41), cervical cancer (n=37) and locally advanced/metastatic urothelial (mUC, n=23) tumors. In addition, 21 patients who had other solid-tumor types were enrolled during dose escalation.

The multi-center Phase 1/2 study is being conducted in the U.S and Europe. The study was designed as an "all comers" trial with no enrollment restrictions for biomarkers (Nectin-4, PDL-1 or HPV status) or the number of prior lines of therapy. Patients were heavily pretreated with a median of 3 prior lines of therapy (range: 1–9), and the mean age was 60 years (range: 30–90). Baseline performance status, as assessed by the Eastern Cooperative Oncology Group ("ECOG"), was ≤2 for all patients, with 43.1% classified as ECOG 0, 55.1% as ECOG 1, and 1.8% as ECOG 2.

Efficacy data for HNSCC patients in the Western study demonstrated an unconfirmed objective response rate ("ORR") of 33.3% and a disease control rate ("DCR") of 75% at the 2.7 mg/kg dose and 47.6% ORR and 61.9% DCR at the 3.6 mg/kg dose. A summary of this efficacy data is depicted as a waterfall plot (Figure 2) and swimmer plot (Figure 3) below.

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[1] 122 evaluable patients includes 84 patients with either HNSCC, cervical or mUC tumors dosed at 2.7 mg/kg (n=38) or 3.6 mg/kg (n=46), 7 patients with either HNSCC, cervical or mUC tumors dosed during dose escalation at 1.8 mg/kg, 21 patients who had other solid-tumor types that were enrolled during dose escalation, 8 non-evaluable patients, 1 patient with a -60.7% reduction in the size of mUC tumor not included in ORR and DCR calculations due to missing data and 1 patient with a HNSCC tumor dosed with the combination of CRB-701 (at 2.7 mg/kg) and pembrolizumab.

Figure 2: HNSCC Waterfall Plots

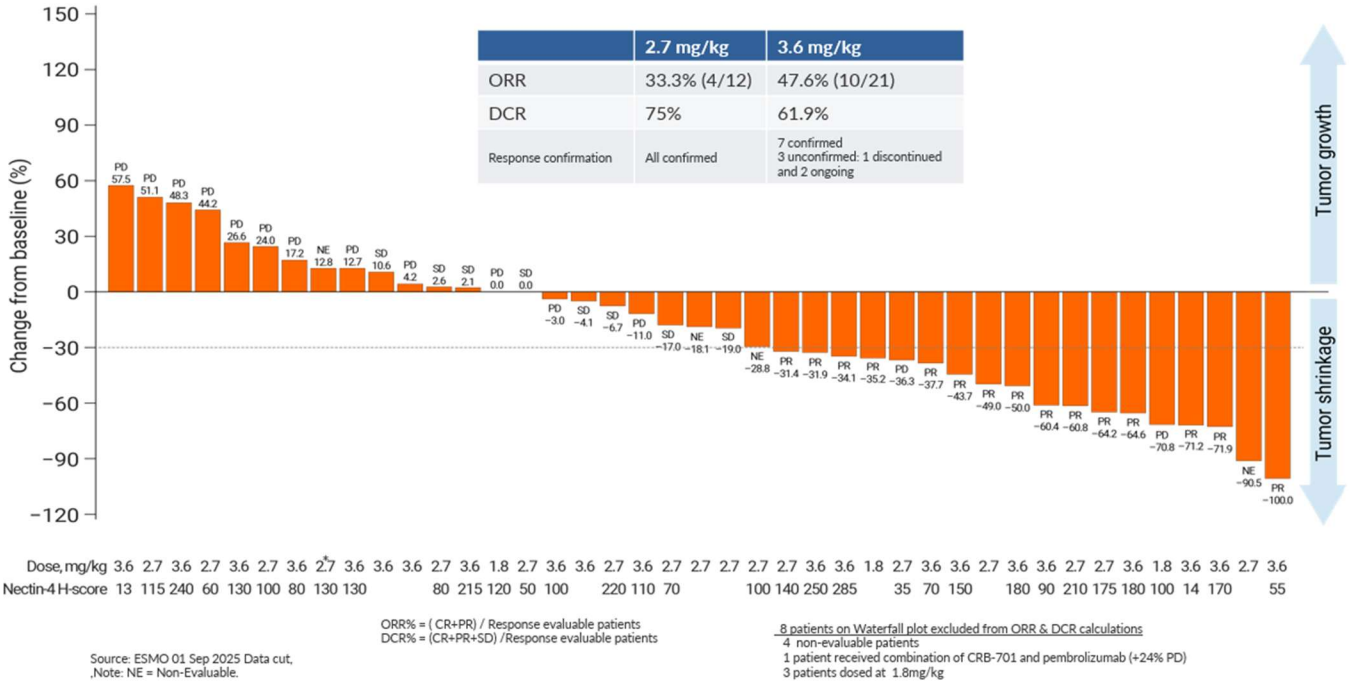
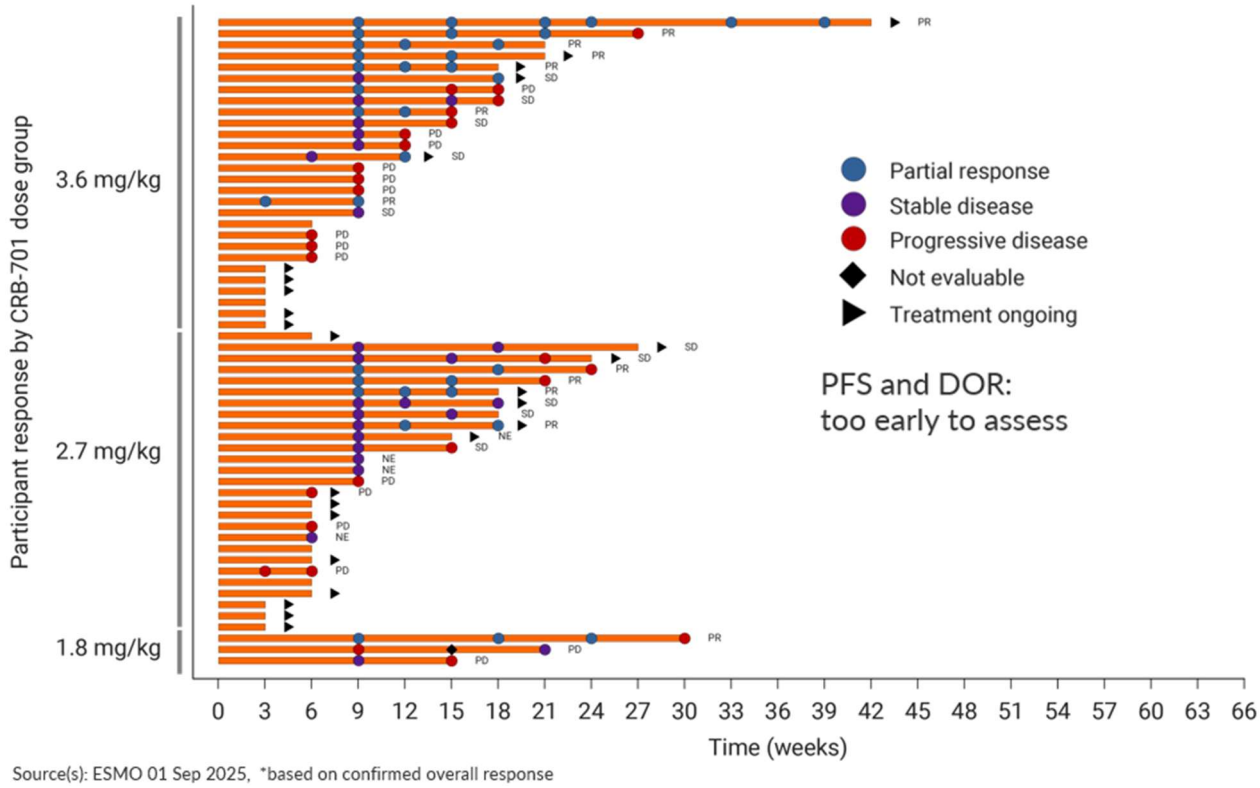
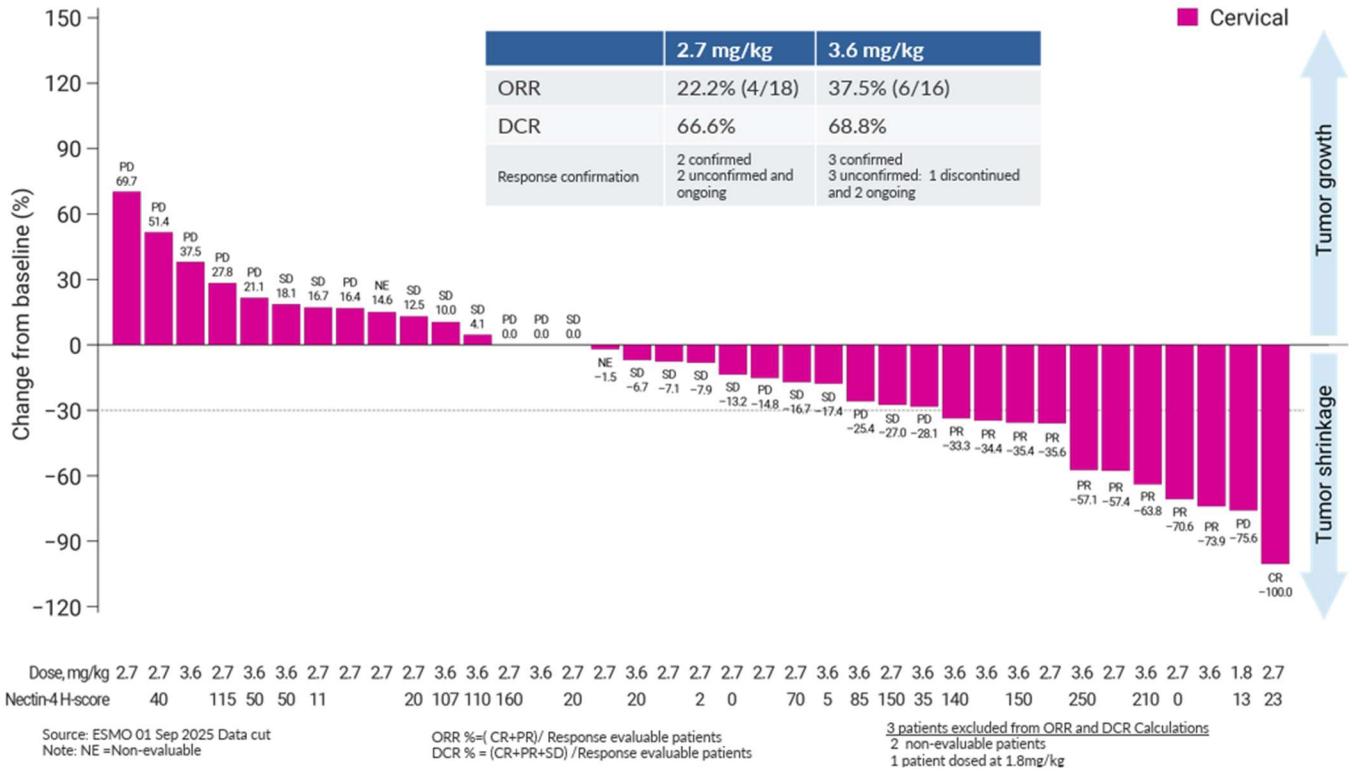


Figure 3: HNSCC Swimmer Plots



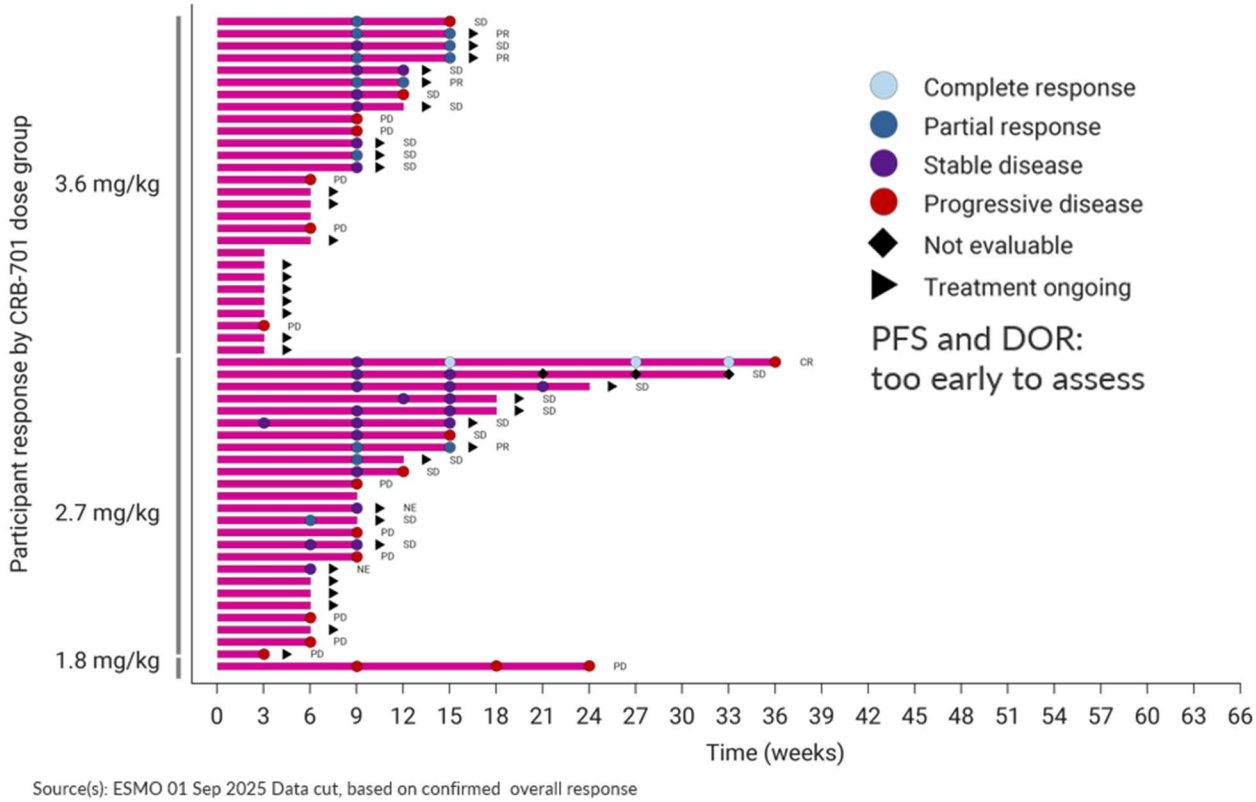
Efficacy data for cervical cancer patients in the Western study demonstrated an unconfirmed ORR of 22.2% and a DCR of 66.6% in the 2.7 mg/kg dose and 37.5% ORR and 68.8% DCR in the 3.6 mg/kg dose. A summary of this efficacy data is depicted as a waterfall plot (Figure 4) and swimmer plot (Figure 5) below.

Figure 4: Cervical Cancer Waterfall Plots



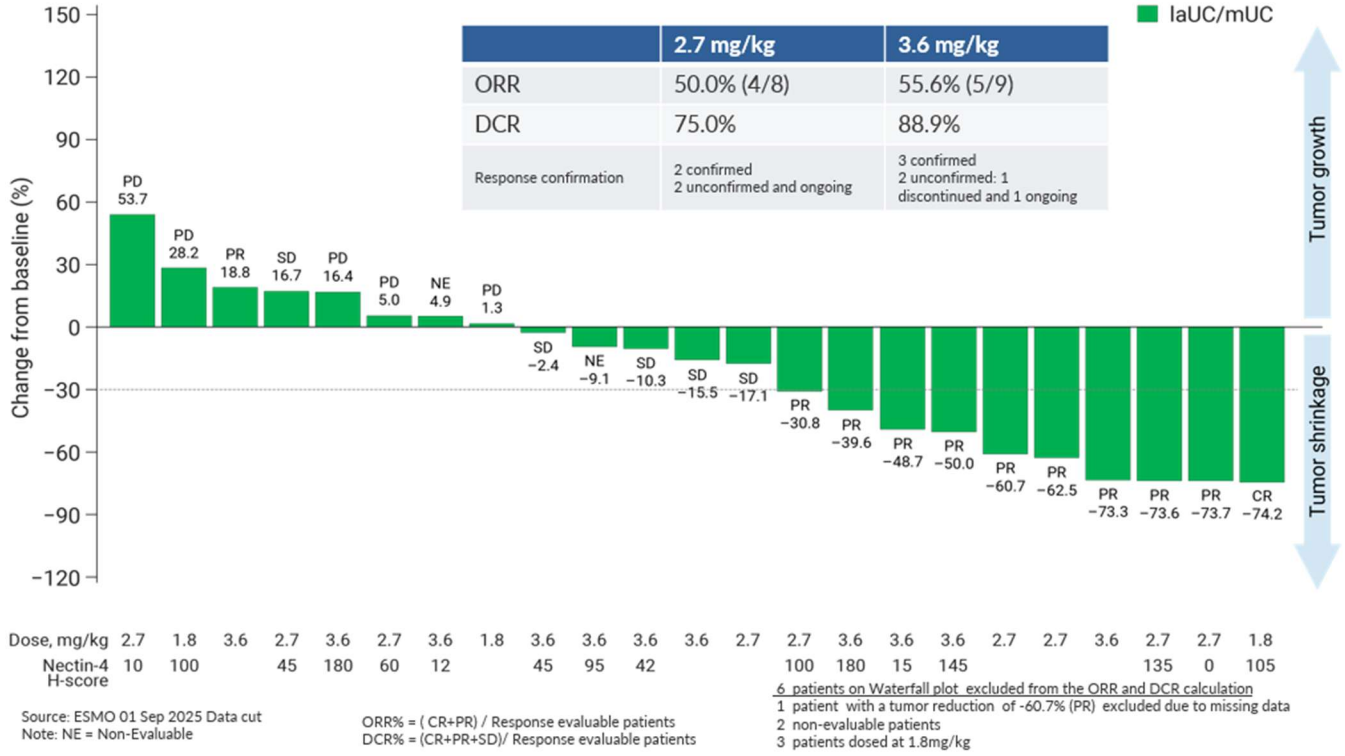
	2.7 mg/kg	3.6 mg/kg
ORR	22.2% (4/18)	37.5% (6/16)
DCR	66.6%	68.8%
Response confirmation	2 confirmed 2 unconfirmed and ongoing	3 confirmed 3 unconfirmed: 1 discontinued and 2 ongoing

Figure 5: Cervical Cancer Swimmer Plots



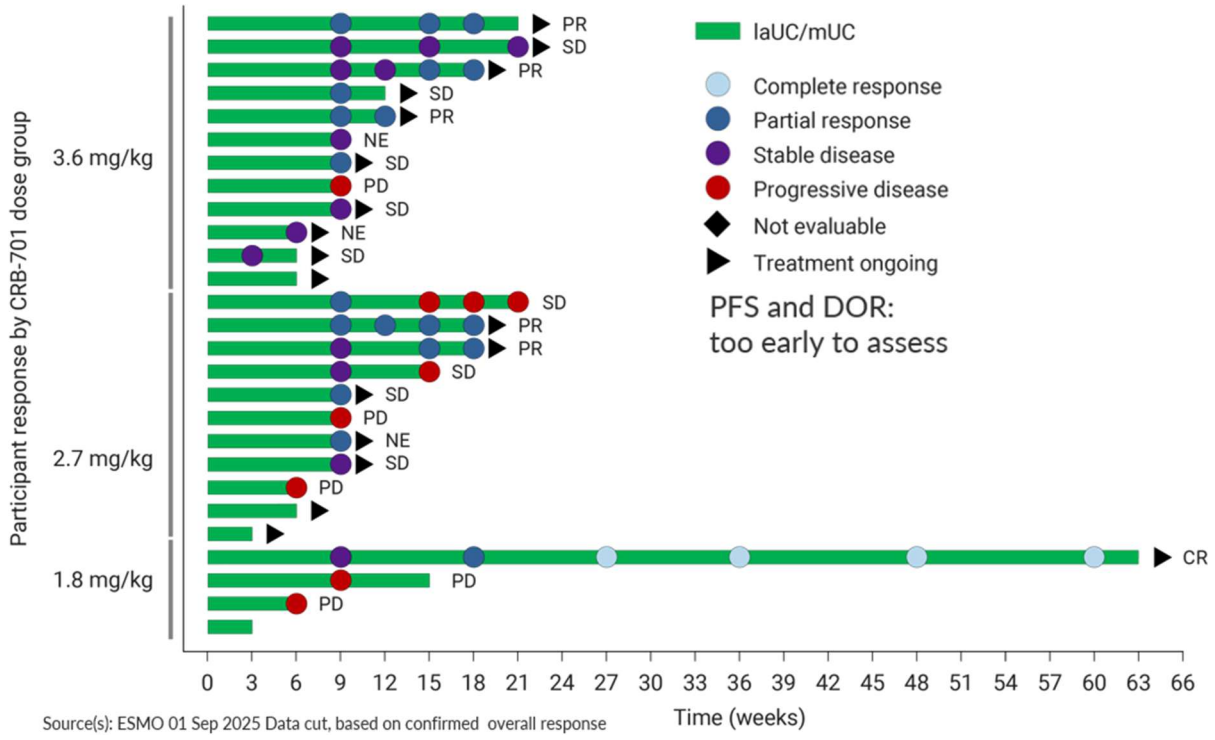
Efficacy data for mUC patients in the Western study demonstrated an unconfirmed ORR of 50.0% and a DCR of 75.0% in the 2.7 mg/kg dose and 55.6% ORR and 88.9% DCR in the 3.6 mg/kg dose. A summary of this efficacy data is depicted as a waterfall plot (Figure 6) and swimmer plot (Figure 7) below.

Figure 6: mUC Waterfall Plots



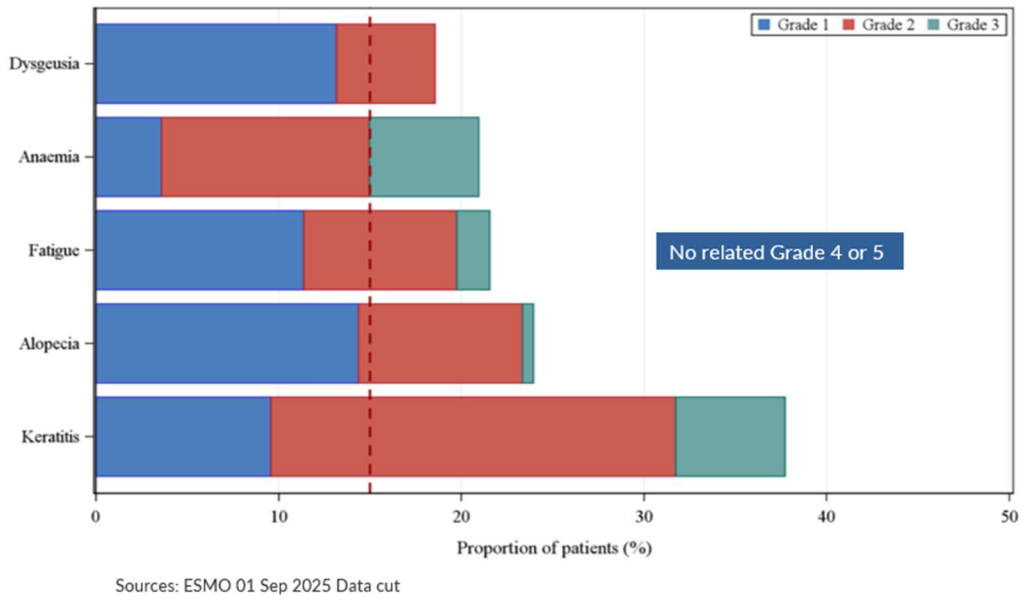
	2.7 mg/kg	3.6 mg/kg
ORR	50.0% (4/8)	55.6% (5/9)
DCR	75.0%	88.9%
Response confirmation	2 confirmed 2 unconfirmed and ongoing	3 confirmed 2 unconfirmed: 1 discontinued and 1 ongoing

Figure 7: mUC Swimmer Plots



Across all patients included in the September 1, 2025 data, CRB-701 was well-tolerated and no dose limiting toxicities ("DLTs") were encountered during dose escalation. The 2.7 mg/kg and 3.6 mg/kg doses were selected for dose optimization. The most common treatment emergent adverse events ("TEAEs") at a frequency of ≥15% were dysgeusia (18.6%), anemia (21.0%), fatigue (21.6%), alopecia (24.0%) and keratitis (32.3%). Grade 3 treatment-related adverse events were reported in 30 patients (18.0%). There were no grade 4 or 5 treatment related-adverse events (Figure 8).

Figure 8: Treatment Emergent Adverse Events



Sources: ESMO 01 Sep 2025 Data cut

A low number of cases of peripheral neuropathy or skin rash have been reported to date:

- The rate of peripheral neuropathy was low at 8.4% (all Grade 1 or 2), based on a broad, standardized MedRA category search.
- The rate of skin adverse events was low at 28.7% (excluding alopecia). Grade 3 or above events were even lower at 1.8% (n=3/167).

So far, CRB-701 has demonstrated a favorable emerging safety profile versus competitive Nectin-4 ADC drugs with MMAE payload (Figure 9).

Figure 9: Safety Profile vs. Competitive Nectin-4 MMAE Peers[1]

	PADCEV® [1]	BT8009[2]	9MW-2821[3,4]	CRB-701[5]	
Upper dose limit	1.25 mg/kg	5 mg/m^2	1.25 mg/kg	2.7mg/kg	3.6mg/kg
Schedule	D1, D8, D15 /28 days	Q1W	D1, D8, D15 /28 days	Q3W	
≥ Grade 3 AE rate	62.5% (n=237/379)	53% (n=24/45)	70%	35.7% (n=25/70)	35.5% (n=27/76)
Peripheral neuropathy (broad terms)	48% (n=182/379)	36% (n=16/45)	22.5% (n=54/240)	8.6% (6/70)	6.6% (5/76)
Rash (broad terms*)	50.7% (n=192/379)	18% (n=8/45)	30% (n=72/240)	32.9% (n=23/70)	23.7% (n=18/76)
Neutropenia (Gr 3)	10% (31/310)	4% (n=2/45)	27.9% (n=67/240)	0%	0%
Dose reduction	27.7% (n=105/379)	27% (n=12/45)	Not released	10% (7/70)	19.7% (15/76)
Dose interruptions	55.9% (n=212/379)	53% (n=24/45)	Not released	38.6% (27/70)	51.3% (39/76)
Discontinuations	20.6% (78/379)	4% (n=2/45)	Not released	5.7% (4/70)	7.9% (6/76)

Source(s):
1. NDA/BLA Multidisciplinary Review and Evaluation BLA 761137 PADCEV® (enfortumab vedotin)
2. Torras, O. Reig, et al. "652P BT8009 monotherapy in enfortumab vedotin (EV)-naïve patients with metastatic urothelial carcinoma (mUC): Updated results of Duravelo-1."Annals of Oncology 35 (2024): S515-S516.
3. ASCO 2024, Zhang, et al.
4. SGO plenary March 2024, Yang et al.
5. ESMO 01 Sep 2025 Data cut *Rash (Broad terms): Skin and subcutaneous tissue disorders SOC, excluding alopecia

CRB-701 pharmacokinetic ("PK") data indicated a longer ADC half-life and lower free-MMAE exposure relative to PADCEV® at comparable dose levels (Figure 10).

Figure 10: Pharmacokinetic Profile for CRB-701 vs. PADCEV®[1]

Company	21-day PK	Comparison	% ADC		% Free MMAE	
			C_{max}	AUC_{0-21d}	C_{max}	AUC_{0-21d}
Pfizer	PADCEV® 1.24 mg/kg Q1W x 3	PADCEV® Benchmark	100%	100%	100%	100%
CORBUS PHARMACEUTICALS	2.7 mg/kg Q3W	Matched for MMAE dose (DAR)	183%	274%	35%	38%
	3.6 mg/kg Q3W	2.9-fold PADCEV® ADC Dose®	228%	361%	59%	62%

Source(s):
PADCEV® reference data from BLA761137 17 December 2019
Corbus data: ESMO 01 Sep 2025 Data cut

The CRB-701 dose expansion phase of the Phase 1/2 Western study is ongoing. The Company expects to meet with the FDA to review and discuss the clinical data and registrational study protocols for HNSCC and cervical tumors in Q1 2026.

[1] Data is not from comparative trials

CRB-913

CRB-913 is a highly peripherally restricted oral small molecule CB1 receptor inverse agonist for the treatment of obesity. CB1 inverse agonism is a clinically validated mechanism to induce weight loss and is a distinct mechanism of action separate from GLP-1s. CRB-913 has been specifically formulated to shift the drug exposure from the brain to the periphery to improve safety and tolerability, including reducing gastrointestinal ("GI") adverse events observed with the GLP-1 class. CRB-913 offers potential to address the three major unmet needs in obesity today: (1) patients who don't respond to GLP drugs, (2) patients who discontinue treatment with GLP drugs due to intolerability, and (3) patients who are ineligible for treatment with GLP-1 drugs or discontinue treatment due to sarcopenia. CRB-913 could potentially be utilized as a daily oral pill to maintain weight loss after treatment with GLP-1 drugs or in combination with a GLP-1 drug to potentially improve weight loss or tolerability.

The Company initiated a single ascending dose ("SAD") and multiple ascending dose ("MAD") Phase 1a study in the first quarter of 2025. On December 11, 2025, the Company announced the completion of the double-blinded placebo-controlled SAD/MAD Phase 1a study conducted in the United States. The clinical trial assessed the safety, tolerability, and PK data of escalating once-daily doses of CRB-913. The SAD portion of the study (n=64) comprised of 8 cohorts that received ascending doses of CRB-913 (maximum dose of 600 mg/day) or placebo dosed orally once (2 placebo and 6 CRB-913 per cohort). Seven of the SAD cohorts enrolled healthy participants (mean BMI=28), and one enrolled people with obesity (mean BMI=36). The MAD portion of the study (n=48) comprised 4 cohorts who received ascending doses of CRB-913 (25 mg, 75 mg or 150 mg) or placebo orally once daily (3 placebo and 9 CRB-913-treated per cohort) over 7 days and followed by a further 7 days of continuous, in-clinic observation. Three of the MAD cohorts enrolled healthy participants and one enrolled people with obesity.

Safety

No serious treatment-emergent adverse events were reported in the SAD/MAD study. CRB-913 was not associated with GI intolerability. There were no reported cases of nausea, vomiting, or constipation and only a single case of mild diarrhea. Daily neuropsychiatric assessments using the Columbia-Suicide Severity Rating Scale ("CSSRS"), the Patient Health Questionnaire-9 ("PHQ-9"), and the General Anxiety Disorder-7 ("GAD-7") questionnaires remained stable and negative at all time points for all participants. No cases of suicidality, depression, or insomnia were reported in the study.

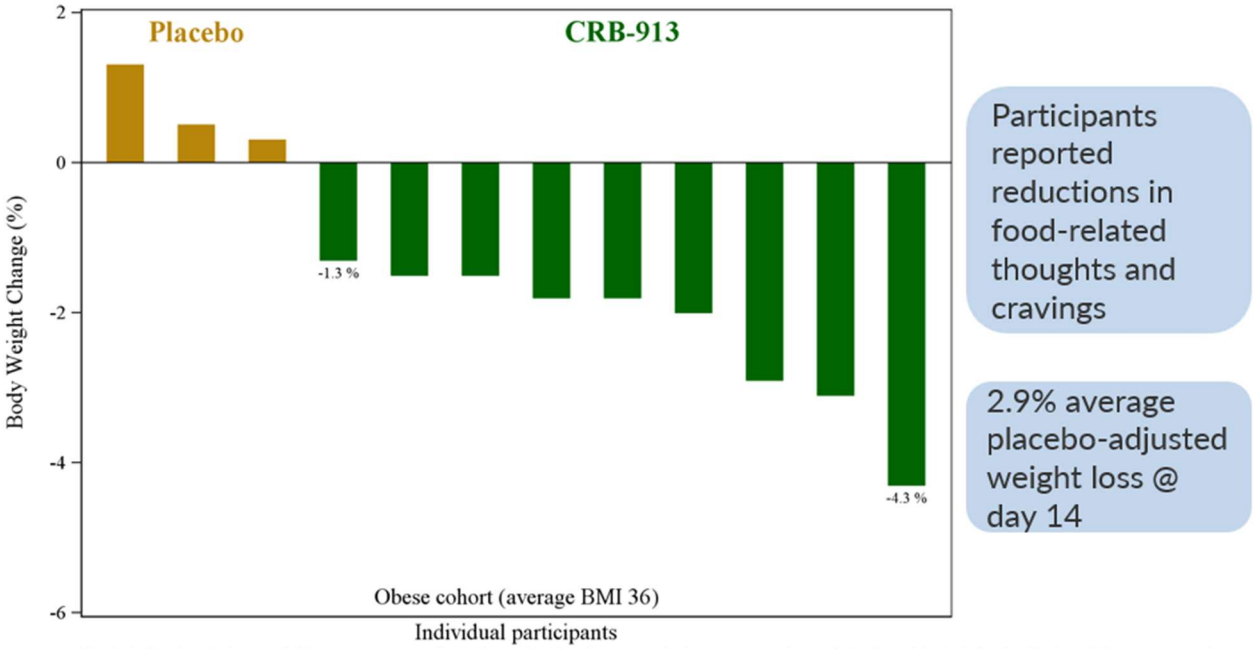
No neuropsychiatric adverse events were noted in any of the cohorts of non-obese participants. Three adverse events of mild anxiety and one of mild irritability were reported in the obese MAD cohort at 150 mg/day. They were all transient, and symptoms resolved completely without need for medical intervention.

The PK profile for CRB-913 was established and was found to be suitable for a once-daily oral dosing.

Weight Loss

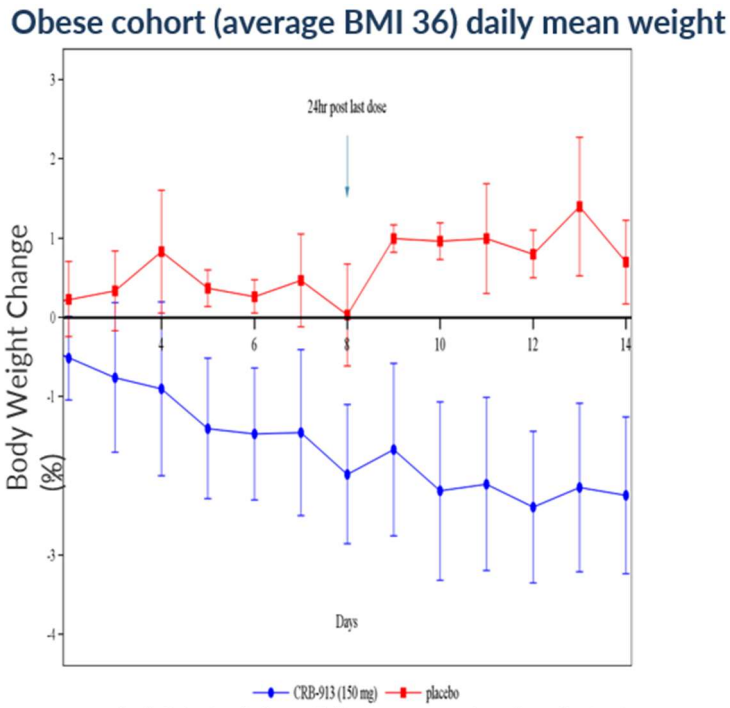
In the dedicated obese MAD cohort (150 mg QD), all CRB-913-treated participants (n=9), and none in the placebo group (n=3), experienced weight loss. The CRB-913-treated participants achieved a mean 2.9% placebo-adjusted weight loss by Day 14. Individual participant weight loss ranged from 1.3% to 4.3% (Figure 11). Weight loss started early and deepened with time (Figure 12). Notably, several participants treated with CRB-913 reported reduction in food-related thoughts and cravings. Placebo-adjusted weight loss was also seen in healthy, non-obese participants in the 75 mg and 150 mg MAD cohorts (Figure 13).

Figure 11: Emerging Weight Loss with CRB-913 in Participants with Obesity



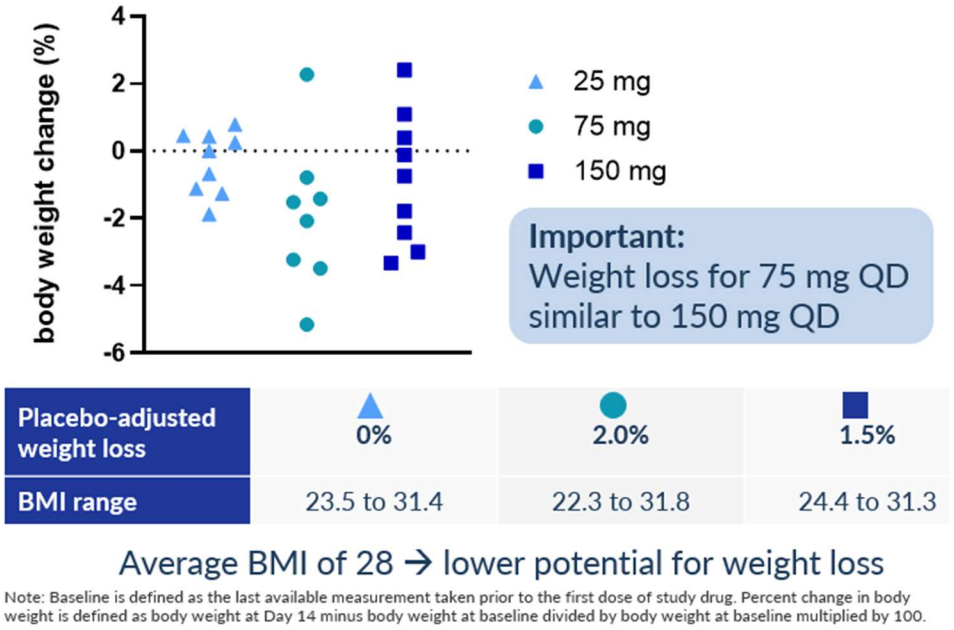
Note: Baseline is defined as the last available measurement taken prior to the first dose of study drug. Percent change in body weight is defined as body weight at Day 14 minus body weight at baseline divided by body weight at baseline multiplied by 100.

Figure 12: Weight Loss with CRB-913 Starts Early and Deepens



Note: Baseline is defined as the last available measurement taken prior to the first dose of study drug. Percent change in body weight is defined as body weight at the given day minus body weight at baseline divided by body weight at baseline multiplied by 100.

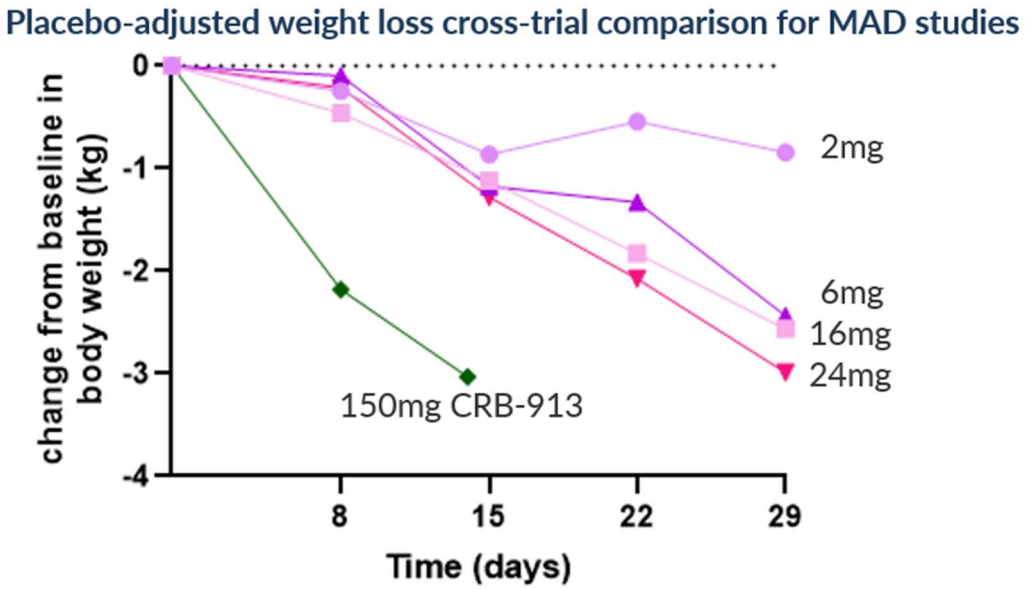
Figure 13: Signals of Weight Loss in Lower MAD Doses



Note: Baseline is defined as the last available measurement taken prior to the first dose of study drug. Percent change in body weight is defined as body weight at Day 14 minus body weight at baseline divided by body weight at baseline multiplied by 100.

When the dedicated obese MAD cohort (150 mg QD) is compared to orfoglipron over a similar period, deeper and faster weight loss is observed (Figure 14), as well as a differentiated, more favorable emerging safety profile.

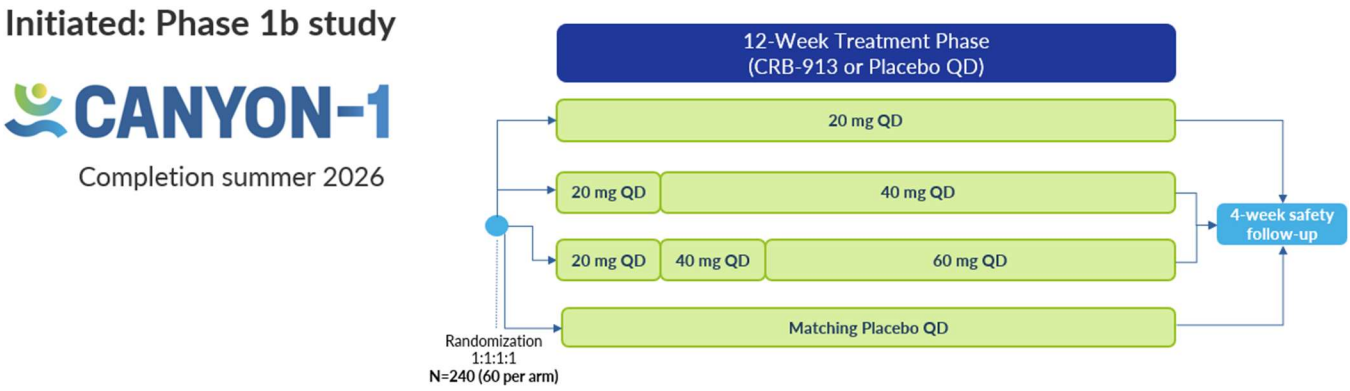
Figure 14: Emerging Data CRB-913 vs. Orfoglipron



Source: All comparator data points are approximated and based on extracted figures reported from Pratt *et al* 2023 and Corbus data. Data is derived from cross-trial comparison.

The Company initiated a Phase 1b dose-range finding study ("CANYON-1") in December 2025. The Phase 1b study will follow 240 U.S. subjects randomized into 4 arms (placebo, 20 mg, 40 mg, and 60 mg) over a 12-week treatment period followed by a 4-week safety follow-up (Figure 15). Completion is expected in summer 2026.

Figure 15: Canyon-1 Study design



	CRB-913 phase 1b (CANYON-1)	Monlunabant phase 2a
Subjects with obesity	240	240
Location	USA	Canada
Cohorts (all QD)	Placebo, 20, 40 and 60 mg	Placebo, 10, 20 and 50 mg
Titration	Yes	No
Exclude PHQ-9 > 4 at baseline	Yes	No

CRB-601

Our pipeline formerly included CRB-601, a potent and selective anti-αvβ8 integrin monoclonal antibody for the treatment of solid tumors. CRB-601 is an anti-αvβ8 monoclonal antibody that blocks the activation of latent TGFβ present on cancer cells in the tumor microenvironment. CRB-601 was being evaluated as a potential treatment for patients with solid tumors in combination with existing therapies, including checkpoint inhibitors. The Company has completed a Phase 1 dose escalation study. In November 2025, we presented a study-in-progress poster at the 2025 Society for Immunotherapy of Cancer conference. The Company has deprioritized the program and does not plan to enroll additional patients.

Research and Development

We incurred expenses of $70.1 million and $32.2 million for research and development activities for the years ended December 31, 2025 and 2024, respectively. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs for our pipeline. Research and development expenses are incurred for the development of our drug candidates and consist primarily of payroll and payments to contract research and development companies. To date, these costs are related to generating pre-clinical data in support of IND filings, manufacturing and purchasing drug product for clinical trials, and conducting clinical trials.

Intellectual Property

Our commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for our technologies, products and processes, including proprietary protection for CRB-701, CRB-913, and CRB-601. All patent expiry terms are stated without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees.

CRB-701: Antibody Drug Conjugate Targeting Nectin-4

We entered into a license agreement (the "CSPC License Agreement") with CSPC effective February 12, 2023. Pursuant to the CSPC License Agreement, we received an exclusive license to CRB-701 for the prevention and treatment of all oncology indications in the U.S., Canada, the European Union (including the European Free Trade Area), the U.K, and Australia. The license includes several patent applications covering CRB-701, or a use of CRB-701, that, if granted, are projected to expire in 2042 and 2045.

CRB-913: Second Generation CB1 Receptor Inverse Agonist

On September 20, 2018, we entered into an exclusive license agreement (the "Jenrin License Agreement") with Jenrin Discovery, LLC (“Jenrin”), which provides us with an exclusive worldwide license to develop and market cannabinoid compounds covered by the Jenrin issued patents and patent applications that cover the composition and method of use of selective cannabinoid receptor modulators. The Jenrin intellectual property portfolio includes eight granted U.S. patents and nine granted patents outside of the U.S. The portfolio includes U.S. Patent No. 8,853,252 which granted with claims relating to the cannabinoid receptor blocker CRB-913 and methods of using the same for treating obesity, diabetes, hepatic disorders, and/or cardiometabolic disorders. The licensed intellectual property portfolio provides intellectual property protection in the U.S. for CRB-913 and these uses through November 2028. We own a patent family filed in the U.S., Europe, Japan, India, and China, among other countries, covering CRB-913 that, if granted, will result in patent rights projected to expire in 2043. We also own patent applications covering CRB-913 formulations, CRB-913 dosing regimens, and/or CRB-913 methods of synthesis that, if granted, are projected to expire in 2046.

CRB-601: Anti-Integrin Monoclonal Antibody

We entered into a license agreement (the “UCSF License Agreement”) with the Regents of the University of California (“The Regents”) effective May 26, 2021, as amended to include additional inventions effective November 17, 2022, and further amended to include certain new technology rights effective August 14, 2023. Pursuant to the UCSF License Agreement, we received an exclusive worldwide license to certain patent applications relating to humanized antibodies against integrin αvβ8, an antibody for diagnostic use, along with non-exclusive licenses to certain related know-how and materials. The last of the licensed patent applications, if granted, is projected to expire in 2043. We own a patent family covering CRB-601 that, if granted, would be scheduled to expire in 2044.

Other Intellectual Property Matters

Our commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for our technologies, to operate without infringing the proprietary right of others and to prevent others from infringing our proprietary rights. We strive to protect our intellectual property through a combination of patents and trademarks, as well as through the confidentiality provisions in our contracts. With respect to our candidates, we endeavor to obtain and maintain patent protection in the U.S. and internationally on all patentable aspects of each product candidate. We cannot be sure that the patents will be granted with respect to any patent applications we may own or license in the future, nor can we be sure that any patents issued or licensed to us in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, see “Risk Factors—Risks Relating to Our Intellectual Property Rights."

In addition to patent protection, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, aspects of our proprietary technology platform are based on unpatented trade secrets and know-how related to the manufacturing of our product candidates. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also seek and will continue to seek trademark protection in the U.S. and outside of the U.S. where available and when appropriate. We use and intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

Manufacturing and Supply of CRB-701, CRB-913, and CRB-601

We do not own or operate manufacturing facilities and rely on third-party contract manufacturing organizations or licensing partners to supply us with drugs for pre-clinical and clinical studies and commercial activities. If a manufacturer or licensing partner is unable to supply us with drugs in a timely manner, we may encounter substantial delays in commencement, enrollment, or completion of our clinical trials or an inability to successfully commercialize any product candidates we may develop. If we are unable to advance our product candidates into and through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

CRB-701 is designed to be an improved next-generation site-specific Nectin-4 targeting antibody drug conjugate. CRB-701 is a monoclonal antibody attached to an MMAE cytotoxic payload using a proprietary linker technology. CSPC has developed a manufacturing process under current good manufacturing practice ("cGMP") to produce batches of drug substance and drug product for clinical studies. We have a clinical supply agreement with CSPC to supply drug substance and drug product in support of clinical activities and we will seek to negotiate a commercial supply agreement with CSPC prior to a marketing application.

CRB-913 is a highly peripherally restricted oral small molecule CB1 receptor inverse agonist for the treatment of obesity, and we have developed manufacturing processes with contract manufacturers under cGMP to produce batches of drug substance and drug product for clinical studies.

CRB-601 is a monoclonal antibody and we have developed a manufacturing process under cGMP to produce batches of drug substance and drug product for pre-clinical and clinical studies. CRB-601 is produced by a contract manufacturer through recombinant DNA technology utilizing genetically engineered host cells, upstream cell culture processes and downstream purification methods as required to manufacture the drug substance for use in the manufacture of the drug product.

Competition

The biotechnology and pharmaceutical industries are characterized by a rapid pace of new innovation and discoveries, fierce competition and strong defense of intellectual property. We face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others.

Competitors to CRB-701 who have ADCs which target Nectin-4 with MMAE include Bicycle Therapeutics plc and Mabwell, in addition to Pfizer Inc. and its approved PADCEV® product. Additional competitors with different mechanisms of action, but are targeting similar indications include Bicara Therapeutics, Inc., Genmab A/S, Johnson and Johnson, and Pfizer Inc. Competitors to CRB-913 who are also targeting the CB-1 receptor include Novo Nordisk A/S and Skye Bioscience. Additional competitors with different mechanisms of action, but are targeting weight loss by an oral drug include AstraZeneca PLC, Lilly, Novo Nordisk A/S, Structure Therapeutics Inc., and Viking Therapeutics, Inc., among others.

Regulatory Matters

Government Regulation

Our activities and products are significantly regulated by a number of governmental entities, including the FDA in the U.S. and by comparable authorities in other countries. These entities regulate, among other things, the design, research, pre-clinical and clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. We must obtain regulatory approval from the FDA and comparable authorities in other countries, as applicable, for our drug candidates before we can commercialize such drugs in the U.S. and foreign jurisdictions. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data are often generated in two distinct development states: pre-clinical and clinical. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. Many drug candidates that initially appear promising ultimately do not reach the market because they are found to be unsafe or ineffective when tested. Our inability to commercialize a product would impair our ability to earn future revenues.

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Development of Drugs in the U.S.

FDA Approval Process

In the U.S., the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. CRB-701 and CRB-601 are regulated as biologics; and CRB-913 is regulated as a drug. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, civil penalties and criminal prosecution.

The process required by the FDA before a drug or biological product may be marketed in the U.S. generally involves the following:

- completion of pre-clinical studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an investigational new drug ("IND") application which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCP") to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of a marketing application, such as a new drug application ("NDA"), or a biologics license application ("BLA") as applicable;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the marketing application.

Data obtained at any stage of testing is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Moreover, during the regulatory process, new or changed drug approval policies may cause unanticipated delays or rejection of our product. We may not obtain necessary regulatory approvals within a reasonable period of time, if at all, or avoid delays or other problems in testing our products. Moreover, even if we received regulatory approval for a product, the approval may require limitations on use, which could restrict the size of the potential market for the product.

Clinical Trials

The FDA provides that human clinical trials may begin 30 days after receipt and review of an IND application, unless the FDA requests additional information or changes to the study protocol within that period. An IND must be sponsored and filed for each of our proposed drug candidates. Authorization to conduct clinical trials in no way assures that the FDA will ultimately approve the product.

The clinical stage of development can generally be divided into three sequential phases that may overlap: Phase 1, Phase 2, and Phase 3 clinical trials. In Phase 1, generally, small numbers of healthy volunteers are initially exposed to single escalating doses and then multiple escalating doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action and general safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits, common short-term side effects and risks. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 3 trials are intended to gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects and are closely controlled and monitored. In addition to these Phase 1-3 trials, other trials may be conducted to gather additional safety, pharmacokinetic and pharmacodynamic information. Pharmaceutical products with active ingredients equal or similar to those already approved by the FDA often have more streamlined development programs than compounds entirely new to the agency, often skipping Phase 1 and 2 trials.

A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed studies, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards responsible for overseeing studies at particular sites and protecting human research study subjects. An independent institutional review board may also suspend or terminate a study once initiated. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that once begun, issues will not arise that could cause the trial to be suspended or terminated.

Post-approval studies, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. Sometimes, these studies are used to gain additional experience from the treatment of patients in the intended therapeutic condition. In certain instances, the FDA may mandate the performance of Phase 4 studies. In other situations, post-approval studies aim to gain additional indications for a medication or develop new dosage forms for a medication.

A product's safety and effectiveness in one clinical trial is not necessarily indicative of its safety and effectiveness in another clinical trial. Moreover, we may not discover all potential problems with a product even after completing clinical trials on it. Some of our products and technologies have undergone only pre-clinical testing. As a result, we do not know whether they are safe or effective for humans. Also, regulatory authorities may decide, contrary to our findings, that a product is unsafe or not as effective in actual use as its clinical trial results indicated. This could prevent the product's widespread use, require its withdrawal from the market or expose us to liability. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Any such action could materially harm us. Clinical trials are critical to the success of our products but are subject to unforeseen and uncontrollable delay, including delay in enrollment of patients. Any delay in clinical trials could delay our commercialization of a product.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Special Protocol Assessment

The Federal Food, Drug, and Cosmetic Act directs the FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a marketing application. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment ("SPA"). While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has latitude to change its assessment if certain exceptions apply. Exceptions include public health concerns emerging that were unrecognized at the time of the protocol assessment, identification of a substantial scientific issue essential to the safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

Chemistry, Controls and Manufacturing Development

Concurrent with clinical trials, companies typically complete additional animal and laboratory studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current cGMP requirements. The manufacturing process must consistently produce quality batches of the drug, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.

Review and Approval in the U.S.

Following pivotal or Phase 3 trial completion, data are analyzed to determine safety and efficacy. Data are then filed with the FDA in a marketing application, along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. In the U.S., FDA approval of a marketing application must be obtained before marketing a pharmaceutical product. The marketing application must contain proof of safety, purity, potency, and efficacy, which entails extensive pre-clinical and clinical testing.

The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take several years to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current good manufacturing practice requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will act favorably or quickly in making such reviews and significant difficulties or costs may be encountered in our efforts to obtain FDA approvals. The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of the marketing application on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized. Further, the FDA may place conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the marketing application must submit a proposed REMS; the FDA will not approve the marketing application without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur.

Biologics Exclusivity and Biosimilars

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The BPCIA includes, among other provisions:

- a 12-year exclusivity period from the date of first licensure, or BLA approval, of the reference product, during which approval of a 351(k) application referencing that product may not be made effective;
- a four-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted;
- an exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars; and
- procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA is complex and its interpretation and implementation by the FDA remains unpredictable. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan product designation must be requested before submitting a marketing application. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for our products.

Special Regulatory Procedures

Fast track designation — The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product, concurrent with or after the filing of the IND for the drug candidate. A drug that receives fast track designation is eligible for some or all of the following: (i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for accelerated approval and priority review, if relevant criteria are met; and (iv) "Rolling Review," which means that a drug company can submit completed sections of its BLA or NDA for review by the FDA, rather than waiting until every section of the marketing application is completed before the entire application can be reviewed. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the marketing application is submitted. In addition, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review — Under FDA policies, a drug candidate may be eligible for priority review. The priority review program provides for expedited review on a marketing application, typically within a six- to eight-month time frame from the time a complete application is accepted for filing. Products regulated by the FDA's Center for Drug Evaluation and Research ("CDER") are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Products regulated by the FDA's Center for Biologics Evaluation and Research ("CBER"), are eligible for priority review if they provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. A fast track designated drug candidate could be eligible for priority review if supported by clinical data at the time of the marketing application submission.

Accelerated approval — Under the law and the FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough therapy designation — The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate.

Pediatric Information

Under the Pediatric Research Equity Act of 2003, a marketing application or supplement to a marketing application must contain data that are adequate to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Under the Food and Drug Administration Safety and Innovation Act ("FDASIA"), the FDA has additional authority to take action against manufacturers not adhering to pediatric study requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our current and potential product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a marketing application plus the time between the submission date of the marketing application and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Drug Development in the European Union

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the U.S., the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the U.S., the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

Review and Approval in the European Union

In the European Union, approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure, and the decentralized procedure. We intend to determine which process we will follow, if any, in the future.

Mutual Recognition Procedure — An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state.

Centralized Procedure — This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other "innovative medicinal products with novel characteristics." Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

Decentralized Procedure — The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, "clock stops" during the procedure.

Brexit and the Regulatory Framework in the U.K.

The U.K. ceased being a Member State of the European Union on January 31, 2020. As a result of the Northern Ireland Protocol, following Brexit, the European Medicines Agency ("EMA") remained responsible for approving novel medicines for supply in Northern Ireland under the European Union centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). On February 27, 2023, the U.K. government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." The Windsor Framework was approved by the European Union-U.K. Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the U.K. In particular, the Medicines and Healthcare products Regulatory Agency (the "MHRA") is now responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the European Union centralized procedure. A single U.K.-wide marketing authorization will be granted by the MHRA for all novel medicinal products to be sold in the U.K., enabling products to be sold in a single pack and under a single authorization throughout the U.K. However, although a separate authorization is now required to market medicinal products in the U.K., under an international recognition procedure which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a U.K. marketing authorization.

There is now no pre-marketing authorization orphan designation in the U.K. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding Marketing Authorisation Application. The criteria are essentially the same, but have been tailored for the U.K. market, i.e., the prevalence of the condition in the U.K. (rather than the European Union) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the U.K.

Following the end of the Brexit transition period, the MHRA continues to authorize clinical trials in the U.K. The U.K. has implemented the now-repealed Clinical Trials Directive into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004. On April 10, 2025, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024 came into force, with a 12-month implementation period before entering full effect on April 10, 2026. These amendments modernize the U.K. clinical trials framework and introduce significant changes including: (i) a risk-proportionate approach whereby low-risk trials can receive faster approval through automatic authorization without prior regulatory review; (ii) a combined review process integrating ethics committee and regulatory approvals into a single streamlined approval pathway; (iii) enhanced transparency requirements mandating registration of clinical trials in a public registry and publication of trial results within 12 months of trial completion; (iv) provisions to streamline approvals and enable innovation in clinical trial design; and (v) measures to promote patient and public involvement in clinical trials.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, and NDA and BLA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current good manufacturing practice and other laws. NDA and BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Centers for Medicare & Medicaid Services ("CMS") other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent. The government may assert that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback law or related to off-label promotion constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- the Federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members;
- the Health Insurance Portability and Accountability Act ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act;
- The Lanham Act and federal antitrust laws; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, traceability, and storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Moreover, some pharmaceutical products may be classified as controlled substances and the handling of any controlled substances must comply with the U.S. Controlled Substances Act and the Controlled Substances Import and Export Act.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. The requirement for state registrations could also result in delay of the manufacturing, distribution of our drugs or in the completion of our current clinical studies. We and our manufacturing vendors and clinical sites must also obtain separate state registrations, permits or licenses to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Third-Party Payer Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our drug candidates that ultimately may obtain regulatory approval. In both the U.S. and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the U.S., governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payer has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payers.

The U.S. Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, the two-year spending law signed by the President of U.S. on February 9, 2018 includes a provision raising the manufacturer discount to 70% in 2019 in the Medicare Part D coverage gap, also known as the "donut hole." Under prior law, manufacturers were required to provide a 50% discount on prescription drugs purchased in the donut hole. Manufacturers of branded drugs will face much higher liabilities from donut hole payments beginning in 2019, estimated at multiple billions of dollars for some of the largest companies.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be significantly lower.

Employees

We had 36 full-time employees at December 31, 2025. All our employees are engaged in administration, finance, clinical, biology, and manufacturing functions. We believe our relations with our employees are good. In addition, we utilize and will continue to utilize consultants, clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, manufacturing, and regulatory functions.

Corporate Information

Corbus Pharmaceuticals, Inc. (formerly known as JB Therapeutics Inc.), was incorporated on April 24, 2009 under the laws of the State of Delaware. On April 11, 2014, JB Therapeutics, Inc. completed a merger with Corbus Pharmaceuticals Holdings, Inc. and changed its name to Corbus Pharmaceuticals, Inc. Upon the consummation of the merger, Corbus Pharmaceuticals, Inc. became a wholly-owned subsidiary of Corbus Pharmaceuticals Holdings, Inc. which continues to operate the business of Corbus Pharmaceuticals, Inc. Our principal executive offices are located at 500 River Ridge Drive, Norwood, Massachusetts 02062, and our telephone number is (617) 963-0100. Our website address is www.corbuspharma.com.

We make available free of charge through the Investor Relations link on our website, www.corbuspharma.com, access to press releases and investor presentations, as well as all materials that we file electronically with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after electronically filing such materials with, or furnishing them to, the SEC. During the period covered by this Form 10-K, we made all such materials available through our website as soon as reasonably practicable after filing such materials with the SEC. In addition, the SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

This report and the information incorporated herein by reference contain references to trademarks, service marks and trade names owned by us or other companies. Solely for convenience, trademarks, service marks and trade names referred to in this report and the information incorporated herein, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. We do not intend our use or display of other companies' trade names, service marks or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, trade names and service marks appearing in this report are the property of their respective owners.

ITEM 1A. RISK FACTORS

An investment in our common stock is highly speculative and involves a high degree of risk, including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks occur, our business, financial condition, results of operations and stock price could be materially adversely affected.

Summary of Risks Associated with Our Business

Our business and an investment in our company is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this summary. Some of these risks include:

- We have never generated any product revenues;
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- We will need substantial additional funding, and certain terms included in our financing transactions may restrict our ability to raise such capital at the times and in the manner we may require;
- We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates, and if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed;
- Changes in geopolitical conditions, U.S.-China trade relations and other factors beyond our control may adversely impact our business and operating results;
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates;
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome;
- If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited;
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our product candidates;
- We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices;
- We have in-licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property; and
- We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

Risk Related to our Company and our Business

Risks Related to Our Business, Financial Position and Need for Capital

We are a biopharmaceutical company with a limited operating history.

We are a biopharmaceutical company with a limited operating history. All our product candidates are in the discovery stage, pre-clinical, or clinical development stage. We must complete clinical studies and other development activity and receive regulatory approval of a marketing application before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully manufacture our clinical products and establish commercial drug supply;
- successfully complete the pre-clinical and clinical trials necessary to obtain regulatory approval for the marketing of our drug candidates;
- secure market exclusivity and/or adequate intellectual property protection for our drug candidates;
- attract and retain an experienced management and advisory team;
- secure acceptance of our drug candidates in the medical community and with third-party payors and consumers;
- launch commercial sales of our drug candidates, whether alone or in collaboration with others; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we cannot successfully execute any one of the foregoing, our business may not succeed, and your investment will be adversely affected.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if we achieve profitability, be able to sustain profitability.

We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. To date, we have not generated any revenue from our drug candidates, and we expect to incur significant expense to complete our pre-clinical and clinical program for our drug candidates in the U.S. and elsewhere. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the U.S. or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net loss was approximately $78.5 million and $40.2 million, for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately $555.4 million.

We may elect to pursue FDA approval for our drug candidates, which will result in significant additional research and development expenses. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses will increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our cash, cash equivalents, or investments will only fund our operations for a limited time, and we will need to raise additional capital to support our development and commercialization efforts.

We are currently operating at a loss and expect our operating costs will increase significantly as we incur further costs related to pre-clinical development and the clinical trials for our drug candidates. As of December 31, 2025, we held cash, cash equivalents, and investments of approximately $163.3 million.

On May 31, 2023, we entered into Amendment No. 1 to the Open Market Sale Agreement originally dated August 6, 2020 (the "Open Market Sale Agreement") with Jefferies LLC ("Jefferies") pursuant to which Jefferies is serving as the sales agent. Under the Open Market Sale Agreement, we may issue and sell, from time to time through Jefferies, shares of our common stock having an aggregate offering price of up to $150.0 million (the "Open Market Offering"). For the year ended December 31, 2025, we sold an aggregate of 563,504 shares of common stock for net proceeds of approximately $7.0 million under the Open Market Sale Agreement. As of December 31, 2025, approximately $69.1 million is available for issuance and sale under the Open Market Offering.

On October 30, 2025, we entered into an underwriting agreement with Jefferies, as representative (the "Representative") of the several underwriters (the "Underwriters"), relating to an underwritten public offering of 4,744,231 shares of our common stock at a price to the public of $13.00 per share, and, to certain investors in lieu of common stock, pre-funded warrants to purchase 1,025,000 shares of common stock at a public offering price of $12.9999 per pre-funded warrant. The purchase price per share of each pre-funded warrant represents the per share public offering price for the common stock, minus the $0.0001 per share exercise price of each such pre-funded warrant. On November 3, 2025, we completed the public offering raising net proceeds of $70.2 million after deducting underwriting discounts and commissions and other offering expenses payable by us.

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt.

Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we may choose to pursue, as an alternative, strategic collaborations that could require us to share commercial rights to our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for our drug candidates or otherwise expand more rapidly than we presently anticipate we may also need to raise additional capital sooner than expected.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

Our success is dependent upon successful development of our drug candidates in our pipeline or that we may acquire. If we are unable to generate revenues from any product candidates, our ability to create stockholder value will be limited.

We do not generate revenues from any FDA approved drug products. Our current business currently depends on the successful development, regulatory approval, and commercialization of our drug candidates, which may never occur.

CRB-701 is currently in a Phase 1/2 study in the U.S. and Europe conducted by us (referred to herein as the Western study) and a Phase 3 clinical trial being conducted in China by CSPC (referred to herein as the China study). CRB-913 is currently in a Phase 1b study being conducted in the U.S. CRB-601 is currently in a Phase 1 clinical trial being conducted in the U.S. and U.K. We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our pre-clinical and clinical trials may be unsuccessful, which would materially harm our business. Even if our initial trials are successful, we will be required to conduct additional trials to establish the safety and efficacy of our drug candidates before marketing application can be filed with the FDA for marketing approval of any of our drug candidates.

Drug testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the drug testing process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, which regulations differ from country to country. We are not permitted to market any of our drug candidates as prescription pharmaceutical products in the U.S. until we receive approval of a marketing application from the FDA or in foreign markets until we receive the requisite approval from comparable regulatory authorities in such countries. In the U.S., the FDA generally requires the completion of pre-clinical and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before a marketing application is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of a marketing application to the FDA and even fewer are eventually approved for commercialization. We have never submitted marketing application to the FDA or any comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for our planned indications, or if adequate demand for our drug candidates is not generated, our business will be harmed.

Receipt of necessary regulatory approval is subject to a number of risks, including the following:

- pre-clinical testing may not yield results that justify progressing to clinical testing;
- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidates;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, EMA, MHRA or other comparable foreign regulatory authorities for marketing approval;
- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA, or other submission or to obtain regulatory approval in the U.S. or elsewhere (collectively, "marketing application");
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- the FDA or comparable foreign regulatory authorities may decide that the clinical trial endpoints we have chosen, the statistical analysis plans that we use, or any other parameter that we rely on to show the safety and efficacy of our drugs, are not parameters that can be used to support approval of our products.

Failure to obtain regulatory approval for any of our drug candidates for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with the endpoints that we have chosen to use in our clinical trials, our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. The FDA, EMA, MHRA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for any of our drug candidates in any indication will prevent us from commercializing such product candidates, and our ability to generate revenue will be materially impaired.

Reductions in staffing and funding at FDA and other federal agencies could cause delays in the development and approval of our products.

Under the Federal Food, Drug, and Cosmetic Act, our products cannot be investigated in humans or marketed without approval from FDA. In addition, companies developing new therapies routinely seek and receive guidance from FDA regarding their methods and plans for developing their products. We and companies like us may also benefit from FDA-administered programs like orphan drug designation and expedited development pathways, e.g., breakthrough designation. Any material reductions in the ability of FDA to perform these and other functions may delay development and approval of our product candidates. Recent actions by the United States federal government have caused concern in the industry that this may occur. For example, beginning on February 13, 2025, the Department of Health and Human Services began firing a large number of its probationary employees, a category that includes new federal employees and employees recently promoted or transferred to new positions or agencies. Larger layoffs may follow, according to a memorandum issued by the Office of Personnel Management on February 26, 2025. These terminations, if they withstand legal challenges, may significantly delay and impede our interactions with the FDA. Similar results may stem from the recent confirmed resignations of some senior FDA employees with responsibility for regulation of drugs and biologics, as well as possible future layoffs and resignations. There are also reports that the United States federal government intends to request Congress to reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of our products.

If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.

Drug testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Our drug candidates are in various stages of discovery, pre-clinical, and clinical testing. Pre-clinical tests are performed at an early stage of a product's development and provide information about a drug candidate's safety and effectiveness on laboratory animals. Pre-clinical tests can last years. If a product passes its pre-clinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and if the FDA gives its approval, we would begin Phase 1 clinical tests. Although drug candidates can take various paths, generally if Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Once clinical testing is completed and a marketing application is filed with the FDA, it may take more than a year to receive FDA approval.

The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of our drug candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In all cases, we must show that a drug candidate is both safe and effective before the FDA, or drug approval agencies of other countries where we intend to sell the product, will approve it for sale. Our research and testing programs must comply with drug approval requirements both in the U.S. and in other countries, since we are developing our drug candidates with the intention to, or could later decide to, commercialize them both in the U.S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of pre-clinical and clinical testing. In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for our drug candidates. For example, our trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics, including demographic factors and health status.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through pre-clinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials.

Approval may be delayed or denied because we cannot satisfy FDA's Chemistry, Manufacturing and Control Requirements.

Formulation and manufacturing of biologic products such as ours is complex and expensive. Our marketing applications must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with FDA's current cGMP requirements. The manufacturing process must consistently produce quality batches of the biologic, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our biologic may be delayed or denied.

Even if we receive regulatory approval for our drug candidates, we still may not be able to successfully commercialize any of our products, and the revenue that we generate from sales, if any, may be limited.

If approved for marketing, the commercial success of our drug candidates will depend upon their acceptance by the medical community, including physicians, patients and health-care payors. The degree of market acceptance of our drug candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates and of the target patient population to try new therapies;
- safety, tolerability and efficacy of our drug candidates compared to competing products;
- safety of competing products may impact our drug candidates;
- the introduction of any new products that may in the future become available to treat indications for which our drug candidates may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health-care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health-care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve our drug candidates for fewer or more limited indications than we request, may not approve the prices we intend to charge for our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our drug candidates with labels that do not include the labeling claims necessary or desirable for the successful commercialization of a particular indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the marketing application must submit a proposed REMS; the FDA will not approve the marketing application without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

Even if we obtain marketing approval for our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates.

Even if we obtain U.S. regulatory approval of our drug candidates for an indication, the FDA may still impose significant restrictions on their indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval, continued compliance with the CSA and ongoing review by the DEA. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the U.S. and similar legal requirements in other countries. In the U.S., the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for an indication, our product labeling, advertising, and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for any of our drug candidates, physicians may nevertheless legally prescribe such products to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, or if we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension of, or imposition of restrictions on, operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way; the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

We have entered into, and may in the future enter into, collaboration agreements for the licensing, development, and ultimate commercialization of some of our drug candidates. In such cases, we will depend greatly on our third-party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations.

We may enter into co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development, and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore, some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable.

If we enter into collaboration agreements for one or more of our drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make our drug candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our drug candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the U.S., under the Medicare Modernization Act, or MMA, Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician-administered drugs on the basis of the drug's average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly.

Both Congress and the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the 2010 Affordable Care Act, drug manufacturers are required to provide a 50% discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." There have been legislative proposals to repeal the "non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

The 2010 Affordable Care Act is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on "line extensions" (such as extended-release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners and incur substantial costs to ensure compliance.

In addition, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the U.S. since the ACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. In addition, various states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our future growth depends, in part, on our ability to enter into and succeed in markets outside of the U.S., where we may choose to rely on third-party collaborations and will be subject to additional regulatory and commercial burdens, risks and other uncertainties.

Our future profitability will depend, in part, on our ability to gain approval of and commercialize our drug candidates in non-U.S. markets. In some or all of these non-U.S. markets, we intend to enter into licensing and contractual collaborations with third parties to handle some or all of the tasks and responsibilities necessary to succeed. Our activities in non-U.S. markets are subject to additional risks and uncertainties, including:

- our ability to enter into favorable licensing and contractual arrangements with our partners;
- our ability to select partners who are capable of achieving success at the tasks they agree to perform;
- obtaining timely and sufficient favorable approval terms for our drug candidates;
- obtaining favorable pricing and reimbursement;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

International sales of our drug candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, and trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health-care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health-care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredients of our drug candidates, or the finished drug products, for use in our clinical trials or for commercial product, if any. As a result, we will be obligated to rely on contract manufacturers if and when our drug candidates are approved for commercialization.

We currently rely on contract suppliers for the manufacturing of our drug candidates. We have limited experience contracting third parties to manufacture our drug candidates and we do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with current good manufacturing practices ("cGMPs") for manufacture of all active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market our drug candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our active pharmaceutical ingredient, or API, or our finished products or should cease doing business with us, we could experience significant interruptions in the supply of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of our drug candidates if we decided to transfer the manufacture of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

In addition, we currently rely on foreign third parties to manufacture certain materials used in clinical trials of our product candidates or to provide services in connection with certain clinical trials and will likely continue to rely on foreign third parties in the future. Foreign third parties may be subject to U.S. legislation, including the proposed BIOSECURE bill, and other foreign regulatory requirements. In addition, recently there has been a significant increase in the imposition of tariffs and other trade restrictions around the world. In many cases, the imposition of tariffs or other trade restrictions have resulted in retaliatory actions by governments in affected countries. Uncertainty surrounding the length, severity, scope and timing of these trade actions may disrupt trade throughout the world which could result in difficulty procuring material and may increase our costs, which could materially and adversely affect our business. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our drug candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to manufacture our drug candidates at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

There are risks associated with scaling up manufacturing to commercial scale. If our contract manufacturers are unable to manufacture our drug candidates on a commercial scale, this could potentially delay regulatory approval and commercialization or materially adversely affect our results of operations.

There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical problems with process scale-up, process reproducibility, stability issues, and lot consistency. We have limited experience contracting with third parties to manufacture drug candidates and will need to be able to successfully scale up and produce batches of our drug candidates to commence clinical studies. We are dependent on our licensing partner, CSPC, to manufacture antibody drug conjugates and we do not have control over their chemistry, manufacturing, and control strategy for CRB-701 to ensure successful development and supply of drug to commence clinical studies or support commercial demand. Even if we obtain regulatory approval for our drug candidates, there is no assurance that our contract manufacturers or licensing partners will be able to manufacture the approved products to specifications acceptable to the FDA or other regulatory authorities, to produce them in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of approved products for commercialization, either on a timely basis or at all, our commercialization efforts would be impaired, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed.

We expect to enter into agreements with third-party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for our drug candidates and we will control only certain aspects of conducting the clinical studies. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage and assist us with the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

In addition, we currently rely on foreign CROs to manufacture certain materials used in clinical trials of our product candidates or to provide services in connection with certain clinical trials and will likely continue to rely on foreign CROs in the future. Foreign CROs may be subject to U.S. legislation, including the proposed BIOSECURE bill, and other foreign regulatory requirements. In addition, recently there has been a significant increase in the imposition of tariffs and other trade restrictions around the world. In many cases, the imposition of tariffs or other trade restrictions have resulted in retaliatory actions by governments in affected countries. Uncertainty surrounding the length, severity, scope and timing of these trade actions may disrupt trade throughout the world which could result in difficulty procuring material and may increase our costs, which could materially and adversely affect our business. If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Any termination or suspension of or delays in the commencement or completion of any necessary studies of our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical study on hold;
- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports of similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGCP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason;
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial; and
- delays related to the impacts of pandemics, including slowdowns in enrollment or our ability to complete our clinical trials on our expected timeline.

Product development costs for our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, any IRBs, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of our drug candidates, our commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our drug candidates could be significantly reduced.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We may seek orphan drug designation in the U.S. and in the European Union for our product candidates. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the U.S. under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication, or which may receive orphan drug designation in the future will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $0.4 million per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications if we elect to seek such designation. Even if orphan designation is granted it may be withdrawn by the FDA for non-compliance with regulations.

Third-party coverage and reimbursement and health-care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market our drug candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which our drug candidates are expected to be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the U.S., government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our drug candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health-care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health-care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Our collaboration partners are conducting and may intend to conduct additional clinical trials for certain of our drug candidates at sites outside the U.S., and the FDA may not accept data from trials conducted in such locations or may require additional U.S.-based trials.

Our collaboration partners are currently conducting and may intend in the future to conduct clinical trials outside the U.S., particularly in China where CSPC is conducting their own clinical trials. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with cGCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside of the U.S. must be representative of the population for which we intend to seek approval in the U.S. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the U.S. If the FDA does not accept the data from our clinical trials conducted outside the U.S., it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these or other drug candidates in the U.S. In addition, there are risks inherent in conducting clinical trials in jurisdictions outside the U.S. including:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that patient populations in such trials are not considered representative as compared to patient populations in the U.S. and other markets.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our success will depend, in part, on maintaining and obtaining additional patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges, and successfully enforcing these patents against third-party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable in our pending applications or, the enforceability of our existing and future patents. Our pending patent applications may never be approved by U.S. or foreign patent offices and the existing patents and patent applications relating to our product candidates may be challenged, invalidated, or circumvented by third parties and may not protect us against competitors with similar products or technologies.

The degree of our current and future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical, or competitive to our product candidates, or important to our business. We cannot be certain that any patents or patent application owned by a third party will not have priority over patents and patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U.S. or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants, and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If we fail to maintain or obtain additional patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us, or our business partners, will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

We have in-licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to license agreements with Jenrin and The Regents pursuant to which we licensed exclusive worldwide rights to develop, manufacture and market drug candidates. We may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, potential cannabinoid and monoclonal antibody developmental candidates. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

We are a party to a license agreement with CSPC pursuant to which we licensed the exclusive rights in the U.S., Canada, the European Union (including the European Free Trade Area), the U.K., and Australia to develop and market a drug candidate from CSPC. This agreement is important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, potential antibodies, monoclonal antibody, and antibody drug conjugate developmental candidates. Our existing license agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by any of our product candidates. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. We are aware of patents or patent applications owned by third parties that relate to some aspects of our programs that are still in development. In some cases, because we have not determined the final methods of manufacture, the method of administration or the therapeutic compositions for these programs, we cannot determine whether rights under such third-party positions will be needed. In addition, in some cases, we believe that the claims of these patents are invalid or not infringed or will expire before commercialization. However, if such patents are needed and found to be valid and infringed, we could be required to obtain licenses, which might not be available on commercially reasonable terms, or to cease or delay commercializing certain product candidates, or to change our programs to avoid infringement. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign any product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition, and operating results.

A number of companies, including several major pharmaceutical companies, have conducted research in the same therapeutic areas as our company, which resulted in the filing of many patent applications in the same areas as our research. If we were to challenge the validity of these or any U.S.-issued patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S.-issued patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

If we were to challenge the validity of these or any U.S.-issued patent in an administrative trial before the Patent Trial and Appeal Board in the U.S. Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity, or enforceability.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We are, and may become, subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets that, regardless of merit, could result in significant expense and loss of our intellectual property rights.

We have entered into and may in the future enter into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners and other third parties. We may become subject to litigation where a third-party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from developing, marketing or otherwise commercializing our product candidates. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not aware of any asserted third-party claims challenging inventorship on our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self-executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we are more closely analyzing all facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of fact and applications of sometimes-unsettled patent law, resulting in inherent uncertainties regarding ownership rights. Determining the history of development of certain of our intellectual property is made more difficult by the fact that certain of our intellectual property was developed by other companies for other indications before being acquired by us. Consequently, we cannot be sure that we have all the documentary records relevant to such an analysis.

If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third-parties marketing competing products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

General Company-Related Risks

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had 36 full-time employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our drug candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceuticals industry depends, in large part, upon our ability to attract highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in the price of our common stock that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop our drug candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have entered into employment agreements with certain of our executive officers. However, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, or financial condition. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face a potential risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize our drug candidates. For example, we may be sued if any product we develop or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize our drug candidates; and
- a decline in the value of our stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses, assets, or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses, assets, or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing, and marketing any new delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors, and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged.

In addition, such a breach may require notification to governmental agencies, the media, or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws.

Under the EU regulation and notably the General Data Protection Regulation, or GDPR, No. 2016/679, which entered into force on May 25, 2018 and is applicable personal data that we process in relation to our presence in the EU, the offering of products or services to individuals in the EU or the monitoring of the behavior of individuals in the EU, we have also a legal responsibility to report personal data breaches to the competent supervisory authority. The EU data protection regulation includes a broad definition and a short deadline for the notification of personal data breaches, which may be difficult to implement in practice and requires that we implement robust internal processes. Under this regulation, we must report personal data breaches to the competent supervisory authority within 72 hours of the time we become aware of a breach "unless the personal data breach is unlikely to result in a risk to the right and freedoms of natural persons" (Article 33 of the GDPR). In addition, the GDPR requires that we communicate the breach to the Data Subject if the breach is "likely to result in a high risk to the rights and freedoms of natural persons" (Article 34 of the GDPR). In order to fulfill these requirements, we have to implement specific internal processes to be followed in case of a personal data breach, which will allow us to (a) contain and recover the breach, (b) assess the risk to the data subjects, (c) notify, and possibly communicate the breach to the data subjects, (d) investigate and respond to the breach. The performance of these processes implies substantial costs in resources and time.

Moreover, as we may rely on third parties that will also process as processor the data for which we are a data controller—for example, in the context of the manufacturing of our drug candidates or for the conduct of clinical trials, we must contractually ensure that strict security measures, as well as appropriate obligations including an obligation to report in due delay any security incident are implemented, in order to allow us fulfilling our own regulatory requirements.

We would also be exposed to a risk of loss or litigation and potential liability for any security breach on personal data for which we are data controller. The costs of above-mentioned processes together with legal penalties, possible compensation for damages and any resulting lawsuits arising from a breach may be extensive and may have a negative impact on reputation and materially adversely affect our business, results of operations and financial condition.

Changes in geopolitical conditions, U.S.-China trade relations and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend, in part, on global and regional economic and geopolitical conditions, given our current third-party license agreement with CSPC, which is headquartered in China, and our reliance on global suppliers. Changes in U.S.-China trade policies, including the proposed BIOSECURE bill, and a number of other economic and geopolitical factors both in China and abroad could have a material adverse effect on our business, financial condition, results of operations or prospects. Such factors may include:

- instability in political or economic conditions, such as inflation, recession, foreign currency exchange restrictions and devaluations, restrictive governmental controls on the movement and repatriation of earnings and capital, and actual or anticipated military or political conflicts, particularly in emerging markets;
- expanded jurisdiction of the Committee for Foreign Investment in the U.S. (CFIUS);
- tariffs, including the announced tariffs on foreign goods; and
- intergovernmental conflicts or actions, such as armed conflict, trade wars, and acts of terrorism or war.

As a result of these events, our ability to obtain data or regulatory support from our China-based licensing partner may be limited or adversely affected, and we may ourselves be subject to sanctions, diminished public perception and operational constraints.

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

The disruptions to the global economy due to geopolitical events have impeded, and may continue to impede in the future, global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain, and inflationary pressures, will not have a material adverse effect on our business, financial condition and results of operations.

Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, any negative financial impacts affecting U.S. as a result of tax reform or changes to existing trade agreements or tax conventions, may adversely impact our business.

In addition, the global macroeconomic environment could be negatively affected by, among other things, pandemics or epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of military conflict and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

Further, with rising international trade tensions or sanctions, our business may be adversely affected following new or increased tariffs. In 2025, the United States announced tariffs on all foreign goods and individualized higher reciprocal tariffs on goods imported from certain countries. Tariffs could result in increased global clinical trial costs as a result of international transportation of clinical drug supplies, as well as the costs of materials and products imported into the U.S. Tariffs, trade restrictions or sanctions imposed by the U.S. or other countries could increase the prices of our and our collaboration partners' drug products, affect our and our collaboration partners' ability to commercialize such drug products, or create adverse tax consequences in the U.S. or other countries. As a result, changes in international trade policy, changes in trade agreements and the imposition of tariffs or sanctions by the U.S. or other countries could materially adversely affect our results of operations and financial condition.

Risks Related to our Common Stock

An active, liquid trading market for our common stock may not be sustained.

Presently, our common stock is traded on The Nasdaq Capital Market, or Nasdaq, and an investment in our company may require a long-term commitment, with no certainty of return. If we are unable to maintain an active, liquid active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The lack of an active market could impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on The Nasdaq Capital Market or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of investors in general that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy the continued listing requirements of The Nasdaq Stock Market LLC ("Nasdaq") to maintain the listing of our common stock on The Nasdaq Capital Market.

There can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we are unable to maintain compliance with the continued listing requirements, our securities may be delisted from Nasdaq. A delisting could substantially decrease trading in our common stock, adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further, and stockholders may lose some or all of their investment.

The market price of our common stock may be significantly volatile.

The market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the U.S. or elsewhere.

In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agencies;
- developments or disputes concerning a company's intellectual property rights;
- technological innovations of such companies or their competitors;
- changes in market valuations of similar companies;

- announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing a product.

The securities market has from time-to-time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

Future sales of shares by existing stockholders could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

As of December 31, 2025, we had outstanding options to purchase an aggregate of 1,386,020 shares of our common stock at a weighted average exercise price of $37.40 per share, 498,543 shares of common stock issuable upon the vesting of restricted stock units, pre-funded warrants to purchase 1,025,000 shares of our common stock at an exercise price of $0.0001 per share and warrants to purchase an aggregate of 2,873 shares of our common stock at a weighted average exercise price of $208.80 per share. The exercise of such outstanding options and warrants and vesting of restricted stock units will result in further dilution of your investment. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our investors have purchased their shares.

If we fail to maintain effective internal controls, we may not be able to report financial results accurately or on a timely basis, or to detect fraud, which could have a material adverse effect on our business or share price.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We do not expect that our disclosure controls or internal control over financial reporting will prevent or detect all errors or all fraud. We may in the future discover weaknesses in our system of internal control over financial reporting that could result in a material misstatement of our financial statements. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we identify one or more material weaknesses in our internal controls, investors could lose confidence in the reliability of our financial statements, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the SEC or other regulatory authorities. Failure of our control systems to detect or prevent error or fraud could materially adversely impact us.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We may not be able to complete our evaluation and testing of our internal control over financial reporting and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

If we identify a material weakness, our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses for tax years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused net operating losses expire. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020 is limited to 80% of taxable income. In addition, as a result of our merger in April 2014 with Corbus Pharmaceuticals, Inc., our wholly-owned subsidiary, our ability to utilize our federal net operating loss, carryforwards and federal tax credit prior to that date may be limited under Sections 382 of the Internal Revenue Code. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. For example, the Tax Act made significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); and, subject to certain changes in tax law made by the CARES Act as discussed above, limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks generated in tax years ending after December 31, 2017; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures.

The One Big Beautiful Bill Act, or the OBBBA, was signed into law on July 4, 2025, and includes the permanent extension of certain expiring provisions of the Tax Act, modifications to the international tax framework, changes to the business interest deduction limitation, the restoration of expensing for domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures over 15 years), and changes to the bonus depreciation deduction rules. The OBBBA has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. We continue to examine the impact of this tax reform legislation, including the OBBBA, on our business. Regulatory guidance under the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes in federal tax legislation.

Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act, the OBBBA and other tax reform legislation is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our certificate of incorporation, as amended, allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our Board will have the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our Board could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 1C. CYBERSECURITY

We have processes for assessing, identifying and managing cybersecurity risks, which are informed by industry standards and are built into our overall information technology and cybersecurity functions. We maintain an internal information technology specialist who is responsible for the design, implementation, and operation of our information technology ecosystem and cybersecurity governance processes. We also engage with certain external parties, including consultants, computer security firms and risk management advisors, wherever appropriate, in an effort to enhance our cybersecurity oversight and risk management strategy. We conduct risk-based reviews of significant third-party vendors that support our information technology environment to assess whether they maintain appropriate cybersecurity and information security controls. Our Head of IT is responsible for managing the cybersecurity risk and reports to the Chief Financial Officer.

We are not currently aware of any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, other than those that are common to all businesses with internet connectivity, results of operations or financial condition. The audit committee of our board of directors (the "Board") provides oversight over cybersecurity risk and provides updates to the Board regarding such oversight, as needed. The audit committee receives periodic updates from management regarding cybersecurity matters and is notified of significant new cybersecurity threats or incidents occurring between such updates when management determines such matters to be significant and reportable.

To deter and detect cyber threats, we provide annual cybersecurity, data protection, and incident response training to employees, including part-time and temporary employees. This training addresses topics such as phishing and other social engineering threats, password management, confidential data protection, acceptable asset use, and mobile security, and emphasizes the importance of prompt reporting of suspected security incidents. We also deploy technology-based tools designed to mitigate cybersecurity risks and to complement our employee training and awareness programs.

Item 2. PROPERTIES

Our principal offices are located at 500 River Ridge Drive, Norwood, MA 02062 and consists of 63,256 square feet of leased office space at December 31, 2025. The lease term for this office space ends on November 30, 2026.

Item 3. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is currently listed on The Nasdaq Capital Market under the symbol "CRBP." Our shares of common stock began trading on The Nasdaq Global Market under the symbol "CRBP" effective April 16, 2015. Effective July 8, 2022, our shares of common stock were transferred to The Nasdaq Capital Market under the same symbol "CRBP."

Dividends

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends, if any, on the common stock will rest solely within the discretion of our Board and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Record Holders

As of March 6, 2026 there are approximately 84 record holders of shares of our common stock.

Item 6. [RESERVED]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report, particularly those under "Risk Factors."

Overview

We are a clinical stage company focused on promising new therapies in oncology and obesity and are committed to helping people defeat serious illness by bringing innovative scientific approaches to well-understood biological pathways. Our pipeline includes CRB-701, a next-generation antibody drug conjugate ("ADC") that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload of monomethyl auristatin E ("MMAE") and CRB-913, a highly peripherally restricted cannabinoid type-1 ("CB1") receptor inverse agonist for the treatment of obesity.

- CRB-701 (SYS6002) is a next-generation clinical stage ADC that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload of MMAE. In February 2023, we obtained a license from CSPC Megalith Biopharmaceutical Co. Ltd. ("CSPC"), a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize the drug in the United States ("U.S."), Canada, the European Union (including the European Free Trade Area), the United Kingdom ("U.K.") and Australia. We are conducting a Phase 1/2 study in the U.S. and Europe (the "Western study") enrolling patients with advanced solid tumors associated with Nectin-4 expression. The dose expansion phase of the clinical trial is ongoing. In June 2025, we began dosing participants in the PD-1 combination arm with CRB-701 in combination with Keytruda® (pembrolizumab). We received fast track designation for CRB-701 from the U.S. Food and Drug Administration (the "FDA") for the treatment of relapsed or refractory metastatic cervical cancer in December 2024 and in recurrent or metastatic head and neck squamous cell carcinoma ("HNSCC") previously treated with platinum-based chemotherapy and an anti-PD(L)-1 therapy in September 2025. CRB-701 is currently being investigated by CSPC in a Phase 3 clinical trial in patients with cervical cancer in China (the "China study").

  We presented dose optimization data at the European Society for Medical Oncology ("ESMO") in October 2025. Data as of September 1, 2025 was presented from 167 patients, of whom 122 were evaluable for efficacy, from the U.S. and Europe with HNSCC, cervical, locally advanced/metastatic urothelial ("mUC") tumors and other solid-tumor types. The CRB-701 dose expansion phase of the Phase 1/2 Western study is ongoing. The Company expects to meet with the FDA to review and discuss the clinical data and registrational study protocols for HNSCC and cervical tumors in Q1 2026.

- CRB-913 is a highly peripherally restricted oral small molecule CB1 receptor inverse agonist for the treatment of obesity. CB1 inverse agonism is a clinically validated mechanism to induce weight loss and is a distinct mechanism of action separate from GLP-1s. CRB-913 has been specifically formulated to shift the drug exposure from the brain to the periphery to improve safety and tolerability, including reducing gastrointestinal ("GI") adverse events observed in the GLP-1 class. We initiated a single ascending dose ("SAD") and multiple ascending dose ("MAD") Phase 1a study in the first quarter of 2025. On December 11, 2025, we announced the completion of the double-blinded placebo-controlled SAD/MAD Phase 1a study, conducted in the United States, which assessed the safety, tolerability, and PK data of escalating once-daily doses of CRB-913. No serious treatment-emergent adverse events were reported in the SAD/MAD study. We initiated a Phase 1b dose-range finding study ("CANYON-1") in December 2025. The Phase 1b study will follow 240 U.S. subjects randomized into 4 arms (placebo, 20 mg, 40 mg, and 60 mg) over a 12-week treatment period followed by a 4-week safety follow-up. Completion is expected in summer 2026.

Our pipeline formerly included CRB-601, a potent and selective anti-αvβ8 integrin monoclonal antibody for the treatment of solid tumors. CRB-601 is an anti-αvβ8 monoclonal antibody that blocks the activation of latent TGFβ present on cancer cells in the tumor microenvironment. CRB-601 was being evaluated as a potential treatment for patients with solid tumors in combination with existing therapies, including checkpoint inhibitors. We completed a Phase 1 dose escalation study. In November 2025, we presented a study-in-progress poster at the 2025 Society for Immunotherapy of Cancer conference. We have deprioritized the program and do not plan to enroll additional patients.

Financial Operations Overview

We are a clinical stage company focused on promising new therapies in oncology and obesity and have not generated any revenues from the sale of products. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for the marketing of one of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. We have never been profitable and at December 31, 2025, we had an accumulated deficit of $555.4 million. Our net losses for the years ended December 31, 2025 and 2024 were $78.5 million and $40.2 million, respectively.

We expect to continue to incur significant expenses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of our product candidates. We will continue to incur significant operating losses as we move into the clinical phase and, accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity, debt financings or other sources, which may include government grants and collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect to continue to incur operating losses for at least the next several years in connection with our ongoing activities, as we:

- conduct pre-clinical and clinical trials for our product candidates;
- continue our research and development efforts; and
- manufacture and purchase drugs for clinical studies.

Key Components of Our Results of Operations

Research and Development Expense

Our research and development expense has historically consisted primarily of the following:

- compensation, employee benefits and other staff-related expenses of personnel involved in research and development activities;
- external research and development costs incurred under agreements with contract research organizations and consultants to conduct our clinical trials and other pre-clinical studies;
- costs related to manufacturing and purchasing of our product candidates;
- costs associated with the licensing of research and development programs; and
- allocated expenses, including equipment, insurance and costs of facilities.

Research and development activities are the focus of our business model. We expect that our research and development expenses will increase in the future in connection with the continuation of our CRB-701 and CRB-913 clinical trials.

General and Administrative Expense

General and administrative expense primarily consists of compensation, employee benefits and travel expenses of personnel in our executive, finance, legal, human resources, and other administrative functions. Other costs include legal fees related to intellectual property and corporate matters, insurance costs, facilities costs not otherwise included in research and development expense, board compensation, professional fees for accounting, tax, and investor relations services, and information technology expense.

We anticipate that our general and administrative expenses will increase in the future to support increased and progressed research and development activities and to operate as a public company.

Interest and Investment Income, Net

Interest income consists of interest and investment income earned on our cash equivalents and investments.

Interest Expense

Interest expense relates primarily to interest expense on a loan from K2 HealthVentures LLC. The loan was repaid in full on August 1, 2024.

Other Income, Net

Other income, net includes tax credits in the form of refundable research and development tax credits and the employee retention tax credit ("ERTC"), as well as changes in foreign currency exchange gains and losses.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to accrued research and development expense and stock-based compensation expense. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. See Note 3 "Significant Accounting Policies" to the consolidated financial statements included under Part II, Item 8 of this Annual Report on Form 10-K for information about our significant accounting policies.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves: communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost; estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs and research institutions in connection with pre-clinical studies;
- fees paid to contract manufacturers in connection with the production of drugs for studies and clinical trials;
- fees paid to our licensing partner for drug product utilized in clinical trials;
- fees paid to CROs and research institutions in connection with conducting clinical studies; and
- professional service fees for consulting and related services.

We base our expense accruals related to pre-clinical and clinical activities on our estimates of the services performed pursuant to contracts with multiple research institutions and CROs that conduct and manage pre-clinical and clinical work on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful animal trials and the completion of study milestones. Our service providers invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses following each applicable reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information regarding the status or conduct of our pre-clinical and clinical studies and other research activities.

Stock-Based Compensation

We recognize compensation expense for stock-based awards, including grants of restricted stock units and stock options, granted to employees, non-employee directors and non-employee consultants based on the estimated fair value on the date of grant, over the requisite service period. The fair value of restricted stock units was estimated based on the market price of our common stock on the date of grant. The fair value of each stock option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. We estimate volatility by analyzing the volatility of the trading price of our common stock. The expected term of employee and non-employee director stock options granted under our stock plans, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to our limited operating history. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. For non-employee stock options, excluding directors, we have elected to utilize the contractual term as the expected term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with that used to value the stock option. We account for forfeitures as they occur. We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our stock-based compensation.

The following assumptions were used to estimate the fair value of stock options granted using the Black-Scholes option pricing model for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.35%	4.23%
Expected dividend yield	0%	0%
Expected term in years	6.15	6.18
Expected volatility	131.47%	124.60%

Recently Issued Accounting Pronouncements

Recent accounting pronouncements which may be applicable to us are described in Note 3 "Significant Accounting Policies" to our Consolidated Financial Statements included under Part II, Item 8 of this Annual Report on Form 10-K.

Results of Operations

Comparison of Year Ended 2025 to 2024

Revenue from Awards. No revenue was recognized for the years ended December 31, 2025 and 2024 in accordance with U.S. GAAP.

Operating Expenses. The following table summarizes our operating expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Research and development expense	$ 70,095	$ 32,222	$ 37,873	118%
General and administrative expense	15,215	16,499	(1,284)	-8%
Total operating expenses	$ 85,310	$ 48,721	$ 36,589	75%

Research and Development. The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Program specific costs:				
CRB-701	$ 33,623	$ 12,826	$ 20,797	162%
CRB-913	13,354	7,167	6,187	86%
CRB-601	12,156	4,763	7,393	155%
Other drug development	503	251	252	100%
Total program specific costs	59,636	25,007	34,629	138%
Unallocated internal costs:				
Personnel related	8,787	5,316	3,471	65%
Other unallocated	1,672	1,899	(227)	-12%
Total research and development expenses	$ 70,095	$ 32,222	$ 37,873	118%

Research and development expenses for the year ended December 31, 2025 totaled $70.1 million, an increase of $37.9 million over the $32.2 million recorded for the year ended December 31, 2024.

Total program-specific costs increased by $34.6 million in 2025 as compared to 2024. Costs related to CRB-701 increased by $20.8 million as a result of higher clinical and drug supply related costs as more sites were activated and participants enrolled in the ongoing Phase 1/2 clinical trial, which began in April 2024. CRB-913 costs increased by $6.2 million due to enrolling and completing the SAD/MAD portion of the Phase 1a clinical study, which began in March 2025, and the beginning of the Phase 1b enrollment in December 2025 partially offset by a decrease in research costs related to IND-enabling studies completed in 2024. Costs related to CRB-601 increased by $7.4 million as a result of higher clinical and drug supply related costs as the first participant in a Phase 1 dose escalation study was dosed in December 2024.

Personnel related costs increased by $3.5 million in 2025 as compared to 2024. The increase is primarily due to an increase in headcount.

Unallocated research and development costs were comparable between December 31, 2025 and December 31, 2024.

We have a subsidiary in each of the U.K. and Australia and approximately 35% and 37% of research and development expenses recorded for the years ended December 31, 2025 and 2024 respectively were recorded in these entities.

General and Administrative. General and Administrative expenses for the year ended December 31, 2025 totaled $15.2 million, a decrease of $1.3 million from the $16.5 million recorded for the year ended December 31, 2024. The decrease in fiscal 2025 as compared to fiscal 2024 was primarily attributable to a decrease in legal expenses of $0.7 million and a decrease in facility expense of $0.4 million.

Other Income (Expense), Net. The following table summarizes our other income (expense), net for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Interest and investment income, net	$ 5,530	$ 6,311	$ (781)	-12%
Interest expense	—	(1,872)	1,872	-100%
Other income, net	1,243	4,073	(2,830)	-69%
Total other income, net	$ 6,773	$ 8,512	$ (1,739)	-20%

Other income (expense), net for 2025 was $6.8 million as compared to $8.5 million recorded for 2024. Other income, net includes $1.1 million in employee retention tax credits for 2025 and refundable research and development credits from a foreign tax authority of $4.0 million for 2024. This decrease is partially offset by no interest expense on debt in 2025 as principal payments were made in 2024 leading to the final payment in August 2024.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At December 31, 2025, our accumulated deficit since inception was approximately $555.4 million.

At December 31, 2025, we had total current assets of $167.0 million and current liabilities of $20.7 million resulting in working capital of $146.3 million. Of our total cash, cash equivalents, investments, and restricted cash of $163.9 million at December 31, 2025, $162.7 million was held within the U.S.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2025 and December 31, 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (64,491)	$ (41,794)
Net cash used in investing activities	(1,641)	(121,310)
Net cash provided by financing activities	77,426	166,578
Net increase in cash, cash equivalents, and restricted cash	$ 11,294	$ 3,474

Net cash used in operating activities for the year ended December 31, 2025 was $64.5 million which includes a net loss of $78.5 million, adjusted for non-cash expenses of $4.9 million, largely related to stock-based compensation expense offset by net amortization of premiums and discounts on investments, and $9.1 million of cash provided by net working capital items, principally related to an increase in accrued expenses and a decrease in accounts payable due to the timing in which we pay and receive invoices from our vendors.

Cash used by investing activities for the year ended December 31, 2025 totaled $1.6 million, which was largely due to purchases of investments, partially offset by proceeds from sales and maturities of investments.

Cash provided by financing activities for the year ended December 31, 2025 totaled $77.4 million. This is mainly related to proceeds from issuance of common stock under an open market sale agreement, as well as a public offering as noted below.

Open Market Sale Agreement

On May 31, 2023, we entered into Amendment No. 1 to the Open Market Sale Agreement originally dated August 6, 2020 (as amended, the “Open Market Sale Agreement”) with Jefferies LLC ("Jefferies"), as sales agent. Under the Open Market Sale Agreement, we may issue and sell, from time to time through Jefferies, shares of its common stock having an aggregate offering price of up to $150.0 million (the “Open Market Offering”).

Under the Open Market Sale Agreement, Jefferies may sell the common stock by any method permitted by law deemed to be an “at-the-market offering” as defined by Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. We may sell common stock in amounts and at times to be determined by us subject to the terms and conditions of the Open Market Sale Agreement, but we have no obligation to sell any of the common stock in the Open Market Offering.

During the years ended December 31, 2025 and 2024, we sold an aggregate of 563,504 and 2,484,517 shares of common stock, respectively, under the Open Market Sale Agreement, for net proceeds of approximately $7.0 million and $91.4 million, respectively. As of December 31, 2025, approximately $69.1 million was available for issuance and sale under the Open Market Offering.

Public Offerings

On October 30, 2025, we entered into an underwriting agreement with Jefferies, as representative of the several underwriters, relating to an underwritten public offering of 4,744,231 shares of our common stock at a price to the public of $13.00 per share, and, to certain investors in lieu of common stock, pre-funded warrants to purchase 1,025,000 shares of common stock at a public offering price of $12.9999 per pre-funded warrant. The purchase price per share of each pre-funded warrant represents the per share public offering price for the common stock, minus the $0.0001 per share exercise price of each such pre-funded warrant. On November 3, 2025, we completed the public offering raising gross proceeds of approximately $75.0 million and net proceeds of approximately $70.2 million after deducting underwriting discounts and commissions and other offering expenses payable by us. The pre-funded warrants were classified as a component of permanent equity on the balance sheet as they are freestanding financial instruments that are immediately exercisable and permit the holders to receive a fixed number of shares of common stock upon exercise. As of December 31, 2025, all of the pre-funded warrants from the 2025 offering remain outstanding.

On January 31, 2024, we entered into an underwriting agreement with Jefferies, as representative of the several underwriters, relating to an underwritten public offering of 4,325,000 shares of our common stock, par value $0.0001, at a price to the public of $19.00 per share. The underwriters were also granted a 30-day option to purchase up to an additional 648,750 shares of common stock at the public offering price. On January 31, 2024, Jefferies gave notice to us of the underwriters' election to exercise the option to purchase additional shares, in full. On February 2, 2024, we completed the public offering raising gross proceeds of approximately $94.5 million and net proceeds of $88.6 million after deducting underwriting discounts and commissions and other offering expenses payable by us.

Based on current operating plans and assumptions regarding clinical timelines and other planned expenditures, we expect our cash, cash equivalents, and investments of $163.3 million at December 31, 2025 will be sufficient to meet our operating and capital requirements through at least twelve months from the issuance of these consolidated financial statements.

We will need to raise significant additional capital to continue to fund operations, including pre-clinical and clinical costs for our product candidates. If we are unable to raise sufficient capital in the future, we may be required to undertake cost-cutting measures, including delaying or discontinuing certain clinical activities. We may seek to sell common stock, preferred stock, or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs.

Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate expenses including some or all of our planned clinical trials.

Contractual Obligations and Commitments

Our contractual obligation as of December 31, 2025 consist of our amended lease agreement ("February 2019 Lease Agreement") for an aggregate total of 62,756 square feet of leased office space ("Total Premises") through November 30, 2026. As of December 31, 2025, our contractual commitment under this lease was $1.7 million, which will be paid over the remaining term of the lease. See Note 8 "Commitments and Contingencies" to the consolidated financial statements included under Part II, Item 8 of this Annual Report on Form 10-K for additional information about our lease.

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material. As of December 31, 2025, other than our leases, we had no material contractual obligations or commitments that will affect our future liquidity.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors, other than future royalty payments under development award agreements discussed as follows:

License Agreement with Jenrin

Pursuant to the terms of the license agreement (the "Jenrin License Agreement") with Jenrin Discovery, LLC (“Jenrin”), we are obligated to pay potential milestone payments to Jenrin totaling up to $18.4 million for each compound we elect to develop based upon the achievement of specified development and regulatory milestones. In addition, we are obligated to pay Jenrin royalties in the mid, single digits based on net sales of any Licensed Products, as defined in the Jenrin License Agreement, subject to specified reductions. A $0.4 million milestone payment was achieved and paid in 2025. We are obligated to pay Jenrin up to $18.0 million in additional potential milestone payments for further development of CRB-913.

The Jenrin License Agreement terminates on a country-by-country basis and product-by-product basis upon the expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the later of seven years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country. The Jenrin License Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the Jenrin License Agreement by either party, termination by Jenrin in specified circumstances, termination by us with advance notice, and termination upon a party’s insolvency or bankruptcy.

License Agreement with UCSF

Pursuant to the terms of the license agreement (the "UCSF License Agreement") with the Regents of the University of California, we are obligated to pay up to $150.8 million in remaining potential milestone payments based upon the achievement of specified development and regulatory milestones, excluding indication milestones for antibodies used for diagnostic products and services that will be an additional $50.0 thousand for each new indication. In addition, we are obligated to pay royalties in the lower, single digits based on net sales of any Licensed Products, as defined in the UCSF License Agreement, and any diagnostic products and services. During the first quarter of 2025, we paid $1.6 million under the UCSF License Agreement for previously achieved milestone payments. This amount was included within accounts payable within the consolidated balance sheet as of December 31, 2024.

The UCSF License Agreement will remain in effect until the expiration or abandonment of the last of the Patent Rights licensed. The Royalty Term is the duration of Patent Rights in that country covering the applicable Licensed Product or Licensed Services Sold in the country. The UCSF License Agreement may be terminated earlier in specified situations, including termination for material breach, termination by us with advance notice, and termination upon a party's bankruptcy.

License Agreement with CSPC

Pursuant to the terms of the license agreement (the "CSPC License Agreement") with CSPC, we are obligated to pay potential milestone payments to CSPC totaling up to $130.0 million based upon the achievement of specified development and regulatory milestones and $555.0 million in potential commercial milestone payments. In addition, we are obligated to pay CSPC royalties in the low, double digits based on net sales of any Licensed Products, as defined in the CSPC License Agreement.

The CSPC License Agreement will remain in effect on a Licensed Product and on a country-by-country basis, until the expiration of the Royalty Term of the Licensed Product in the country. The Royalty Term is the period beginning from the First Commercial Sale of the Licensed Product in the country until the later of the expiration of the last-to-expire Valid Claim in any Licensor Patent in the country that Covers the Licensed product, 10 years after the date of the First Commercial Sale in the country, or expiration of the Regulatory Exclusivity for the Licensed Product in the country. The CSPC License Agreement may be terminated earlier in specified situations, including termination for material breach, termination by us with advance notice, and termination upon a party's bankruptcy.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of three months or less. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

Foreign Exchange Risk

The majority of our operations are based in the U.S. and, accordingly our transactions are denominated in U.S. Dollars. However, we have foreign currency exposures related to our cash valued in the U.K. in British Pounds and Euros and our cash valued in Australia in Australian Dollars because our functional currency is the U.S. Dollar in our foreign-based subsidiaries. Our foreign denominated assets and liabilities are remeasured each reporting period with any exchange gains and losses recorded in our consolidated statements of operations and comprehensive loss.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-1 through F-23 following the Exhibit Index of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our principal executive officer and our principal financial officer, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act, as amended) as of the end of the period covered by this report. Based upon, and as of the date of, this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of December 31, 2025 are effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in the "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This annual report does not include an attestation report of our registered public accounting firm on internal control over financial reporting. We are currently a non-accelerated filer and are therefore not required to provide an attestation report on our internal control over financial reporting until such time as we are an accelerated filer or large accelerated filer.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. OTHER INFORMATION

Director and Officer Trading Arrangements

No directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fiscal quarter ended December 31, 2025.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors and their ages as of the date of this filing are set forth below. Each director is elected annually to serve until the next annual meeting of shareholders, or until his or her successor is duly elected.

Name	Age	Position(s)	Served as an Officer or Director Since
Yuval Cohen, Ph.D.	50	Chief Executive Officer and Director	2014
Rachelle Jacques	54	Director (Chair of the Board)	2019
John Jenkins	68	Director	2018
Anne Altmeyer	61	Director	2022
Yong Ben	52	Director	2023
Winston Kung	50	Director	2024

There are no family relationships between any of our directors or executive officers.

The biographies of our directors and certain information regarding each director's experience, attributes, skills and/or qualifications that led to the conclusion that the director should be serving as a director of our Company are as follows:

Yuval Cohen, Ph.D., Chief Executive Officer and Director

Dr. Cohen has served as our Chief Executive Officer and as a director since April 11, 2014. Prior to joining Corbus Pharmaceuticals, Inc., he was the President and co-founder of Celsus Therapeutics PLC ("Celsus"). Dr. Cohen holds a BSc (Hons) in microbiology and biochemistry from University of Cape Town, South Africa, and has a Ph.D., summa cum laude, from the Curie Institute of Cancer Research in Paris and the University of Paris V. Dr. Cohen was selected as a director because of his business and leadership experience in the biopharmaceutical sector, as well as a result of his experience serving as our Chief Executive Officer since our inception.

Rachelle S. Jacques, Chair of the Board

Ms. Jacques has served as a director since April 2019 and chair of our Board since May 2025. Ms. Jacques currently serves as a member of the board of directors of uniQure N.V. (Nasdaq: QURE) since 2021. She currently serves as the Chief Executive Officer of Vasque Bio, a private, pre-clinical stage biopharmaceutical company dedicated to the development of therapeutics to improve patient outcomes in areas of high unmet medical need. Ms. Jacques previously served as the President and Chief Executive Officer of Akari Therapeutics, Plc (Nasdaq: AKTX) a late-stage biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where complement (C5) and/or leukotriene systems (LBT4) are implicated, and on its board of directors from March 2022 to May 2024. Ms. Jacques served as the Chief Executive Officer of Enzyvant Therapeutics, Inc., a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. (TSE: 4506), focused on developing therapies for patients with rare diseases, from February 2019 to March 2022. Beginning in 2017, she served as the Senior Vice President and Global Complement Franchise Head at Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN), where she was responsible for commercialization strategy and execution. From 2016 to 2017, Ms. Jacques was Vice President of U.S. Hematology Marketing at Shire plc, which acquired Baxalta Inc. ("Baxalta") in 2016. Prior to this role, from 2015 to 2016, Ms. Jacques served as Vice President of Business Operations at Baxalta after its spinoff from Baxter International Inc. (NYSE: BAX) in 2015. From 2013 to 2015, Ms. Jacques served in leadership positions, including Vice President of Finance, US BioScience Business, at Baxter. Prior to joining Baxter, Ms. Jacques served in various roles of increasing responsibility at Dow Corning Corporation, including U.S. and international operational management roles, from 1995 to 2013. Ms. Jacques previously served as a member of the board of directors of Viela Bio, Inc. (Nasdaq: VIE) from April 2020 until it was acquired by Horizon Therapeutics plc in March 2021. Ms. Jacques received her B.A. degree in business administration from Alma College. Ms. Jacques was selected as a director due to her multinational business leadership and commercialization experience, particularly in the biotechnology industry.

John K. Jenkins, M.D., Director

Dr. Jenkins has served as a director since June 2018. Dr. Jenkins is currently Managing Member of John K. Jenkins Advisors, LLC, an FDA-focused strategic regulatory advisory firm located in Washington, DC. Previously he served as Principal, Drug and Biological Products at Greenleaf Health from 2017 to 2023. In that role, he advised companies developing new drugs and seeking FDA approval. Dr. Jenkins also worked in various positions of increasing responsibility at the FDA from May 1992 until his retirement in January 2017. During his tenure at the FDA, Dr. Jenkins served as Director of the Division of Pulmonary Drug Products from 1995 to 1999, Director of the Office of Drug Evaluation II from 1999 to 2002, and Director of the Office of New Drugs from 2002 to 2017. In his role as Director of the Office of New Drugs, Dr. Jenkins was responsible for oversight of all new drug reviewing divisions for small molecule drugs, therapeutic biologic proteins, and biosimilars. Dr. Jenkins was also a member of the Center for Drug Evaluation and Research Senior Leadership Team and represented the FDA during Congressional testimony on a variety of issues and during negotiations related to the renewal of the Prescription Drug User Fee Act. Prior to joining the FDA, Dr. Jenkins served as an Assistant Professor of Pulmonary and Critical Care Medicine at VCU/MCV, and as a Staff Physician at the Hunter Holmes McGuire VA Medical Center in Richmond, Virginia. Dr. Jenkins is board certified in internal medicine and pulmonary diseases by the American Board of Internal Medicine. He received his medical degree from the University of Tennessee, Memphis and completed his post-graduate medical training in internal medicine, pulmonary diseases, and critical care medicine at Virginia Commonwealth University/Medical College of Virginia in Richmond. Dr. Jenkins was selected as a director due to his medical knowledge and strategic regulatory expertise.

Anne Altmeyer, Ph.D., Director

Dr. Altmeyer has served as a director since September 20, 2022. Until its acquisition in 2025, Dr. Anne Altmeyer served as President and Chief Executive Officer of TigaTx, Inc., where she led the company's strategic direction, financing, and ultimate exit. Previously, she served as the Chief Business Officer at Sigilon Therapeutics (acquired by Eli Lilly) and Adicet Bio (Nasdaq: ACET). Dr. Altmeyer brings more than 15 years of experience in global pharmaceutical organizations, holding leadership roles of increasing responsibility in corporate development, oncology business development, and portfolio strategy. She served as Vice President, Global Business Development at Baxalta (acquired by Shire Plc), and as Vice President, Oncology Business Development and Companion Diagnostics at Novartis. She began her industry career in program management roles at Merck & Co., Inc. (NYSE: MRK), building a foundation in cross-functional drug development execution. Dr. Altmeyer holds a Ph.D. from the University Louis Pasteur in Strasbourg, France, and completed postdoctoral fellowships at New York University and Cornell University Medical College in New York City. She also earned an MBA from Rutgers University and a Master of Public Health from Robert Wood Johnson Medical School in New Jersey. Dr. Altmeyer was selected as a director because of her business leadership experience and extensive prior experience in the biopharmaceutical industry.

Yong Ben, M.D., Director

Dr. Ben has served as a director since March 1, 2023. Dr. Ben has over 20 years of clinical development expertise including strategic planning, oncology clinical trial design and execution and successful BLA/NDA submissions. Dr. Ben is currently the Chief Medical and Development Officer at BridgeBio Oncology Therapeutics since September 2024. Prior to that, he was a venture partner at Eight Roads Venture (formerly known as Fidelity Ventures) since August 2022. Prior to Eight Roads Venture, Dr. Ben served as Chief Medical Officer for BeiGene, Ltd. (Nasdaq: BGNE), a global biotechnology company specializing in drugs for cancer treatment, from February 2019 to February 2022, and served as a clinical advisor with the company until July 2022. Prior to BeiGene, Dr. Ben served as Chief Medical Officer for BioAtla, Inc. (Nasdaq: BCAB), an immunotherapy company, from May 2017 to February 2019. Prior to BioAtla, Dr. Ben was the Global Clinical Leader, Immuno-Oncology Clinical Development, for AstraZeneca PLC (Nasdaq: AZN) from August 2014 to May 2017. Dr. Ben received his medical degree from Norman Bethune College of Medicine and was a surgical oncologist at Peking Union Medical College Hospital with a post-doctoral fellowship at California Pacific Medical Center. Dr. Ben also received an M.B.A. from the University of California, San Diego. Dr. Ben was selected as a director due to his medical knowledge and extensive business leadership experience in the biopharmaceutical industry.

Winston Kung, Director

Mr. Kung has served as a director since August 16, 2024. Mr. Kung serves as the Chief Financial Officer and Treasurer of ArriVent BioPharma, Inc. (Nasdaq: AVBP), a clinical-stage biopharmaceutical company dedicated to the identification, development and commercialization of differentiated medicines to address the unmet needs of patients with cancer, since January 2024. Mr. Kung has served as a member of the board of Janux Therapeutics, Inc. (Nasdaq: JANX), a clinical-stage biopharmaceutical company developing a broad pipeline of novel immunotherapies by applying its proprietary technology to its Tumor Activated T Cell Engager (TRACTr) and Tumor Activated Immunomodulator (TRACIr) platforms, since September 2022 and has served as a member of the audit committee since June 2023. From December 2017 to January 2024, Mr. Kung served as the Chief Operating Officer and Chief Financial Officer of PMV Pharmaceuticals, Inc. (Nasdaq: PMVP), a precision oncology company. From April 2013 to November 2017, Mr. Kung held multiple positions at Celgene Corporation, a global biopharmaceutical company (acquired by Bristol-Myers Squibb), including Vice President of Business Development and Global Alliances, and Chief Business Officer at Celgene Cellular Therapeutics (a wholly-owned subsidiary of Celgene Corporation). Prior to Celgene, Mr. Kung worked at Citigroup from June 2010 to April 2013 in its Global Healthcare Investment Banking group and at Lehman Brothers (which was subsequently acquired by Barclays) from May 2007 to June 2010 in its Global Mergers and Acquisition Group. From August 2004 to May 2007, Mr. Kung worked at Amgen Inc. (Nasdaq: AMGN), as a co-founder of the Alliance Management group, and served as the deal lead on multiple acquisitions as part of the Corporate Development group. Mr. Kung also worked at Genentech Inc., a biotechnology company (acquired by Roche Holding AG), from November 1999 to September 2002 as part of the Business and Corporate Development group. Mr. Kung received a B.A. in Biology and International Relations from Brown University and a M.B.A. from Harvard Business School. Mr. Kung was selected as a director due to his financial expertise and his extensive background in life science industry business development and the capital markets.

Executive Officers

Our executive officers and their ages as of the date of this filing are set forth below. Our executive officers are elected by, and serve at the discretion of, our Board.

Name	Age	Position(s)	Serving in Position Since
Yuval Cohen, Ph.D.	50	Chief Executive Officer, Director	2014
Sean Moran	68	Chief Financial Officer	2014
Dominic Smethurst	52	Chief Medical Officer	2024
Ian Hodgson	53	Chief Operating Officer	2025

The business experience for the past five years, and in some instances, for prior years, of each of our executive officers is as follows:

Yuval Cohen, Ph.D., Chief Executive Officer and Director

See description in the above section entitled “Directors.”

Sean Moran, CPA, MBA, Chief Financial Officer

Mr. Moran has served as our Chief Financial Officer since April 11, 2014. Mr. Moran joined Corbus Pharmaceuticals, Inc. (formerly JB Therapeutics), our wholly-owned subsidiary, as its Chief Financial Officer in January 2014. Mr. Moran has over twenty-five years of senior financial experience with emerging biotechnology, drug delivery and medical device companies. Mr. Moran has worked at three different companies that completed initial public offerings and maintained a listing on a public exchange. Before joining our company, Mr. Moran served as Director of Finance and then as Chief Financial Officer for InVivo Therapeutics Corporation from 2010 to 2013 and served as Chief Financial Officer of Celsion Corporation from 2008 to 2010, Transport Pharmaceuticals Inc. from 2006 to 2008, Echo Therapeutics Inc. from 2002 to 2006, SatCon Technology Corporation from 2000 to 2002, and Anika Therapeutics Inc. from 1993 to 2000. Mr. Moran is a CPA by training and earned his M.B.A. and a B.S. in Accounting from Babson College.

Dominic Smethurst, MA, MBChB, MRCP, Chief Medical Officer

Dr. Smethurst has served as our Chief Medical Officer since February 27, 2024. Before joining our company, Dr. Smethurst served as the Chief Medical Officer of Bicycle Therapeutics PLC (Nasdaq: BCYC), a clinical-stage biopharmaceutical company developing a class of medicines for diseases that are underserved by existing therapeutics in the United States and the United Kingdom, from August 2020 to October 2023. Prior to his position at Bicycle Therapeutics, from February 2019 to August 2020, Dr. Smethurst served as interim Chief Medical Officer for Nordic Nanovector ASA, where he was responsible for design, strategy and implementation of clinical trials for drug development. Dr. Smethurst earned his MA and MBChB degrees in Medicine at Christ's College, Cambridge, UK, and his MRCP degree in Medicine from Queens Medical Center, Nottingham, UK.

Ian Hodgson, Chief Operating Officer, Ph.D.

Dr. Hodgson has served as our Chief Operating Officer since March 15, 2025. Dr. Hodgson previously served as our head of operations and vacated such position upon appointment as Chief Operating Officer. Dr. Hodgson has over 25 years of experience in drug development and operations across biotech, large pharmaceutical companies and contract research organizations. Dr. Hodgson joined Corbus International Ltd. in October 2022 as Head of Clinical and European Operations and transitioned to Head of Operations in March of 2024. Since May 2021, Dr. Hodgson has served as a non-executive director and board advisor for MD Group Ltd., a privately owned patient services company, and Skyelarke, a health-tech company specializing in delivering patient payments in clinical trials. Previously, he held several leadership positions, including Vice President, Head of Clinical Services at TMC Pharma Services Ltd., a rare disease consultancy from September 2021 through September 2022, Vice President, Clinical Development – Rare Diseases at Syneos Health from November 2020 through September 2021, and Head of Clinical Operations at Mereo Biopharma from 2015 through 2020. Dr. Hodgson earned a PhD in Medical Microbiology from Queen Margaret University in collaboration with the University of Edinburgh (awarded by the Open University) and a BSc (Hons) in Food Technology from Reading University.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our employees, officers and directors. A copy of the code is posted under the “Investors” tab under “Governance” in our website, which is located at www.corbuspharma.com. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above or in a Current Report on Form 8-K.

Insider Trading Policy

We have an insider trading policy governing the purchase, sale and other dispositions of the Company’s securities that applies to all Company personnel, including directors, officers, and employees. We believe that our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of the Company’s insider trading policy is incorporated by reference to this Annual Report on Form 10-K as Exhibit 19.1.

Anti-Hedging Policy

Under the terms of our insider trading policy, we prohibit each officer, director and employee, and each of their family members and controlled entities, from engaging in certain forms of hedging or monetization transactions. Such transactions include those, such as zero-cost collars and forward sale contracts, that would allow them to lock in much of the value of their stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock, and to continue to own the covered securities but without the full risks and rewards of ownership.

Board Composition

Our Board is composed of six directors. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our Board met five times in 2025. Each of the directors attended at least 75% of the aggregate of (i) the total number of meetings of our Board (held during the period for which such directors served on the Board) and (ii) the total number of meetings of all committees of our Board on which the director served (during the periods for which the director served on such committee or committees) during 2025. Mr. Alan Holmer, the former Chairman of the Board prior to his retirement on December 31, 2025, Ms. Jacques and Dr. Cohen attended the 2025 annual meeting of stockholders. We do not have a formal policy requiring members of the Board to attend our annual meetings.

Director Independence

Our common stock is listed on The Nasdaq Capital Market. Under the Nasdaq Listing Rules, independent directors must comprise a majority of our Board. In addition, the Nasdaq Listing Rules require that all the members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Compensation committee members must also satisfy the independence criteria established by the Nasdaq Listing Rules in accordance with Rule 10C-1 under the Exchange Act. Under the Nasdaq Listing Rules, a director will only qualify as an "independent director" if, among other qualifications, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our Board undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board has determined that Ms. Jacques, Dr. Jenkins, Dr. Altmeyer, Dr. Ben and Mr. Kung do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules and the SEC.

In making this determination, our Board considered the relationships that each non-employee director has with our Company and all other facts and circumstances our Board deemed relevant in determining their independence. We intend to comply with the other independence requirements for committees within the time periods specified above.

Board Committees

Our Board has established an audit committee (the "Audit Committee"), a compensation committee (the "Compensation Committee") and a nominating and corporate governance committee (the "Nominating and Corporate Governance Committee"). Our Board may establish other committees to facilitate the management of our business. The composition and functions of each committee named above are described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees operate under a charter that has been approved by our Board.

Audit Committee. Our Audit Committee currently consists of Ms. Jacques, Dr. Jenkins and Mr. Kung. Mr. Kung is the Chair of the Audit Committee. Our Audit Committee met seven times in 2025. Our Board has determined that the directors currently serving on our Audit Committee are independent within the meaning of the Nasdaq Listing Rules and Rule 10A-3 under the Exchange Act. In addition, our Board has determined that Mr. Kung qualifies as an audit committee financial expert within the meaning of SEC regulations and the Nasdaq Listing Rules.

The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to our Board any substantive issues found during the audit. The Audit Committee will be directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties. Our Board has adopted a written charter for the Audit Committee. A copy of the charter is posted under the "Investors" tab under "Governance" in our website, which is located at www.corbuspharma.com.

Compensation Committee. Our Compensation Committee currently consists of Dr. Altmeyer, Dr. Ben and Dr. Jenkins. Dr. Jenkins is the Chair of the Compensation Committee. Our Compensation Committee met ten times in 2025. Our Board has determined that the directors currently serving on our Compensation Committee are independent under the Nasdaq Listing Rules, are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act and are "outside directors" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

The Compensation Committee provides advice and makes recommendations to our Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other officers and makes recommendations in that regard to our Board as a whole.

In discharging its responsibilities, the Compensation Committee works with our Chief Executive Officer, who assists the Compensation Committee by providing information on corporate and individual performance, perspectives on performance issues and recommendations on compensation matters.

Typically, our Chief Executive Officer will make recommendations to the Compensation Committee regarding compensation matters, including adjustments to annual cash compensation, long-term incentive compensation opportunities for our executive officers, including our other Named Executive Officers. At the beginning of each year, our Chief Executive Officer reviews the performance of our executive officers based on such individual's level of success in accomplishing the business objectives established for him or her for the prior year and his or her overall performance during that year, and then shares these evaluations with, and makes recommendations to, the Compensation Committee for each element of compensation as described above. The Compensation Committee reviews and discusses these recommendations and proposals with our Chief Executive Officer.

Our Chief Executive Officer attends meetings of the Compensation Committee at which executive compensation matters are addressed, but does not participate in the Compensation Committee's deliberations involving his own compensation.

The Compensation Committee has directly engaged independent compensation consultant, Compensia, Inc., to provide advice and recommendations on the structure, amount and form of executive and director compensation and the competitiveness thereof. At the request of the Compensation Committee, the compensation consultants provided, among other things, comparative data from selected peer companies. The compensation consultants report directly to the Compensation Committee. The Compensation Committee's decision to hire the compensation consultants was not made or recommended by Company management. The compensation consultant did not perform any work for the Company in 2025 except with respect to the work that was done directly for the Compensation Committee.

Our Board has adopted a written charter for the Compensation Committee. A copy of the charter is posted under the "Investors" tab under "Governance" in our website, which is located at www.corbuspharma.com.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee currently consists of Dr. Ben, Ms. Jacques and Dr. Altmeyer. Dr. Altmeyer is the Chair of the Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee met five times in 2025. The Nominating and Corporate Governance Committee nominates individuals to be elected to the full board by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws and will apply the same criteria to all persons being considered. All members of the Nominating and Corporate Governance Committee are independent directors as defined under the Nasdaq Listing Rules. Our Board has adopted a written charter for the Nominating and Corporate Governance Committee. A copy of the charter is posted under the "Investors" tab under "Governance" in our website, which is located at www.corbuspharma.com.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers, and persons who are beneficial owners of more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission, or the SEC. These persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us, and written representations that no other reports were required during the fiscal year ended December 31, 2025, all reports required to be filed under Section 16(a) during 2025 were filed on a timely basis.

Item 11. EXECUTIVE COMPENSATION

Executive Compensation

Our named executive officers for the year ended December 31, 2025 were Yuval Cohen, Ph.D., Director and Chief Executive Officer; Sean Moran, CPA, Chief Financial Officer; and Dominic Smethurst, MA, MBChB, MRCP.

Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by, or paid to our chief executive officer and the two most highly-compensated executive officers (other than the chief executive officer) who were serving as executive officers as of December 31, 2025 and 2024 for services rendered in all capacities to us for the years ended December 31, 2025 and 2024. These individuals are our named executive officers for 2025.

Name and Principal Position	Year	Salary	Bonus	Stock Awards (2)	Option Awards (2)	Non-equity Incentive Plan Compensation	All Other Compensation (3)	Total
Yuval Cohen	2025	$646,566	$373,682	$666,699	$2,039,294	$—	$23,884	$3,750,125
Chief Executive Officer	2024	$621,883	$380,868	$1,700,781	$1,518,871	$—	$23,035	$4,245,438
Sean Moran	2025	$481,137	$185,382	$269,225	$824,453	$—	$29,226	$1,789,423
Chief Financial Officer	2024	$462,769	$188,947	$924,048	$825,215	$—	$28,526	$2,429,505
Dominic Smethurst (1)	2025	$519,313	$168,078	$266,288	$812,866	$—	$33,597	$1,800,142
Chief Medical Officer	2024	$408,914	$—	$1,303,500	$1,165,650	$—	$14,908	$2,892,972

(1) Dr. Smethurst was appointed Chief Medical Officer on February 27, 2024. All compensation to Dr. Smethurst was paid in Great British Pounds and was converted to US dollars using the average foreign exchange rate for the fiscal years 2025 and 2024 of 1 GBP = $1.3175 and $1.2771, respectively, based on the yearly average currency exchange rates from the IRS website.

(2) Amounts reflect the grant date fair value of option awards and restricted stock units granted in accordance with Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 3 to our Consolidated Financial Statements and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies - Stock-Based Compensation" included in Item 7 of this Annual Report on Form 10-K for the fiscal year ended December 31, 2025. These amounts do not correspond to the actual value that may be received by the named executive officers if the stock options are exercised or restricted stock units vest.

(3) Includes the following amounts in respect to company matching contributions under our 401(k) plan for Dr. Cohen and Mr. Moran and U.K.-based retirement account for Dr. Smethurst, individual health savings accounts, company-paid premiums for group term life insurance, and company-paid internet allowance. The company-paid life insurance premiums reflect payments for group term life policies maintained for the benefit of all employees.

Name	Year	Company 401(k) or U.K. Pension Matching Contribution	Company Health Savings Account Matching Contribution	Company-Paid Group Term Life Insurance Premiums	Company-Paid Internet Allowance	Total All Other Compensation
Yuval Cohen	2025	$17,500	$4,167	$1,242	$975	$23,884
	2024	$17,250	$4,000	$810	$975	$23,035
Sean Moran	2025	$17,500	$4,167	$6,584	$975	$29,226
	2024	$17,250	$4,000	$6,301	$975	$28,526
Dominic Smethurst	2025	$32,689	$—	$—	$908	$33,597
	2024	$14,688	$—	$—	$220	$14,908

Narrative Disclosure to Summary Compensation Table Employment Agreements

Yuval Cohen

Effective April 11, 2022, we entered into a fourth amended and restated employment agreement with Dr. Cohen (the "Cohen 2022 Agreement"), which is effective for a period of two (2) years. The Cohen 2022 Agreement provides for Dr. Cohen to serve as Chief Executive Officer and provides for an annual base salary of $598,850. In addition, Dr. Cohen is eligible to receive an annual bonus, which is targeted at up to 60% of his base salary but which may be adjusted by our Board based on his individual performance and our performance as a whole. Pursuant to the terms of the Cohen 2022 Agreement, Dr. Cohen is eligible to receive, from time to time, equity awards under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by our Board or Compensation Committee, in their discretion. Dr. Cohen is subject to non-compete provisions, which apply during the term of his employment and for a period of six (6) months from the date of cessation of his employment, subject to the Company providing as severance ((x) if we terminate Dr. Cohen's employment without cause or he terminates his employment for good reason during the term of his employment agreement and (y) Dr. Cohen timely executes and does not revoke a general release, which will include a non-compete covenant, and complies with such covenants) twelve (12) months of his base salary, other than during the Change in Control Period (as defined below), in which case it will be increased to twenty-four (24) months. Dr. Cohen will be subject to non-solicitation provisions, which apply during the term of his employment and for a period of twelve (12) months from the date of cessation of his employment. In addition, the employment agreement contains customary confidentiality and assignment of inventions provisions. If we terminate Dr. Cohen's employment without cause or he terminates his employment for good reason during the term of his employment agreement, other than during the Change in Control Period, we are required to pay him as severance reimbursement of the cost of COBRA coverage (or to use commercially reasonable best efforts to provide the cost of other comparable coverage if COBRA reimbursement would incur tax penalties or violate the law) for twelve (12) months, and he may be paid a pro-rated bonus, each subject to his timely execution of a general release, which will include a non-compete covenant, and continuing compliance with such covenants. If we terminate Dr. Cohen's employment without cause or he terminates his employment for good reason during the term of the employment agreement, and within the three (3) months immediately prior to a change in control or the twelve (12) months immediately following a change in control (the "Change in Control Period"), we are required to provide as severance reimbursement of the cost of COBRA coverage (or to use commercially reasonable best efforts to provide the cost of other comparable coverage if COBRA reimbursement would incur tax penalties or violate the law) for twenty-four (24) months, accelerated vesting of all of his outstanding options, restricted stock and other equity incentive awards and his current year bonus at two (2) times target levels, each subject to his timely execution and non-revocation of a general release which will include a non-compete covenant, and continuing compliance with such covenants. Dr. Cohen's severance payments and other applicable payments and benefits will be subject to reduction to the extent doing so would put him in a better after-tax position after taking into account any excise tax he may incur under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment. The Cohen 2022 Agreement expired on April 11, 2024.

Effective April 10, 2024, we entered into a fifth amended and restated employment agreement with Dr. Cohen (the "Cohen 2024 Agreement"), which is effective for a period of two (2) years from the date thereof and expires on April 10, 2026. The Cohen 2024 Agreement provides for an annual base salary of $622,804, and extends the Change in Control Period to within the six (6) months immediately prior to a change in control or the twelve (12) months immediately following a change in control. Except for the foregoing, the material terms of the Cohen 2024 Agreement are unchanged from the Cohen 2022 Agreement.

Sean Moran

Effective April 11, 2022, we entered into a fifth amended and restated employment agreement with Mr. Moran (the "Moran 2022 Agreement"), which is effective for a period of two (2) years. Mr. Moran's employment agreement provides for Mr. Moran to serve as Chief Financial Officer and provides for an annual base salary of $428,490. In addition, Mr. Moran is eligible to receive an annual bonus, which is targeted at up to 40% of his base salary but which may be adjusted by our Board based on his individual performance and our performance as a whole. Pursuant to the terms of the employment agreement, Mr. Moran is eligible to receive, from time to time, equity awards under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by our Board or Compensation Committee, in their discretion. Mr. Moran is subject to non-compete provisions, which apply during the term of his employment and for a period of six (6) months from the date of cessation of his employment, subject to the Company providing as severance ((x) if we terminate Mr. Moran's employment without cause or he terminates his employment for good reason during the term of the employment agreement and (y) he timely executes and does not revoke a general release, which will include a non-compete covenant, and complies with such covenants) twelve (12) months of his base salary, other than during the Change in Control Period, in which case it will be increased to eighteen (18) months. Mr. Moran will be subject to non-solicitation provisions, which apply during the term of his employment and for a period of twelve (12) months from the date of cessation of his employment. In addition, the employment agreement contains customary confidentiality and assignment of inventions provisions. If we terminate Mr. Moran's employment without cause or he terminates his employment for good reason during the term of his employment agreement, other than during the Change in Control Period, we are required to pay him as severance reimbursement of the cost of COBRA coverage (or to use commercially reasonable best efforts to provide the cost of other comparable coverage if COBRA reimbursement would incur tax penalties or violate the law) for twelve (12) months, and he may be paid a pro-rated bonus, each subject to his timely execution of a general release, which will include a non-compete covenant, and continuing compliance with such covenants. If we terminate Mr. Moran's employment without cause or he terminates his employment for good reason during the term of the employment agreement, and during the Change in Control Period, we are required to pay him as severance reimbursement of the cost of COBRA coverage (or to use commercially reasonable best efforts to provide the cost of other comparable coverage if COBRA reimbursement would incur tax penalties or violate the law) for eighteen (18) months, accelerated vesting of all of his outstanding options, restricted stock and other equity incentive awards and his current year bonus at target levels, each subject to his timely execution and non-revocation of a general release, which will include a non-compete covenant, and continuing compliance with such covenants. Mr. Moran's severance payments and other applicable payments and benefits will be subject to reduction to the extent doing so would put him in a better after-tax position after taking into account any excise tax he may incur under Internal Revenue Code Section 4999 in connection with any change in control of the Company or his subsequent termination of employment. The Moran 2022 Agreement expired on April 11, 2024.

Effective April 10, 2024, we entered into a sixth amended and restated employment agreement with Mr. Moran (the "Moran 2024 Agreement"), which is effective for a period of two (2) years from the date thereof and expires on April 10, 2026. The Moran 2024 Agreement provides for an annual base salary of $463,455. Except for the foregoing the material terms of the Moran 2024 Agreement are unchanged from the Moran 2022 Agreement.

Dominic Smethurst

On February 27, 2024, we entered into a Service Agreement with Dr. Smethurst (the "Smethurst Agreement"). The Smethurst Agreement provides for Dr. Smethurst to serve, until terminated, as Chief Medical Officer and provides for an annual base salary of £379,000. In addition, Dr. Smethurst is eligible to receive an annual bonus, which is targeted at up to 40% of his base salary, but may be adjusted by the Board based on his individual performance and the Company's performance as a whole. Dr. Smethurst's annual base salary and his targeted annual bonus may be adjusted annually by the Board. Dr. Smethurst received an initial grant of (i) 50,000 restricted stock units and (ii) an option to purchase up to 50,000 shares of the Company's common stock pursuant to the Company's 2014 Equity Compensation Plan, and is eligible, from time to time, to receive additional stock options or other awards, in amounts, if any, to be approved by the Board or the Compensation Committee in its discretion. Pursuant to the terms of the Smethurst Agreement, Dr. Smethurst is subject to non-compete and non-solicitation provisions, which apply during the term of his employment and for a period of three (3) months and six (6) months, respectively, following termination of his employment. In addition, the Smethurst Agreement contains customary confidentiality and assignment of inventions provisions. Dr. Smethurst or the Company may terminate the Smethurst Agreement with three (3) month's prior notice. The Company may also terminate Dr. Smethurst without notice, with payment in lieu of notice, in an amount equal to his base salary as of the termination date which he would have been entitled to receive pursuant to the Smethurst Agreement during the three (3) month notice period, but not including any bonus or commission payments, benefits or holiday entitlements, in each case, for which he would have been entitled to receive during such three (3) month notice period. Pursuant to the Smethurst Agreement, the Company has the right to terminate Dr. Smethurst, without notice and with no liability to make any further payments (other than amounts which have accrued due to the date of termination), in certain circumstances set forth in the Smethurst Agreement (such circumstances, "Cause"). In the event that Dr. Smethurst is terminated (other than for Cause) within the six (6) months preceding or twelve (12) months following a Change in Control (as defined in the Smethurst Agreement), the Company will be required to pay him twice the amount of his target bonus by March 15th of the calendar year following the Change in Control and fully accelerate vesting of his outstanding stock options, restricted stock and other equity incentive awards upon the later of the Change in Control or the termination of his employment.

Outstanding Equity Awards at Fiscal Year End

The following table summarizes, for each of the named executive officers, the number of shares of common stock underlying unexercised options, stock that has not vested and equity incentive awards held as of December 31, 2025.

	Equity Incentive Plan Awards						
	Option Awards					Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units or Stock that Have Not Vested ($) [1]
Yuval Cohen	17,667[2]	-[2]	-	$42.00	1/7/2026		
	5,000[3]	-[3]	-	$261.30	10/6/2026		
	12,583[4]	-[4]	-	$271.50	3/1/2027		
	14,583[5]	-[5]	-	$250.50	1/4/2028		
	18,833[6]	-[6]	-	$225.90	1/18/2029		
	21,300[7]	-[7]	-	$135.90	3/6/2030		
	63,766[8]	-[8]	-	$77.40	2/2/2031		
	28,987[9]	2,070[9]	-	$14.10	2/1/2032		
	2,763[10]	19,343[10]	-	$4.26	2/13/2033		
	33,892[11]	40,055[11]	-	$23.00	2/12/2034	55,461[12]	451,453
	-[13]	228,800[13]	-	$9.79	1/31/2035	68,100[14]	554,334
Sean Moran	2,917[2]	-[2]	-	$42.00	1/7/2026		
	2,500[3]	-[3]	-	$261.30	10/6/2026		
	1,917[4]	-[4]	-	$271.50	3/1/2027		
	2,917[5]	-[5]	-	$250.50	1/4/2028		
	3,250[6]	-[6]	-	$225.90	1/18/2029		
	3,767[7]	-[7]	-	$135.90	3/6/2030		
	20,486[8]	-[8]	-	$77.40	2/2/2031		
	10,469[9]	748[9]	-	$14.10	2/1/2032		
	1,299[10]	9,087[10]	-	$4.26	2/13/2033		
	18,414[11]	21,762[11]	-	$23.00	2/12/2034	30,132[12]	245,274
	-[13]	92,500[13]	-	$9.79	1/31/2035	27,500[14]	223,850
Dominic Smethurst	22,916[15]	27,084[15]	-	$26.07	2/27/2034	37,500[16]	305,250
	-[13]	91,200[13]	-	$9.79	1/31/2035	27,200[14]	221,408

(1) The market value is calculated by multiplying the number of unvested units by $8.14, the closing price per share of our common stock on December 31, 2025.

(2) Represents options to purchase shares of our common stock granted on January 7, 2016. 25% of these options vested on January 7, 2017 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on February 7, 2017.

(3) Represents options to purchase shares of our common stock granted on October 6, 2016. 25% of these options vested on October 6, 2017 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on November 6, 2017.

(4) Represents options to purchase shares of our common stock granted on March 1, 2017. 25% of these options vested on March 1, 2018 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on April 1, 2018.

(5) Represents options to purchase shares of our common stock granted on January 4, 2018. 25% of these options vested on January 4, 2019 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on February 4, 2019.

(6) Represents options to purchase shares of our common stock granted on January 18, 2019. 25% of these options vested on January 18, 2020 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on February 18, 2020.

(7) Represents options to purchase shares of our common stock granted on March 6, 2020. 25% of these options vested on March 6, 2021 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on April 6, 2021.

(8) Represents options to purchase shares of our common stock granted on February 2, 2021. 25% of these options vested on February 2, 2022 and the remaining 75% of the option vested in equal monthly installments over a period of 36 months commencing on March 2, 2022.

(9) Represents options to purchase shares of our common stock granted on February 1, 2022. 25% of these options vested on February 1, 2023 and the remaining 75% of the option vest in equal monthly installments over a period of 36 months commencing on March 1, 2023.

(10) Represents options to purchase shares of our common stock granted on February 13, 2023. 25% of these options vested on February 13, 2024 and the remaining 75% of the option vest in equal monthly installments over a period of 36 months commencing on March 13, 2024.

(11) Represents options to purchase shares of our common stock granted on February 12, 2024. 25% of these options vested on February 12, 2025 and the remaining 75% of the option vest in equal monthly installments over a period of 36 months commencing on March 12, 2025.

(12) This restricted stock unit award was granted on February 12, 2024 and vests in four years in equal annual installments, subject to continued service through each applicable vesting date.

(13) Represents options to purchase shares of our common stock granted on January 31, 2025. 25% of these options vested on January 31, 2026 and the remaining 75% of the option vest in equal monthly installments over a period of 36 months commencing on February 28, 2026.

(14) This restricted stock unit award was granted on January 31, 2025 and vests in four years in equal annual installments, subject to continued service through each applicable vesting date.

(15) Represents options to purchase shares of our common stock granted on February 27, 2024. 25% of these options vested on February 27, 2025 and the remaining 75% of the option vest in equal monthly installments over a period of 36 months commencing on March 27, 2025.

(16) This restricted stock unit award was granted on February 27, 2024 and vests in four years in equal annual installments, subject to continued service through each applicable vesting date.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

The Board and Compensation Committee grant awards without regard to the share price or the timing of the release of material nonpublic information and does not time grants for the purpose of affecting the value of executive compensation. Accordingly, it is our policy that our management team makes a good faith effort to advise the Board and Compensation Committee whenever it is aware that material nonpublic information is planned to be released to the public in close proximity to the grant of equity awards.

Director Compensation Table

The following table sets forth information concerning the compensation paid to certain of our non-employee directors during 2025.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (1)	Option Awards ($) (1)	Total ($)
Alan Holmer (2)	57,418	35,616	107,584	200,618
Rachelle Jacques (3)	72,582	35,616	107,584	215,782
John Jenkins (4)	65,000	35,616	107,584	208,200
Peter Salzmann (5)	16,690	-	-	16,690
Anne Altmeyer (6)	50,646	35,616	107,584	193,846
Yong Ben (7)	52,500	35,616	107,584	195,700
Winston Kung (8)	60,000	35,616	107,584	203,200

(1) Amounts reflect the aggregate grant date fair value of awards granted in 2025, computed in accordance with the Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that may be received by the directors if the stock options are exercised or restricted stock units vest.

(2) Mr. Holmer retired from the Board effective December 31, 2025. As of December 31, 2025, Mr. Holmer held options to purchase 20,893 shares of our common stock and no restricted stock units. Subsequent to December 31, 2025, the Board of Directors approved a modification to extend the post-termination vesting period and accelerate vesting of Mr. Holmer's awards.

(3) As of December 31, 2025, Ms. Jacques held options to purchase 35,343 shares of our common stock and 4,800 restricted stock units.

(4) As of December 31, 2025, Dr. Jenkins held options to purchase 35,343 shares of our common stock and 4,800 restricted stock units.

(5) Dr. Salzmann determined not to stand for re-election at the 2025 annual meeting. As of December 31, 2025, Dr. Salzmann held options to purchase 18,186 shares of our common stock and no restricted stock units.

(6) As of December 31, 2025, Dr. Altmeyer held options to purchase 28,330 shares of our common stock and 4,800 restricted stock units.

(7) As of December 31, 2025, Dr. Ben held options to purchase 29,390 shares of our common stock and 4,800 restricted stock units.

(8) As of December 31, 2025, Mr. Kung held options to purchase 21,566 shares of our common stock and 4,800 restricted stock units.

Non-Employee Director Compensation Policy

Our Board has approved a director compensation policy for our non-employee directors. Other than reimbursement for reasonable expenses incurred in connection with attending Board and committee meetings, this policy provides for the following cash compensation effective May 2022:

- each non-employee director is entitled to receive an annual fee from us of $40,000;
- the chair of our Board will receive an annual fee from us of $30,000;
- the chair of our audit committee will receive an annual fee from us of $20,000;
- the chair of our compensation committee will receive an annual fee from us of $15,000;
- the chair of our nominating and corporate governance committee will receive an annual fee from us of $10,000; and
- each non-chairperson member of the audit committee, the compensation committee, and the nominating and corporate governance committee will receive annual fees from us of $10,000, $7,500, and $5,000, respectively.

Each non-employee director receives an annual equity award grant in an amount and on vesting terms, if applicable, to be determined annually by our Compensation Committee in consultation with an independent compensation consultant under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future (the "Annual Non-Employee Director Grant"). Each non-employee director that joins our Board receives an initial grant to purchase that number of shares of our common stock under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, equal to two times the Annual Non-Employee Director Grant, which shall vest one year from the grant date, or other award with equivalent value and vesting terms to be determined by the Compensation Committee. Upon a change in control, as defined in our equity incentive plan, 100% of the shares underlying these options shall become vested and exercisable immediately prior to such change in control.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

2024 Equity Compensation Plan

On March 14, 2024, our Board adopted the 2024 Equity Compensation Plan, or the 2024 Plan, subject to stockholder approval, which was received on May 16, 2024.

The general purpose of the 2024 Plan is to provide a means whereby eligible employees, officers, non-employee directors and other individual service providers develop a sense of proprietorship and personal involvement in our development and financial success, and to encourage them to devote their best efforts to our business, thereby advancing our interests and the interests of our stockholders. By means of the 2024 Plan, we seek to retain the services of such eligible persons and to provide incentives for such persons to exert maximum efforts for our success and the success of our subsidiaries.

Pursuant to the 2024 Plan, the Board may grant up to 2,000,000 shares of our common stock through nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units ("RSUs"), performance shares, performance units, incentive bonus awards, other cash-based awards and other stock-based awards to employees, officers, non-employee directors, and other individual service providers.

2014 Equity Compensation Plan

On March 26, 2014, our Board adopted the 2014 Equity Compensation Plan, or the 2014 Plan, subject to stockholder approval, which was received on April 1, 2014. The 2024 Plan succeeded the 2014 Plan, under which no further grants may be made pursuant to the terms of the 2014 Plan; provided, that all awards outstanding under the 2014 Plan as of the date of stockholder approval of the 2024 Plan shall continue in effect in accordance with their terms.

Equity Compensation Plan Information

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2025:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (1) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,884,563	$37.40	869,106
Equity compensation plans not approved by security holders	—	—	—
TOTAL:	1,884,563	$37.40	869,106

(1) The weighted average exercise price is calculated based solely on outstanding stock options. It does not take into account the shares of our common stock underlying restricted stock units, which have no exercise price.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information as of March 6, 2026 with respect to the beneficial ownership of common stock of the Company by the following: (i) each of the Company's current directors; (ii) each of the named executive officers; (iii) all of the current executive officers and directors as a group; and (iv) each person known by the Company to own beneficially more than five percent (5%) of the outstanding shares of the Company's common stock.

For purposes of the following table, beneficial ownership is determined in accordance with the applicable SEC rules and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as otherwise noted in the footnotes to the table, we believe that each person or entity named in the table has sole voting and investment power with respect to all shares of the Company's common stock shown as beneficially owned by that person or entity (or shares such power with his or her spouse). Under the SEC's rules, shares of the Company's common stock issuable under options that are exercisable on or within 60 days after March 6, 2026 ("Presently Exercisable Options") are deemed outstanding and therefore included in the number of shares reported as beneficially owned by a person or entity named in the table and are used to compute the percentage of the common stock beneficially owned by that person or entity. These shares are not, however, deemed outstanding for computing the percentage of the common stock beneficially owned by any other person or entity.

The percentage of the common stock beneficially owned by each person or entity named in the following table is based on 17,736,464 shares of common stock issued and outstanding as of March 6, 2026 plus any shares issuable upon exercise of Presently Exercisable Options held by such person or entity.

Except as otherwise noted below, the address for persons listed in the table is c/o Corbus Pharmaceuticals Holdings, Inc., 500 River Ridge Drive, Norwood, Massachusetts 02062. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or greater Stockholders:		
Cormorant Global Healthcare Master Fund, LP [(1)]	2,344,971	13.2%
Aberdeen Group plc [(2)]	1,321,750	7.5%
OrbiMed Capital LLC [(3)]	1,172,287	6.6%
Citadel Advisors [(4)]	980,610	5.5%
Octagon Capital Advisors LP [(5)]	955,000	5.4%
Officers and Directors		
Yuval Cohen [(6)]	323,232	1.8%
Sean Moran [(7)]	128,516	*
Dominic Smethurst [(8)]	71,608	*
Ian Hodgson [(9)]	30,663	*
Rachelle Jacques [(10)]	22,126	*
John Jenkins [(11)]	19,376	*
Yong Ben [(12)]	16,173	*
Anne Altmeyer [(13)]	13,721	*
Winston Kung [(14)]	11,132	*
All current directors and executive officers as a group (9 total)	636,547	3.5%

(1) Based upon information contained in a Schedule 13G filed on December 15, 2025 by Cormorant Asset Management, LP ("Cormorant") representing shares which are beneficially owned by Cormorant Global Healthcare Master Fund, LP (the "Master Fund"). Cormorant Global Healthcare GP, LLC ("GP LLC") serves as the general partner of the Master Fund. Cormorant serves as the investment manager of the Master Fund. Bihua Chen serves as the managing member of GP, LLC and the general partner of Cormorant. Consists of 2,344,971 shares of our common stock owned by Cormorant and Bihua Chen.

(2) Based upon information contained in a Schedule 13G jointly filed by Aberdeen Group plc and abrdn Inc. on January 16, 2026. Consists of 1,321,750 shares of our common stock owned by Aberdeen Group plc and abrdn Inc.

(3) Based upon information contained in a Schedule 13G jointly filed by OrbiMed Advisors LLC ("Advisors") and OrbiMed Capital LLC ("Capital") on February 14, 2025. Consists of 454,087 shares of our common stock owned by Advisors and 718,200 shares of our common stock owned by Capital. Advisors and Capital exercise investment and voting power over these shares through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of these shares.

(4) Based upon information contained in a Schedule 13G jointly filed by Citadel Advisors LLC ("Citadel Advisors"), Citadel Advisors Holdings LP ("CAH"), Citadel GP LLC ("CGP"), Citadel Securities LLC ("Citadel Securities"), Citadel Securities Group LP ("CALC4"), Citadel Securities GP LLC ("CSGP") and Mr. Kenneth Griffin (collectively with Citadel Advisors, CAH, CGP, Citadel Securities, CALC4 and CSGP, the "Reporting Persons") on November 12, 2025. Consists of 980,610 shares of our common stock owned by Citadel Multi-Strategy Equities Master Fund Ltd., a Cayman Islands company ("CM"), and Citadel Securities. Citadel Advisors is the portfolio manager for CM. CAH is the sole member of Citadel Advisors. CGP is the general partner of CAH. CALC4 is the non-member manager of Citadel Securities. CSGP is the general partner of CALC4. Mr. Griffin is the President and Chief Executive Officer of CGP, and owns a controlling interest in CGP and CSGP.

(5) Based upon information contained in a Schedule 13G jointly filed on February 10, 2026 by Octagon Capital Advisors LP ("Octagon"), Octagon Investments Master Fund LP ("Master Fund") and Ting Jia, as the principal beneficial owner of Octagon. The Master Fund holds the 955,000 common shares for the benefit of its investors.

(6) Includes 286,965 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(7) Includes 100,617 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(8) Includes 55,583 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(9) Includes 25,945 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(10) Includes 19,343 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(11) Includes 19,343 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(12) Includes 13,390 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(13) Includes 12,330 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

(14) Includes 5,566 shares of common stock issuable upon exercise of outstanding stock options exercisable within 60 days of March 6, 2026.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

Other than compensation arrangements for our named executive officers and directors, we describe below each transaction or series of similar transactions, since January 1, 2024, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in the section entitled “Executive Compensation.” There were no other related party transactions identified.

Director Independence

Our common stock is listed on The Nasdaq Capital Market. Under the Nasdaq Listing Rules, independent directors must comprise a majority of our Board. In addition, the Nasdaq Listing Rules require that all the members of such committees be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Compensation Committee members must also satisfy the independence criteria established by the Nasdaq Listing Rules in accordance with Rule 10C-1 under the Exchange Act. Under the Nasdaq Listing Rules, a director will only qualify as an “independent director” if, among other qualifications, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our Board undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board has determined that Ms. Jacques, Dr. Jenkins, Dr. Altmeyer, Dr. Ben and Mr. Kung do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules and the SEC.

In making this determination, our Board considered the relationships that each non-employee director has with our Company and all other facts and circumstances our Board deemed relevant in determining their independence. We intend to comply with the other independence requirements for committees within the time periods specified above.

Indemnification Agreements

We have entered into indemnification agreements with our directors and executive officers whereby we have agreed to indemnify those directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of our Company, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interests of our Company.

Policies and Procedures for Related Party Transactions

Our Board has adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, which we refer to collectively as related parties, are not permitted to enter into a transaction with us without the prior consent of our Board acting through the Audit Committee or, in certain circumstances, the chairman of the Audit Committee. Any request for us to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our Audit Committee, or in certain circumstances the chairman of our Audit Committee, for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee, or the chairman of our Audit Committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Principal Accountant Fees and Services

The following table summarizes the fees for professional services rendered by EisnerAmper LLP, our independent registered public accounting firm, for each of the last two fiscal years:

Fee Category	2025	2024
	(In thousands)	
Audit Fees	$359	$391
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$359	$391

Audit Fees

Represents fees, including out-of-pocket expenses, for professional services provided in connection with the audit of our annual audited financial statements and of our internal control over financial reporting, the review of our quarterly financial statements included in our Forms 10-Q, accounting consultations or advice on accounting matters necessary for the rendering of an opinion on our financial statements, services provided in connection with the offerings of our common stock and audit services provided in connection with other statutory or regulatory filings.

Audit-Related Fees

Audit-related fees are for services regarding financial accounting and reporting standards and other activities not explicitly related to the audit of our financial statements.

The Audit Committee is responsible for appointing, setting compensation and overseeing the work of the independent auditors. The Audit Committee has established a policy regarding pre-approval of all auditing services and the terms thereof and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the PCAOB) to be provided to us by the independent auditor. However, the pre-approval requirement may be waived with respect to the provision of non-audit services for us if the "de minimus" provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied.

The Audit Committee pre-approved all services provided by EisnerAmper LLP during fiscal 2025 and 2024 in accordance with the policy regarding pre-approval of all auditing services.

The Audit Committee is responsible for reviewing and discussing the audit financial statements with management, discussing with the independent registered public accountants the matters required by the applicable requirements of the PCAOB, receiving written disclosures from the independent registered public accountants required by the applicable requirements of the PCAOB regarding the independent registered public accountants' communications with the Audit Committee concerning independence and discussing with the independent registered public accountants their independence, and recommending to the Board that the audit financial statements be included in our annual report on Form 10-K.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) List of Documents filed as part of this Report

(1) Consolidated Financial Statements

The financial statements and related notes, together with the report of EisnerAmper LLP (PCAOB ID: 274) appear as pages F-2 through F-23 following the Exhibit List as required by Part II, Item 8 "Financial Statements and Supplementary Data" of this Form 10-K.

(2) Financial Statement Schedules.

Schedules are omitted because they are either not required, not applicable, or the information is otherwise included.

(3) Exhibits

The Company has filed with this report or incorporated by reference herein certain exhibits as specified below pursuant to Rule 12b-32 under the Exchange Act. See Exhibit Index following the signature page to this report for a complete list of documents filed with this report.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2023).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2023).
4.1	Form of Merger Warrant (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.2	Form of Replacement Warrant (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.3	Form of Investor Warrant (incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.4	Form of Additional Replacement Warrant (incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.5	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.6	Registration Rights Agreement (incorporated by reference to Exhibit 4.6 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.7	Specimen Common Stock Certificate, $0.0001 par value (incorporated herein by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-3 filed with the SEC on November 10, 2015).
4.8	Warrant to Purchase Common Stock, dated as of January 26, 2018, issued to the Cystic Fibrosis Foundation (incorporated herein by reference to Exhibit 4.8 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).
4.9	Form of Warrant to Purchase Common Stock (incorporated herein by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on July 29, 2020).
4.10	Description of Capital Stock (incorporated herein by reference to Exhibit 4.10 of the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2023).

4.11	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on November 3, 2025).
10.1	2014 Equity Compensation Plan (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.2	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.3	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.4	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.5	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.15 of the Company's Registration Statement on Amendment No. 1 to Form S-1 filed with the SEC on September 30, 2014). †
10.6	Award Agreement, dated April 9, 2015, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2015).#
10.7	Consulting Agreement, dated September 20, 2016, between Company and Orchestra Medical Ventures, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2016).
10.8	Lease, dated May 30, 2014, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.9	First Amendment to Lease, dated August 27, 2015, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.10	Second Amendment to Lease, dated March 30, 2016, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.11	Third Amendment to Lease, dated September 13, 2016, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.12	Lease Agreement, dated August 21, 2017, by and between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on August 22, 2017).
10.13	Guarantee, dated August 21, 2017, by Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on August 22, 2017).
10.14	Cystic Fibrosis Program Related Investment Agreement, dated January 26, 2018, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated herein by reference to Exhibit 10.33 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).#
10.15	License Agreement, dated as of September 20, 2018, between Corbus Pharmaceuticals, Inc. and Jenrin Discovery, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2018).#

10.16	Lease Amendment No. 1, dated as of February 26, 2019, among River Ridge Limited Partnership, Corbus Pharmaceuticals, Inc. and Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.40 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2019).
10.17	Separation and General Release Agreement between Corbus Pharmaceuticals Holdings, Inc. and Mark Tepper, dated March 31, 2019 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 1, 2019).
10.18	Lease Amendment No. 2, dated as of October 25, 2019, among River Ridge Limited Partnership, Corbus Pharmaceuticals, Inc. and Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 7, 2019)
10.19	Loan and Security Agreement, dated as of July 28, 2020, by and between Corbus Pharmaceuticals Holdings, Inc., Corbus Pharmaceuticals, Inc., K2 HealthVentures LLC and Ankura Trust Company, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on July 29, 2020).
10.20	Separation and Release Agreement between the Company and Robert Discordia, dated November 30, 2020 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 4, 2020).†
10.21	License Agreement between the Company and Milky Way BioPharma, LLC, dated May 25, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2021).#
10.22	License Agreement between the Company and The Regents of the University of California, dated May 26, 2021 (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2021).#
10.23	Separation and General Release Agreement between the Company and Barbara White, dated September 17, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on September 22, 2021). †
10.24	Employment Agreement between the Company and Rachael Brake, effective as of December 6, 2021(incorporated herein by reference to Exhibit 10.31 of the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2022). †
10.25	Form of Fourth Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Yuval Cohen (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 15, 2022). †
10.26	Form of Fifth Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Sean Moran (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 15, 2022). †
10.27	Form of Second Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Craig Millian (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 15, 2022). †
10.28	Second Amendment to Loan and Security Agreement, dated as of July 28, 2020, by and between Corbus Pharmaceuticals Holdings, Inc., Corbus Pharmaceuticals, Inc., K2 HealthVentures LLC and Ankura Trust Company, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 31, 2022).
10.29	License Agreement between the Company and CSPC Megalith Biopharmaceutical Co., Ltd. (incorporated herein by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2023).

10.30	Separation and General Release Agreement between the Company and Craig Millian, dated April 24, 2023 (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 24, 2023). †
10.31	Open Market Sale Agreement, dated April 7, 2020, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed with the SEC on April 7, 2020).
10.32	Amendment No. 1 to Open Market Sale Agreement, dated May 31, 2023, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.3 of the Company's Registration Statement on Form S-3 filed with the SEC on June 1, 2023).
10.33	Form of Service Agreement between Corbus International Limited and Dominic Smethurst, dated February 27, 2024 (incorporated herein by reference to Exhibit 10.33 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2024). †
10.34	Form of Fifth Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Yuval Cohen (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 10, 2024). †
10.35	Form of Sixth Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Sean Moran (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on April 10, 2024). †
10.36	Corbus Pharmaceuticals Holdings, Inc. 2024 Equity Compensation Plan (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on May 20, 2024). †
10.37	Form of Incentive Stock Option Grant Agreement (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on May 20, 2024). †
10.38	Form of Non-Statutory Stock Option Grant Agreement (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed with the SEC on May 20, 2024).†
10.39	Form of Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K, filed with the SEC on May 20, 2024).†
10.40	Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K, filed with the SEC on May 20, 2024).†
10.41	Service Agreement between Corbus International Limited and Ian Hodgson, effective as of March 15, 2025 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on March 18, 2025).†
19.1	Insider Trading Policy (incorporated herein by reference to Exhibit 19.1 of the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2025).
21.1	List of Subsidiaries of the Company.*
23.1	Consent of EisnerAmper LLP.*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).**
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).**

97.1	Compensation Recovery Policy (incorporated herein by reference to Exhibit 97.1 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2024). †
101.INS	Inline XBRL Instance Document.* – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2025, has been formatted in Inline XBRL*

* Filed herewith

** Furnished, not filed.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

† Indicates a management contract or compensation plan, contract or arrangement.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Date: March 9, 2026

By: */s/ YUVAL COHEN*
Name: Yuval Cohen
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ YUVAL COHEN Yuval Cohen	Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2026
/s/ SEAN MORAN Sean Moran	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2026
/s/ RACHELLE JACQUES Rachelle Jacques	Chair of the Board	March 9, 2026
/s/ ANNE ALTMEYER Anne Altmeyer	Director	March 9, 2026
/s/ YONG BEN Yong Ben	Director	March 9, 2026
/s/ JOHN JENKINS John Jenkins	Director	March 9, 2026
/s/ WINSTON KUNG Winston Kung	Director	March 9, 2026

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Corbus Pharmaceuticals Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accruals for Research and Development Expenses

As described in Note 3 to the financial statements, at each balance sheet date, the Company estimates its accrued research and development expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants in connection with performing pre-clinical and clinical work in preparation for and related to clinical trials, and in making that estimate, may depend on factors such as successful enrollment of certain numbers of patients, site initiation, and the completion of contract milestones. The Company accounts for research and development expenses based on services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when an invoice has not been received, or the Company has not otherwise been notified of the actual cost. The Company estimates the time period over which services will be performed and the level of effort to be expended in each period. The Company's accrual for research and development expenses of $13.7 million is included in Accrued expenses on the December 31, 2025, consolidated balance sheet. The amounts recorded for accrued research and development expenses represent the Company's estimate of the unpaid pre-clinical and clinical trial expenses based on the information available to the Company at that time. The estimation of accrued research and development expenses was also identified as a critical accounting estimate by management.

We identified the accruals for research and development expenses as a critical audit matter due to the significant judgment and estimation required by management in determining progress or state of completion of trials or services completed. This in turn led to a high degree of auditor subjectivity and significant audit effort was required in performing our procedures and evaluating audit evidence relating to estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls over the Company's estimation of accrued pre-clinical and clinical trial expenses, including the process of estimating the expenses incurred to date based on the status of the pre-clinical and clinical work. Our procedures also included, on a test basis, reading agreements and contract amendments entered into with vendors in connection with conducting clinical trials, evaluating the significant assumptions described above and the methods used in developing the estimates and calculating the amounts that were unpaid at the balance sheet date. We confirmed selected amounts and assumptions used directly with the third parties involved in performing the research and development services on behalf of the Company, on a test basis. We also made direct inquiries of financial and clinical client personnel regarding status, and progress towards completion, of clinical trials and the description of future commitments, and we verified amounts paid to date under each contract by vouching to invoices and payment support. We also assessed the historical accuracy of management's estimates, and compared the current estimate of expenses incurred to estimates previously made by management.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014.

EISNERAMPER LLP
Iselin, New Jersey
March 9, 2026

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,492	$ 17,198
Investments	134,777	131,864
Restricted cash	670	285
Prepaid expenses and other current assets	3,015	3,629
Total current assets	166,954	152,976
Restricted cash	—	385
Property and equipment, net	159	385
Operating lease right-of-use assets	1,082	2,133
Total assets	$ 168,195	$ 155,879
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,215	$ 4,786
Accrued expenses	16,844	5,426
Operating lease liabilities, current	1,633	1,606
Total current liabilities	20,692	11,818
Operating lease liabilities, noncurrent	—	1,633
Total liabilities	20,692	13,451
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized, 17,611,511 and 12,179,482 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	2	1
Additional paid-in capital	702,984	619,285
Accumulated deficit	(555,430)	(476,893)
Accumulated other comprehensive (loss) gain	(53)	35
Total stockholders' equity	147,503	142,428
Total liabilities and stockholders' equity	$ 168,195	$ 155,879

The accompanying notes are an integral part of these Consolidated Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	For the Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 70,095	$ 32,222
General and administrative	15,215	16,499
Total operating expenses	85,310	48,721
Operating loss	(85,310)	(48,721)
Other income (expense), net:		
Interest and investment income, net	5,530	6,311
Interest expense	—	(1,872)
Other income, net	1,243	4,073
Total other income, net	6,773	8,512
Net loss	$ (78,537)	$ (40,209)
Net loss per share, basic and diluted	$ (5.90)	$ (3.68)
Weighted average number of common shares outstanding, basic and diluted	13,317,116	10,915,413
Comprehensive loss:		
Net loss	$ (78,537)	$ (40,209)
Other comprehensive income (loss):		
Change in unrealized (loss) gain on marketable debt securities	(88)	36
Total other comprehensive (loss) income	(88)	36
Total comprehensive loss	$ (78,625)	$ (40,173)

The accompanying notes are an integral part of these Consolidated Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	For the Years Ended December 31, 2025 and 2024					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2023	4,423,683	$ —	$ 429,780	$ (436,684)	$ (1)	$ (6,905)
Issuance of common stock, net of issuance costs	7,462,916	1	180,236	—	—	180,237
Issuance of common stock upon cashless exercise of warrants	6,087	—	—	—	—	—
Issuance of common stock upon conversion of K2 Loan and Security Agreement	142,857	—	1,125	—	—	1,125
Issuance of common stock upon exercise of stock options	136,664	—	1,999	—	—	1,999
Issuance of common stock upon vesting of restricted stock	7,275	—	—	—	—	—
Stock-based compensation expense	—	—	6,145	—	—	6,145
Change in unrealized gain (loss) on marketable debt securities	—	—	—	—	36	36
Net loss	—	—	—	(40,209)	—	(40,209)
Balance at December 31, 2024	12,179,482	$ 1	$ 619,285	$ (476,893)	$ 35	$ 142,428
Issuance of common stock and pre-funded warrants, net of issuance costs	5,307,735	1	77,233	—	—	77,234
Issuance of common stock upon exercise of stock options	41,674	—	178	—	—	178
Issuance of common stock upon vesting of restricted stock	82,620	—	—	—	—	—
Stock-based compensation expense	—	—	6,288	—	—	6,288
Change in unrealized gain (loss) on marketable debt securities	—	—	—	—	(88)	(88)
Net loss	—	—	—	(78,537)	—	(78,537)
Balance at December 31, 2025	17,611,511	$ 2	$ 702,984	$ (555,430)	$ (53)	$ 147,503

The accompanying notes are an integral part of these Consolidated Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2025	2024
Cash flows from operating activities:		
Net loss	$ (78,537)	$ (40,209)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,288	6,145
Depreciation expense	233	588
Net amortization of premiums and discounts on investments	(1,366)	(3,327)
Amortization of debt discount	—	396
Other	(229)	189
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	634	(1,229)
Decrease in other assets	—	212
Decrease in operating lease right-of-use asset	1,051	930
Decrease in other long-term liabilities	—	(44)
(Decrease) increase in accounts payable	(2,349)	1,603
Increase (decrease) in accrued expenses	11,390	(5,611)
Decrease in operating lease liabilities	(1,606)	(1,437)
Net cash used in operating activities	(64,491)	(41,794)
Cash flows from investing activities:		
Purchases of property and equipment	(7)	-
Purchases of investments	(163,091)	(180,804)
Proceeds from sales and maturities of investments	161,457	59,494
Net cash used in investing activities	(1,641)	(121,310)
Cash flows from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net	77,426	182,058
Repayment of notes payable	—	(301)
Repayment of long-term borrowings	—	(15,179)
Net cash provided by financing activities	77,426	166,578
Net increase in cash, cash equivalents, and restricted cash	11,294	3,474
Cash, cash equivalents, and restricted cash at beginning of the period	17,868	14,394
Cash, cash equivalents, and restricted cash at end of the period	$ 29,162	$ 17,868
Supplemental disclosure of cash flow information and non-cash transactions:		
Cash paid during the period for interest	$ —	$ 2,818
Write off of fully depreciated property and equipment	$ —	$ 71
Common stock issuance costs not yet paid	$ 62	$ 75
Issuance of common stock for conversion of convertible debt	$ —	$ 1,125

The accompanying notes are an integral part of these Consolidated Financial Statements.

1. NATURE OF OPERATIONS

Business

Corbus Pharmaceuticals Holdings, Inc. (the "Company" or "Corbus") is a clinical stage company focused on promising new therapies in oncology and obesity and is committed to helping people defeat serious illness by bringing innovative scientific approaches to well-understood biological pathways. Corbus' pipeline includes CRB-701, a next-generation antibody drug conjugate ("ADC") that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload of monomethyl auristatin E ("MMAE") and CRB-913, a highly peripherally restricted cannabinoid type-1 ("CB1") receptor inverse agonist for the treatment of obesity. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. The Company's business is subject to significant risks and uncertainties and the Company will be dependent on raising substantial additional capital before it becomes profitable, and it may never achieve profitability.

2. LIQUIDITY

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses since inception and as of December 31, 2025, had an accumulated deficit of $555.4 million. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its pre-clinical and clinical programs, strategic alliances, and the development of its administrative organization. The Company expects the cash, cash equivalents, and investments of $163.3 million at December 31, 2025 will be sufficient to meet its operating and capital requirements at least 12 months from the issuance of these consolidated financial statements.

3. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the consolidated financial statements is as follows:

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The process of preparing financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and changes in estimates may occur. The most significant estimates are related to stock-based compensation expense (See Note 14) and the accrual of research, product development and clinical obligations (see Note 10).

Cash, Cash Equivalents, and Restricted Cash

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within 90 days from the date of purchase to be cash equivalents. At December 31, 2025 and 2024, cash equivalents were comprised of money market funds, commercial paper and corporate debt securities with maturities less than 90 days from the date of purchase.

Restricted cash as of December 31, 2025 and 2024 included security for a standby letter of credit issued in favor of a landlord for $0.7 million.

Cash, cash equivalents, and restricted cash consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Cash	$ 1,351	$ 5,047
Cash equivalents	27,141	12,151
Cash and cash equivalents	28,492	17,198
Restricted cash, current	670	285
Restricted cash, noncurrent	—	385
Restricted cash	670	670
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 29,162	$ 17,868

As of December 31, 2025, all of the Company's cash and cash equivalents was held in the U.S., except for approximately $1.2 million of cash which was held in its subsidiaries in the U.K. and Australia. As of December 31, 2024, all of the Company's cash and cash equivalents was held in the U.S., except for approximately $4.9 million of cash which was held in its subsidiaries in the U.K. and Australia.

Investments

Investments consist of corporate debt securities, commercial paper, U.S. Treasury securities, and U.S. government agency securities with maturities greater than 90 days at their acquisition date. The Company may sell investments at any time for use in current operations even if the investments have not yet reached maturity. As a result, the Company classifies all its investments as current assets.

The Company classifies all of its investments as available-for-sale marketable debt securities. The Company's marketable debt securities are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale marketable debt securities that are not related to credit losses are reported as accumulated other comprehensive gain or loss, which is a separate component of stockholders' equity. The cost of marketable debt securities sold is determined on a specific identification basis, and realized gains and losses are included in interest and investment income, net in the consolidated statements of operations and comprehensive loss.

At each reporting period, the Company evaluates its marketable debt securities with unrealized losses for impairment. When assessing marketable debt securities for potential impairment, the Company considers available evidence, including the extent to which fair value is less than cost, whether an allowance for credit loss is required, and adverse factors that could affect the value of the securities. An impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. To date, the Company has not recorded any credit losses on its marketable debt securities.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk**,** consist primarily of cash and cash equivalents and investments. The primary objectives for the Company's investment portfolio are the preservation of principal, maintenance of liquidity, and maximization of total return. The Company does not enter into any investment transaction for trading or speculative purposes.

The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, commercial paper, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on credit quality, maturities and concentration by type and issuer. The Company maintains cash balances in excess of amounts insured by the FDIC and concentrated within a limited number of financial institutions. The accounts are monitored by management and management believes that the financial institutions are financially sound, and, accordingly, minimal credit risk exists with respect to these financial institutions. As of December 31, 2025 and 2024, the Company has not experienced any significant credit losses in such accounts or investments.

The Company has no significant off-balance sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements.

Fair Value Measurements

Fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, there exists a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date

Level 2 – Inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data

Level 3 – Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date

The Company's financial instruments are carried at fair value determined according to the fair value hierarchy described above. Cash is stated at carrying value which approximates fair value. Cash equivalents and investments are comprised of available-for-sale securities, which are carried at fair value. The carrying values of the Company's prepaid expenses and other current assets, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Property and Equipment

The estimated useful lives for the Company's property and equipment is as follows: three years for computer hardware and software and three to five years for office furniture and equipment. The Company's leasehold improvements are amortized over the shorter of their useful lives or the respective leases. See Note 7 for details of property and equipment and Note 8 for operating lease commitments.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities current and noncurrent in the Company's consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Accruals for Research and Development Expenses and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines accrual estimates by taking into account discussions with applicable internal personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations ("CROs") and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2025 and 2024, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Research and Development Expenses

Costs incurred for research and development are expensed as incurred.

Nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to executory contractual arrangements with third-party research organizations are deferred and recognized as an expense as the related goods are delivered or the related services are performed.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing therapeutics for cancer and obesity. See Note 16 for additional details.

Income Taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded to reduce a net deferred tax benefit when it is not more-likely-than-not that the tax benefit from the deferred tax assets will be realized. Accordingly, given the cumulative losses since inception, the Company has provided a valuation allowance equal to 100% of the deferred tax assets in order to eliminate the deferred tax assets amounts.

Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold, as well as accrued interest and penalties, if any, would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2025 or 2024.

Impairment of Long-lived Assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected undiscounted cash flows of an asset are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. An impairment loss equal to the excess of the fair value of the asset over its carrying amount, is recorded when it is determined that the carrying value of the asset may not be recoverable. The Company notes no impairment charges were taken in 2025 or 2024.

Stock-based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards, including stock options and restricted stock units ("RSUs"), to employees, non-employees, and directors as an expense in the statements of operations and comprehensive loss over the service period based on a measurement of fair value for each stock-based award. The fair value of each stock option grant is estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value of restricted stock units is the quoted closing market price per share on the grant date. The fair value of each grant is recognized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. The Company accounts for forfeitures as they occur.

Government Tax Credits

The Company is eligible to receive tax credits in the form of refundable research and development tax credits and the employee retention tax credit ("ERTC"). The Company may qualify for refundable research and development tax credits from foreign authorities in the form of cash that are earned on certain research and development expenses incurred primarily outside of the United States ("U.S.") by its foreign subsidiaries in the United Kingdom ("U.K.") and Australia. After the R&D tax claim is filed, the relevant tax authority reviews and approves the claim prior to payment. Under the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, the Company was eligible to claim the ERTC, which is a refundable tax credit against certain employment taxes. The Company records these tax credits as other income, net when the Company has reasonable assurance any conditions attached to the assistance have been met and the assistance will be received. The Company recognized $1.1 million and $4.0 million in government tax credits to other income, net for the years ended December 31, 2025 and 2024, respectively. No future conditions impact the recognition of these tax credits. All amounts have been received as of December 31, 2025, except for $1.5 million, which is subject to tax authority review and is included in prepaid expenses and other current assets within the consolidated balance sheets as of December 31, 2025 and 2024.

Foreign Currency

Transaction gains and losses arising from currency exchange rate fluctuations on transactions denominated in a currency other than the U.S. Dollar functional currency are recorded in other income, net in the Company's statements of operations and comprehensive loss. Such transaction gains and losses may be realized or unrealized depending upon whether the transaction settled during the period or remains outstanding at the balance sheet date. The functional currency of the Company's foreign subsidiaries is the U.S. Dollar.

Net Loss Per Common Share

Basic and diluted net loss per share of the Company's common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period. For years in which there is a net loss, options, warrants and RSUs are anti-dilutive and therefore excluded from diluted loss per share calculations. The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2025 and 2024 (in thousands except share and per share amounts):

	Year Ended December 31,	
	2025	2024
Net loss	$ (78,537)	$ (40,209)
Weighted average number of common shares-basic and diluted	13,317,116	10,915,413
Net loss per share of common stock-basic and diluted	$ (5.90)	$ (3.68)

The 1,025,000 pre-funded warrants issued in November 2025 and outstanding as of December 31, 2025 (see Note 13) were included in computing the weighted average common shares outstanding used in calculating basic and diluted net loss per share.

The following common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented because including them would have been anti-dilutive:

	December 31,	
	2025	2024
Stock options	1,386,020	723,153
Unvested restricted stock units	498,543	259,488
Warrants	2,873	36,207

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which requires entities to disclose disaggregated information about their effective tax rate reconciliations as well as expanded information on income taxes by jurisdiction. The standard is effective for fiscal years beginning after December 15, 2024 on a prospective basis. The Company's adoption of this standard effective for the fiscal year ending December 31, 2025 resulted in increased disclosures in the notes to its financial statements (see Note 11).

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*, which will require additional disclosure about specific expense categories included in the income statement. The standard is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The amendments can be applied either prospectively to financial statements issued for reporting periods after the effective date of this update or retrospectively to any or all prior periods presented in the financial statements. The Company is currently assessing the impact of this standard to its financial statements.

In December 2025, the FASB issued ASU 2025-10, *Government Grants - Accounting for Government Grants Received by Business Entities*, which provides guidance on the recognition, measurement and presentation of government grants by business entities. The guidance is effective for fiscal years beginning after December 15, 2028, and interim periods within those annual reporting periods. The Company is currently assessing the impact of this standard to its financial statements.

4. INVESTMENTS

The following table summarizes the Company's investments as of December 31, 2025 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Losses	Fair Value
Debt Securities:				
Commercial paper	$ 33,846	$ -	$ -	$ 33,846
Corporate debt securities	100,983	20	(72)	100,931
Total	$ 134,829	$ 20	$ (72)	$ 134,777

The following table summarizes the amortized cost and fair value of the Company's available-for-sale marketable debt securities by contractual maturity as of December 31, 2025 (in thousands):

	Amortized Cost	Fair Value
Maturing in one year or less	$ 123,934	$ 123,903
Maturing after one year but less than three years	10,895	10,874
	$ 134,829	$ 134,777

The following table summarizes the Company's investments as of December 31, 2024 (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Losses	Fair Value
Debt Securities:				
U.S. Treasury securities	$ 9,452	$ 15	$ -	$ 9,467
U.S. government agency securities	22,075	18	-	22,093
Corporate debt securities	100,302	56	(54)	100,304
Total	$ 131,829	$ 89	$ (54)	$ 131,864

The following table summarizes the amortized cost and fair value of the Company's available-for-sale marketable debt securities by contractual maturity as of December 31, 2024 (in thousands):

	Amortized Cost	Fair Value
Maturing in one year or less	$ 126,870	$ 126,930
Maturing after one year but less than three years	4,959	4,934
	$ 131,829	$ 131,864

5. FAIR VALUE OF FINANCIAL ASSETS AND LIABILITIES

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2025 (in thousands):

	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 23,037	$ —	$ —	$ 23,037
Commercial paper	—	1,488	—	1,488
Corporate debt securities	—	2,616	—	2,616
Investments:				
Commercial paper	—	33,846	—	33,846
Corporate debt securities	—	100,931	—	100,931
	$ 23,037	$ 138,881	$ —	$ 161,918

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2024 (in thousands):

	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 12,151	$ —	$ —	$ 12,151
Investments:				
U.S. Treasury securities	—	9,467	—	9,467
U.S. government agency securities	—	22,093	—	22,093
Corporate debt securities	—	100,304	—	100,304
	$ 12,151	$ 131,864	$ —	$ 144,015

6. LICENSE AGREEMENTS

The Company entered into a license agreement (the "Jenrin License Agreement") with Jenrin Discovery, LLC ("Jenrin"), a privately held Delaware limited liability company, effective September 20, 2018. Pursuant to the Jenrin License Agreement, Jenrin granted the Company exclusive worldwide rights to develop and commercialize the Licensed Products (as defined in the Jenrin License Agreement) which includes the Jenrin library of over 600 compounds and multiple issued and pending patent filings. The compounds are designed to treat inflammatory and fibrotic diseases by targeting the endocannabinoid system.

In consideration of the license and other rights granted by Jenrin, the Company paid Jenrin a $0.3 million upfront cash payment and is obligated to pay Jenrin up to $18.4 million in potential milestone payments for each compound it elects to develop based upon the achievement of specified development and regulatory milestones. In addition, the Company is obligated to pay Jenrin royalties in the mid, single digits based on net sales of any Licensed Products, subject to specified reductions. The Company achieved the first milestone in the amount of $0.4 million associated with the progression into a clinical trial for CRB-913 during the first quarter of 2025, which was subsequently paid in the second quarter of 2025. The Company is obligated to pay Jenrin up to $18.0 million in additional potential milestone payments for further development of CRB-913.

The Company entered into a license agreement (the "UCSF License Agreement") with the Regents of the University of California ("The Regents") effective May 26, 2021. Pursuant to the UCSF License Agreement, the Company received an exclusive license to certain patents relating to humanized antibodies against integrin αvβ8, one of which the Company is referring to as CRB-601, along with non-exclusive licenses to certain related know-how and materials. The Company amended the UCSF License Agreement with The Regents effective November 17, 2022 adding additional antibody patents to the agreement.

In consideration for the license and other rights granted to the Company under the UCSF License Agreement, the Company paid The Regents a license issue fee of $1.5 million. In consideration for the additional antibody patents granted to the Company, the Company paid The Regents a license issue fee of $0.8 million, paid in two equal installments of $0.4 million.

The Company further amended the UCSF License Agreement with The Regents effective August 14, 2023 to incorporate certain new technology rights and amend the payment schedule for the development milestone for the filing of patent rights and the development milestone for the filing of an IND.

In addition to the license issuance fees, the Company is obligated to pay an annual license maintenance fee, as well as up to $150.8 million in remaining potential milestone payments, excluding indication milestones for antibodies used for diagnostic products and services that will be an additional $50.0 thousand for each new indication, for the achievement of certain development, regulatory, and sales milestones. In addition, the Company is also obligated to pay royalties in the lower, single digits on sales of products falling within the scope of the licensed patents, which is subject to a minimum annual royalty obligation, and a percentage share of certain payments received by the Company from sublicensees or in connection with the sale of the licensed program. During the first quarter of 2025, the Company paid $1.6 million under the UCSF License Agreement for previously achieved milestone payments. This amount was included within accounts payable within the consolidated balance sheet as of December 31, 2024.

The Company entered into a license agreement (the "CSPC License Agreement") with CSPC Megalith Biopharmaceutical Co., Ltd. ("CSPC"), a subsidiary of CSPC Pharmaceutical Group Limited, effective February 12, 2023. Pursuant to the CSPC License Agreement, the Company received an exclusive license to develop and commercialize a novel clinical stage ADC targeting Nectin-4, which the Company is referring to as CRB-701, in the U.S., Canada, the European Union (including the European Free Trade Area), the U.K., and Australia.

In consideration for the license granted to the Company under the CSPC License Agreement, the Company paid CSPC an upfront payment of $7.5 million ($5.0 million paid at signing during the first quarter 2023 followed by $2.5 million paid during the third quarter 2024). The Company is obligated to pay potential milestone payments to CSPC totaling up to $130.0 million based upon the achievement of specified development and regulatory milestones and $555.0 million in potential commercial milestone payments. In addition, we are obligated to pay royalties in the low double digits based on net sales of any Licensed Products, as defined in the CSPC License Agreement.

The Company determined that substantially all of the fair value of the Jenrin License Agreement, UCSF License Agreement and CSPC License Agreement was attributable to a single or separate groups of in-process research and development assets which did not constitute a business. The Company concluded that it did not have any alternative future use for the acquired in-process research and development assets. Thus, the Company recorded the various upfront payments to research and development expenses in the quarter the license deals became effective. The Company will account for the development, regulatory, and sales milestone payments in the period that the relevant milestones are achieved as either research and development expense or as an intangible asset as applicable. Research and development expenses associated with upfront payments and clinical milestones was $0.4 million during the year ended December 31, 2025, related to the CRB-913 milestone payment in accordance with the Jenrin License Agreement. No research and development expense associated with upfront payments for clinical milestones were incurred under any of the above agreements during the year ended December 31, 2024. The consolidated balance sheet as of December 31, 2024 includes $1.6 million within accounts payable due to The Regents under the UCSF License Agreement for achieved milestone payments.

7. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Computer hardware and software	$ 20	$ 13
Office furniture and equipment	1,114	1,114
Leasehold improvements	3,331	3,331
Property and equipment, gross	4,465	4,458
Less: accumulated depreciation	(4,306)	(4,073)
Property and equipment, net	$ 159	$ 385

Depreciation expense was $0.2 million and $0.6 million for the years ended December 31, 2025 and 2024, respectively.

8. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

On August 21, 2017, the Company entered into a lease agreement ("August 2017 Lease Agreement"), which was subsequently amended on February 26, 2019 ("February 2019 Lease Agreement") and October 25, 2019 for commercial lease of office space, pursuant to which the Company has agreed to lease an aggregate total of 63,256 square feet of office space ("Total Premises"). The term of the lease is through November 30, 2026.

Per the terms of the August 2017 Lease Agreement and the February 2019 Lease Agreement, the landlord agreed to reimburse the Company for approximately $2.1 million of leasehold improvements. The reimbursements have been deferred and is recognized as a reduction of rent expense over the term of the lease. Additionally, the August 2017 Lease Agreement and the February 2019 Lease Agreement required a standby irrevocable letter of credit of $0.8 million, which will be reduced, if the Company is not in default under the agreement on the third and fourth anniversary of the commencement date and have unencumbered funds in excess of $50.0 million. As of December 31, 2025, the Company has an unsecured letter of credit for $0.7 million in connection with the lease agreements.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Lease cost		
Operating lease cost	$ 1,240	$ 1,240
Total lease cost	$ 1,240	$ 1,240
Other information		
Weighted average remaining lease term	0.9 years	1.9 years
Weighted average discount rate	8.00%	8.00%

Cash paid for rent expense recorded during the years ended December 31, 2025 and 2024 was $1.8 million and $1.7 million, respectively.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at December 31, 2025, the following table summarizes the Company's maturities of operating lease liabilities as of December 31, 2025 (in thousands):

2026	$ 1,688
Total lease payments	1,688
Less: imputed interest	(55)
Total	$ 1,633

9. NOTES PAYABLE

Loan and Security Agreement with K2 HealthVentures LLC

On July 28, 2020, the Company, with its subsidiary, Corbus Pharmaceuticals, Inc., as borrower, entered into a secured Loan and Security Agreement with K2 HealthVentures LLC ("K2HV"), an unrelated third party (the "Loan and Security Agreement") and received $20.0 million upon signing. On August 1, 2024, the loan matured and the Company made a final payment in the amount of $11.8 million, which represented $10.1 million principal outstanding on the maturity date, $1.6 million final payment and accrued interest. The $1.6 million final payment was amortized over the life of the loan through interest expense within the consolidated statements of operations and comprehensive loss. Interest payments were made monthly and accrued at a variable annual rate equal to the greater of (i) 8.5% and (ii) the rate of interest noted in The Wall Street Journal, Money Rates section, as the "Prime Rate" plus 5.25%.

The Company entered into an Amendment to the Loan and Security Agreement (the "Amended Loan and Security Agreement") on October 25, 2022. Pursuant to the Amended Loan and Security Agreement, K2HV could elect to convert up to $5.0 million of the outstanding loan balance into shares of the Company's common stock at conversion prices as follows: $0.9 million of the loan at $4.50 per share, $1.1 million at $7.875 per share, and $3.0 million at $282.00 per share. On June 1, 2023, K2HV converted $0.9 million of the outstanding loan balance into 194,444 shares of the Company's stock at a conversion price of $4.50 per share. On March 6, 2024, K2HV converted $1.1 million of the outstanding loan balance into 142,857 shares of the Company's stock at a conversion price of $7.875 per share.

In connection with the Loan and Security Agreement, on July 28, 2020, the Company issued K2HV a warrant to purchase up to 2,873 common shares (the "K2 Warrant") at an exercise price of $208.80. The K2 Warrant may be exercised either for cash or on a cashless "net exercise" basis and expires on July 28, 2030.

The total debt discount related to the Amended Loan and Security Agreement of $3.0 million was charged to interest expense using the effective interest method over the term of the debt. Interest expense for the year ended December 31, 2024 was $1.8 million. No interest expense was recorded for the year ended December 31, 2025.

10. ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued pre-clinical and clinical costs	$ 12,211	$ 2,424
Accrued product development costs	1,454	280
Accrued compensation	2,859	2,276
Accrued administrative costs	320	446
Total	$ 16,844	$ 5,426

11. INCOME TAXES

No provision or benefit for federal, state or foreign income taxes has been recorded, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

The components of the Company's net loss are as follows (in thousands):

	December 31,	
	2025	2024
United States	$ (52,284)	$ (31,457)
United Kingdom	(26,242)	(8,720)
Australia	(11)	(32)
Total	$ (78,537)	$ (40,209)

Our foreign subsidiaries in the U.K. and Australia may qualify for refundable research and development tax credits in the form of cash that were earned on certain research and development expenses incurred primarily outside of the U.S. In the year ending December 31, 2024, the Company applied for refundable research and development credits from foreign tax authorities of approximately $4.0 million that were recorded in other income, net. No future conditions impact the recognition of these tax credits. The Company did not apply for any refundable research and development credits from foreign tax authorities in the year ended December 31, 2025. All amounts have been received, except for $1.5 million, which is subject to tax authority review and is included in prepaid expenses and other current assets within the consolidated balance sheets as of December 31, 2025 and 2024.

Significant components of the Company's net deferred tax asset are as follows (in thousands):

	December 31,	
	2025	2024
U.S. and state net operating loss carryforwards	$ 78,535	$ 63,063
Foreign net operating loss carryforwards	19,658	13,686
Tax credit carryforward	13,332	11,013
Stock-based compensation	7,244	6,672
Capitalized research and development	7,541	9,890
Accrued expenses	409	312
Other temporary differences	887	1,000
Subtotal	127,606	105,636
Valuation allowance	(127,606)	(105,636)
Net deferred tax asset	$ —	$ —

At December 31, 2025 and 2024, the Company had U.S. federal net operating loss carryforwards of $292.3 million and $233.9 million respectively, of which federal carryforwards will expire in varying amounts beginning in 2029. Of the federal net operating loss carryforwards of $292.3 million, approximately $236.0 million are from periods after 2017 and have no expiration date and are generally limited to 80% of taxable income. At December 31, 2025 and 2024, the Company had State net operating loss carryforwards of approximately $271.5 million and $220.8 million, respectively. Utilization of net operating losses, income tax credits and certain other tax attributes may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company has not yet conducted a study to determine if any such changes have occurred that could limit the Company's ability to use the net operating losses and tax credit carryforwards. The Company also had research and development tax credit carryforwards at December 31, 2025 and 2024 of approximately $13.5 million and $11.2 million, respectively, of which will begin to expire in varying amounts beginning in 2033.

The Company does not provide for U.S. Federal, state, and applicable foreign income and withholding taxes on the financial reporting basis over the tax basis of its foreign subsidiary investment because the Company has the intention and ability to indefinitely reinvest the undistributed earnings of its foreign subsidiaries. As a result, deferred taxes have not been recorded for the outside basis differences in its foreign subsidiary as of December 31, 2025 to the extent such differences are expected to result in future taxable income upon repatriation. The Company reviews its ability and intentions to indefinitely reinvest its foreign earnings at each balance sheet.

For tax years beginning after December 31, 2024, the One Big Beautiful Bill Act ("OBBBA") enacted a new rule under Section 174A allowing companies to immediately expense any domestic research and developmental ("R&D") expenditures. For domestic R&D, companies may either immediately expense or elect to capitalize and amortize over at least 60 months under Section 174A. However, foreign R&D continues to require capitalization subject to the mandatory 15-year amortization period under Section 174. Transition provisions allow taxpayers either to continue amortizing amounts capitalized under the TCJA rules or to deduct remaining unamortized domestic R&D expenditures in the first tax year beginning after December 31, 2024. The Company has elected to continue amortizing previously capitalized domestic R&D expenditures over the remaining amortization period permitted under OBBBA.

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is not more-likely-than-not that some portion or all the net deferred tax assets will be realized. Since the Company cannot determine that it is more-likely-than-not that it will generate taxable income, and thereby realize the net deferred tax assets, a full valuation allowance has been provided. The valuation allowance increased by approximately $22.0 million and $10.7 million in 2025 and 2024, respectively, due to increased net operating loss carryforwards and capitalization of R&D expenditures as required by changes to the tax laws from the TCJA as described above. The Company has no uncertain tax positions at December 31, 2025 and 2024 that would affect its effective tax rate. Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

The reconciliation of the Company's statutory tax rate and effective tax rate is as follows (in thousands):

	December 31,			
	2025		2024	
	Amount	Percent	Amount	Percent
Pretax Income (Loss)	$ (78,537)		$ (40,209)	
US Federal Statutory Tax Rate	(16,493)	21.0%	(8,444)	21.0%
Foreign Tax Effects:				
United Kingdom				
R&D Deduction	—	0.0%	(551)	1.4%
R&D Deductions Surrendered	—	0.0%	3,684	-9.2%
R&D Credit included in PBT	—	0.0%	(1,003)	2.5%
DTA (DTL) True Ups - NOLs	—	0.0%	(2,318)	5.8%
Change in Valuation Allowance	6,159	-7.8%	2,237	-5.6%
Foreign rate differential	(1,050)	1.3%	—	0.0%
Other	400	-0.5%	(217)	0.5%
Other foreign jurisdictions	4	0.0%	6	0.0%
Effect of Cross-Border Tax Laws:				
Net CFC tested income	—	0.0%	439	-1.1%
Tax Credits:				
Tax Credits - Federal R&D Credit	(2,355)	3.0%	(1,399)	3.5%
Change in valuation allowance	12,624	-16.1%	7,493	-18.6%
Nontaxable or Nondeductible Items:				
Stock Compensation	—	0.0%	(522)	1.3%
Other	587	-0.7%	295	-0.7%
Other Adjustments:				
DTA (DTL) True Ups - Other	124	-0.2%	262	-0.7%
DTA (DTL) True Ups - Stock Compensation	—	0.0%	38	-0.1%
Total	$ —	—%	$ —	—%

12. PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, $0.0001 par value per share, of which 0 shares were issued and outstanding as of December 31, 2025 and 2024, respectively.

13. COMMON STOCK

The Company has authorized 300,000,000 shares of common stock, $0.0001 par value per share, of which 17,611,511 and 12,179,482 shares were issued and outstanding as of December 31, 2025 and 2024, respectively.

Public Offerings

On October 30, 2025, the Company entered into an underwriting agreement with Jefferies, as representative of the several underwriters, relating to an underwritten public offering of 4,744,231 shares of common stock at a price to the public of $13.00 per share, and, to certain investors in lieu of common stock, pre-funded warrants to purchase 1,025,000 shares of common stock at a public offering price of $12.9999 per pre-funded warrant. The purchase price per share of each pre-funded warrant represents the per share public offering price for the common stock, minus the $0.0001 per share exercise price of each such pre-funded warrant. On November 3, 2025, the Company completed the public offering raising gross proceeds of $75.0 million and net proceeds of $70.2 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The pre-funded warrants were classified as a component of permanent equity on the balance sheet as they are freestanding financial instruments that are immediately exercisable and permit the holders to receive a fixed number of shares of common stock upon exercise. As of December 31, 2025, all of the pre-funded warrants from the 2025 offering remain available for exercise.

On January 31, 2024, the Company entered into an underwriting agreement with Jefferies LLC ("Jefferies"), as representative of the several underwriters, relating to an underwritten public offering of 4,325,000 shares of the Company's common stock, par value $0.0001, at a price to the public of $19.00 per share. The underwriters were also granted a 30-day option to purchase up to an additional 648,750 shares of common stock at the public offering price. On January 31, 2024, Jefferies gave notice to the Company of the underwriters' election to exercise the option to purchase additional shares, in full. On February 2, 2024, the Company completed the public offering raising gross proceeds of approximately $94.5 million and net proceeds of $88.6 million after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Open Market Sale Agreement

On May 31, 2023, the Company entered into Amendment No. 1 to the Open Market Sale Agreement originally dated August 6, 2020 (as amended, the "Open Market Sale Agreement") with Jefferies, as sales agent. The Company filed a new shelf registration statement and prospectus supplement effective March 20, 2024 under which the Company may issue and sell, from time to time through Jefferies, shares of its common stock having an aggregate offering price of up to $150.0 million (the "Open Market Offering").

Under the Open Market Sale Agreement, Jefferies may sell the common stock by any method permitted by law deemed to be an "at-the-market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company may sell common stock in amounts and at times to be determined by the Company subject to the terms and conditions of the Open Market Sale Agreement, but the Company has no obligation to sell any of the common stock in the Open Market Offering.

The Company has agreed to pay Jefferies a commission of 3.0% of the aggregate gross proceeds from each sale of common stock and have agreed to provide Jefferies with customary indemnification and contribution rights. The Company has also agreed to reimburse Jefferies for certain specified expenses.

During the years ended December 31, 2025 and 2024, the Company sold an aggregate of 563,504 and 2,484,517 shares of common stock, respectively, under the Open Market Sale Agreement, for net proceeds of approximately $7.0 million and $91.4 million, respectively. As of December 31, 2025, approximately $69.1 million was available for issuance and sale under the Open Market Offering.

Other Common Stock Transactions

During the years ended December 31, 2025 and 2024, the Company issued 41,674 and 136,664 shares of common stock upon the exercise of stock options to purchase common stock and the Company received proceeds of $0.2 million and $2.0 million from those exercises, respectively.

During the years ended December 31, 2025 and 2024, the Company issued 82,620 and 7,275 shares of common stock from the vesting of shares from restricted stock, respectively, of which 31,510 were issued under the 2024 Plan and the remaining were issued under the 2014 Plan.

During the years ended December 31, 2025 and 2024, the Company issued 0 and 142,857 shares of common stock in a conversion pursuant to the K2HV Amended Loan and Security Agreement, respectively.

During the years ended December 31, 2025 and 2024, the Company issued 0 and 4,649 shares of common stock upon the vesting of restricted stock units pursuant to a professional services agreement with an investor relations service provider, respectively.

During the years ended December 31, 2025 and 2024, the Company issued 0 and 6,087 shares of common stock upon the exercise of warrants, respectively.

14. STOCK-BASED COMPENSATION AWARDS

On May 16, 2024, the Company's stockholders approved the 2024 Equity Compensation Plan (the "2024 Plan") authorizing the issuance of up to 2,000,000 shares, succeeding the 2014 Equity Incentive Plan (the "2014 Plan"), under which no further grants may be made pursuant to the terms of the 2014 Plan. Pursuant to the 2024 Plan, the Board may grant nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units ("RSUs"), performance shares, performance units, incentive bonus awards, other cash-based awards and other stock-based awards to employees, officers, non-employee directors, and other individual service providers.

Under the terms of the 2024 Plan and 2014 Plan, the Company granted stock options and RSUs to employees, officers, non-employee directors, consultants and advisors. Stock options have a ten-year term and an exercise price equal to the fair market value of a share of our common stock on the grant date. Stock options generally vest over four years with 25% vesting on the one-year anniversary of the grant date and the remainder vesting in equal monthly installments thereafter, except for grants to non-employee directors that vest annually. RSUs generally vest over a period of one to four years in annual installments beginning on the first anniversary of the grant date.

As of December 31, 2025, an aggregate of 785,179 shares of common stock were reserved for issuance upon the exercise or vesting of outstanding awards under the 2014 Plan. No additional grants can be made under the 2014 Plan.

As of December 31, 2025, an aggregate of 1,099,384 shares of common stock were reserved for issuance upon the exercise or vesting of outstanding awards and up to 869,106 shares of common stock may be issued pursuant to awards granted under the 2024 Plan.

Stock-based Compensation Expense

In connection with all stock-based compensation awards, total non-cash, stock-based compensation expense recognized in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 1,961	$ 1,027
General and administrative expenses	4,327	5,118
Total stock-based compensation	$ 6,288	$ 6,145

The total stock-based compensation expense recognized by award type was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Stock options	$ 3,706	$ 4,240
Restricted stock units	2,582	1,905
Total stock-based compensation	$ 6,288	$ 6,145

Stock Options

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes stock option pricing model that uses the assumptions noted in the following table, except for the expected term for non-employees as noted in the following paragraph. The expected term of employee and non-employee director stock options granted under the 2014 Plan and 2024 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited operating history. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among our employee population. For non-employee stock options, excluding directors, the Company has elected to utilize the contractual term as the expected term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with that used to value the stock option. The Company accounts for forfeitures as they occur.

The weighted average assumptions used principally in determining the fair value of stock options granted to employees and non-employee directors were as follows:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.35%	4.23%
Expected dividend yield	0%	0%
Expected term in years	6.15	6.18
Expected volatility	131.47%	124.60%

A summary of stock option activity for years ended December 31, 2025 and 2024 is presented below:

Stock Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	723,153	$ 62.95	6.95	$ 881
Granted	723,375	9.31		
Exercised	(41,674)	4.27		
Forfeited or canceled	(16,000)	7.42		
Expired	(2,834)	47.83		
Outstanding at December 31, 2025	1,386,020	$ 37.40	7.41	$ 371
Exercisable at December 31, 2025	516,227	$ 80.97	4.89	$ 108

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $8.48 and $24.99 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $0.5 million and $4.1 million, respectively. As of December 31, 2025, there was approximately $7.4 million of total unrecognized compensation expense, related to non-vested stock-based compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 1.36 years at December 31, 2025.

Restricted Stock Units

A RSU represents the right to receive one share of our common stock upon vesting of the RSU. The fair value of each RSU is based on the closing price of our common stock on the date of grant. The Company accounts for forfeitures as they occur.

A summary of RSU activity for the years ended December 31, 2025 and 2024 is presented below:

RSUs	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2024	259,488	$ 26.42
Granted	326,475	$ 9.22
Forfeited	(4,800)	$ 7.42
Vested	(82,620)	$ 29.80
Unvested at December 31, 2025	498,543	$ 14.78

As of December 31, 2025, there was $5.4 million of unrecognized compensation costs related to unvested RSUs, which are expected to be recognized over a weighted average period of 1.74 years.

15. WARRANTS

During the year ended December 31, 2024, the Company issued 6,087 shares of common stock upon the exercise of warrants. No warrants were exercised during the year ended December 31, 2025.

At December 31, 2025, there were warrants outstanding to purchase 2,873 shares of common stock with a weighted average exercise price of $208.80 and a weighted average remaining life of 4.58 years. The Company also has pre-funded warrants to purchase 1,025,000 shares of common stock at an exercise price of $0.0001 per share with no expiration date.

On January 26, 2018, the Company entered into an Investment Agreement with the Cystic Fibrosis Foundation ("CFF") that included issuance of a warrant to purchase an aggregate of 33,334 shares of the Company's common stock (the "CFF Warrant") at an exercise price of $396.00 per share. The CFF Warrant expired unexercised on January 26, 2025.

On July 28, 2020, the Company entered into the Loan and Security Agreement with K2HV and in connection with the funding of $20.0 million, the Company issued a warrant exercisable for 2,873 shares of the Company's common stock (the "K2 Warrant") at an exercise price of $208.80 per share. The K2 Warrant is immediately exercisable for 2,873 shares and expires on July 28, 2030.

On October 16, 2020, the Company entered into a professional services agreement with an investor relations service provider. Pursuant to the agreement, the Company issued warrants exercisable for a total of 14,000 shares of the Company's common stock (the "Warrants") at an exercise price of $32.10 per share. The Warrants became fully vested on October 19, 2021 and had an expiration date of November 3, 2025. The Warrants were exercised in full on a cashless basis, resulting in the issuance of 6,087 shares of common stock during the year ended December 31, 2024. No cash proceeds were received and the exercise price settled by reducing the total shares issued in lieu of cash payment.

16. SEGMENT INFORMATION

The Company views its operations and manages its business in one reportable segment, which is developing and commercializing therapeutics for cancer and obesity.

The Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM makes decisions based on net loss. Significant expenses within net loss include research and development and general and administrative expenses, which are each separately presented on the Company's consolidated statements of operations and comprehensive loss. Other segment items within net loss include interest and investment income, net, interest expense and other income, net.

The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets. All material long-lived assets are located in the United States. Long-lived assets consist of property and equipment, net, and operating lease right-of-use assets.