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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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: 001-41740

Apogee Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**93-4958665**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

221 Crescent St., Building 17, Suite 102b
Waltham, MA 02453
(650) 394-5230

(Address including zip code, and telephone number including area code, of registrant's principal executive offices)

Former name, former address and former fiscal year, if changed since last report: N/A

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	APGE	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Exchange 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 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). ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2025 was approximately $1,757.9 million based on the closing price on The Nasdaq Global Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

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

As of February 23, 2026, the registrant had 69,485,247 shares of common stock, $0.00001 par value per share, outstanding, comprised of 55,998,605 shares of voting common stock, $0.00001 par value per share, and 13,486,642 shares of non-voting common stock, $0.00001 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement for the 2026 Annual Meeting of Shareholders, which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this report.

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Explanatory Note

As used in this Annual Report on Form 10-K (this "Annual Report"), unless the context otherwise requires, references to "we," "us," "our," the "Company," "Apogee" and similar references refer: (1) following the consummation of our Reorganization (as defined elsewhere in this Annual Report) on July 13, 2023 in connection with our initial public offering, to Apogee Therapeutics, Inc. and our subsidiary, and (2) prior to the completion of our Reorganization, to Apogee Therapeutics, LLC and its subsidiary. See "Management's Discussion and Analysis of Financial Condition and Results of Operations"—"Reorganization" in this Annual Report for further information.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on current expectations, estimates, forecasts and assumptions. All statements other than statements of historical fact included in this Annual Report, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital requirements or financing needs, capital expenditures, commitments, preclinical studies, clinical trials, plans or intentions relating to product candidates, expected markets and business trends and other statements, including without limitation, those discussed under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations", are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "would," "shall," "objective," "intend," "target," "should," "could," "can," "expect," "anticipate," "believe," "design," "estimate," "forecast," "predict," "potential," "plan," "seek," or "continue" or the negative of these terms and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events. Given the significant risks and uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this Annual Report. Such risks, uncertainties and other factors include, among others, the following:

- our plans to develop and commercialize our programs for the treatment of atopic dermatitis, asthma, eosinophilic esophagitis, chronic obstructive pulmonary disease, and related inflammatory and immunology indications with high unmet need;
- our ability to obtain funding for our operations, including funding necessary to complete the development and potential commercialization of our programs;
- the timing and focus of our ongoing and future preclinical studies and clinical trials and the reporting of data from those studies and trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our programs;
- our plans relating to the further development of our programs, including additional indications we may pursue;
- the size of the market opportunity for our programs, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our continued reliance on third parties to conduct additional preclinical studies and clinical trials of our programs and for the manufacture of our product candidates for preclinical studies and clinical trials;
- the success, cost and timing of our preclinical and clinical development activities and planned clinical trials;
- the continuation of our existing collaborations and licensing and other arrangements and entry into new collaborations and licensing and other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for our programs, as well as future programs;
- the rate and degree of market acceptance of our programs;
- the success of competing treatments that are or may become available;
- our ability to attract and retain key management and technical personnel;
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our programs;

- our financial performance;
- global macroeconomic conditions;
- the period over which we estimate our existing cash and cash equivalents, marketable securities and long-term marketable securities will be sufficient to fund our future operating expenses and capital expenditure requirements; and
- our anticipated use of our existing resources.

These and other risks and uncertainties and other factors, including those discussed under the section titled "Risk Factors" of this Annual Report, may cause our actual results and outcomes, or timing of our results or outcomes, to differ materially and adversely from the forward-looking statements expressed or implied in this Annual Report including factors disclosed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." You should evaluate all forward-looking statements made in this Annual Report in the context of these risks and uncertainties.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this Annual Report may not contain all of the risks, uncertainties and other factors that may affect us, our future results or our operations. Moreover, new risks may emerge from time to time. It is not possible for us to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected.

All forward-looking statements in this Annual Report apply only as of the date made and are expressly qualified in their entirety by this and other cautionary statements included in this Annual Report. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, subsequent events, changes in assumptions or circumstances or otherwise.

In addition, statements such as "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe we have a reasonable basis for such statements, our information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

The Apogee name and logo are our registered trademarks. This Annual Report contains references to our trademarks and to trademarks and service marks belonging to other entities. Solely for convenience, trademarks, service marks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ®, ^{SM}, 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 and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Part I

Item 1. Business

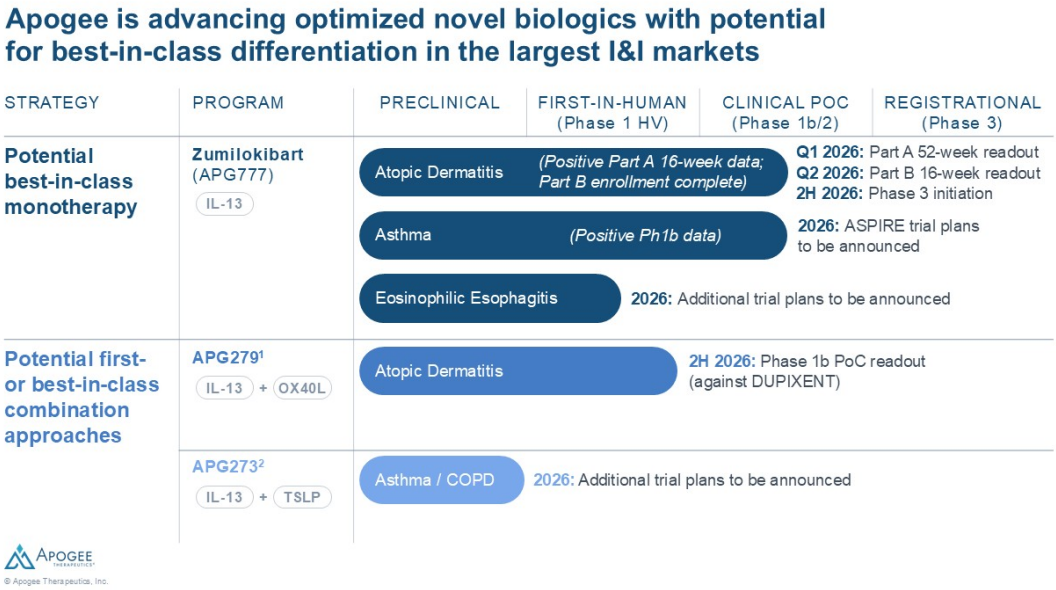
Overview

We are a clinical stage biotechnology company advancing optimized, novel biologics with the potential for differentiated efficacy and dosing in the largest inflammatory and immunology ("I&I") markets, including for the treatment of atopic dermatitis ("AD"), asthma, eosinophilic esophagitis ("EoE"), chronic obstructive pulmonary disease ("COPD"), and other I&I indications. Our antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties.

Our pipeline comprises multiple antibody programs being developed initially for the treatment of I&I indications as monotherapies and combinations, including zumilokibart (APG777), APG279 (zumilokibart + APG990), APG273 (zumilokibart + APG333), and APG808 (each, a "program" or "product candidate"). With four validated targets in our portfolio, we are seeking to achieve best-in-class efficacy and dosing through monotherapies and combinations of our novel antibodies. Based on a broad pipeline and depth of expertise, we believe we can deliver value and meaningful benefit to patients underserved by today's standard of care. We believe each of our product candidates has potential for broad application across multiple I&I indications.

Our Pipeline

We have multiple clinical programs in our pipeline based on four validated targets being developed initially for the treatment of I&I indications, as shown below. We believe each of our programs has potential for broad application across multiple I&I indications.



The agents listed above are currently under investigation. Their safety and effectiveness have not yet been established by any regulatory authority. APG808 (not shown) is a novel half-life extended IL-4Rα antibody. Apogee announced positive interim results from the Phase 1b trial of APG808 in patients with mild-to-moderate asthma in May 2025.

[1] APG279 is a combination of zumilokibart (APG777) and APG990. APG279 will be co-administered in the proof-of-concept Phase 1b trial; coformulation planned for future clinical studies and commercialization.

[2] APG273 is a combination of zumilokibart and APG333.

Zumilokibart (APG777) – anti-IL13 antibody

Zumilokibart is a subcutaneous ("SQ") extended half-life monoclonal antibody ("mAb") targeting IL-13.

Phase 1 Trial in Healthy Volunteers

In August 2023, we initiated a Phase 1 trial of zumilokibart in healthy volunteers. The zumilokibart Phase 1 trial was a double-blind, placebo-controlled study in healthy volunteers and consisted of a single-ascending dose ("SAD") component and a multiple ascending dose component. Eight healthy volunteers, six treated with zumilokibart and two treated with placebo, were enrolled in each cohort, and we enrolled a total of 40 healthy adult subjects in the trial.

In March 2024, we announced positive interim safety and PK data from this trial with zumilokibart demonstrating a potential best-in-class PK profile, including a half-life of 77 days, supporting the potential for every three- to six- month maintenance dosing in AD. Single doses of zumilokibart demonstrated a deep and sustained effect on PD markers out to approximately 12 months. Zumilokibart was well-tolerated across all dose groups.

APEX Phase 2 Trial for Patients with AD

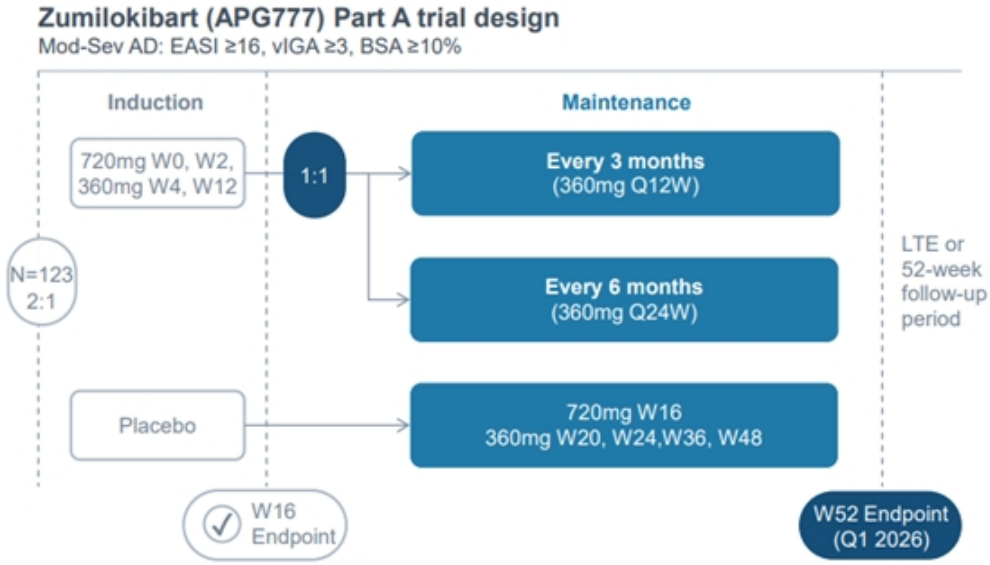
In May 2024, we announced dosing of our first patient in the APEX Phase 2 clinical trial, which is a randomized, placebo-controlled study evaluating zumilokibart in patients with moderate-to-severe AD.

In July 2025, we announced positive 16-week data from the Part A portion of the APEX Phase 2 clinical trial. Part A of the trial enrolled 123 adult patients who were randomized 2:1 to zumilokibart versus placebo and received an induction regimen dosing of 720mg at Weeks 0 and 2, followed by 360mg at Weeks 4 and 12. The primary endpoint for the induction arm of Part A was percentage change in Eczema Area Severity Index ("EASI") score from baseline at Week 16. Secondary endpoints included EASI-75, EASI-90, Validated Investigator Global Assessment ("vIGA") 0/1 and Itch Numeric Rating Scale ("NRS") at Week 16. In non-head-to-head trial comparisons, the initial 16-week findings from Part A included efficacy results, which compared favorably versus standard of care across endpoints, as well as rapid onset of itch relief and lesion reduction, and a favorable safety profile consistent with its class.

The Part A trial met its primary endpoint, with zumilokibart showing significantly greater least squares mean percent change from baseline at Week 16 with an EASI reduction of 71.0% compared to placebo of 33.8% ($p < 0.001$). Zumilokibart showed the highest absolute and placebo-adjusted EASI-75 of any biologic in a 16-week global study with 66.9% of patients treated with zumilokibart achieving EASI-75 compared to 24.6% on placebo ($p < 0.001$). Pre-specified sensitivity analysis showed consistent results in both moderate and severe patients based on baseline EASI score. The results demonstrated a vIGA 0/1 of 34.9% compared to placebo of 17.3% ($p < 0.05$) and an EASI-90 of 33.9% compared to placebo of 14.7% ($p < 0.05$). Treatment of patients with zumilokibart led to rapid and deep onset of itch relief and achieved a statistically significant reduction by Week 1, with a 50.7% reduction of Itch NRS from baseline compared to placebo of 23.2% ($p < 0.01$) at Week 16. Zumilokibart was well tolerated, with 56.1% of zumilokibart -exposed patients experiencing treatment-emergent adverse events ("TEAEs") (vs. 63.4% in placebo). The most common TEAEs, occurring in more than 5% of patients, were non-infective conjunctivitis (14.6% vs. 2.4% in placebo), upper respiratory tract infection (8.5% vs 12.2% in placebo), nasopharyngitis (4.9% vs. 12.2% in placebo), and pain in extremity (0.0% vs. 7.3% in placebo) with the latter three being numerically lower in zumilokibart treated patients compared to placebo. Serious TEAEs were rare for zumilokibart -exposed patients (1.2% vs. 2.4% in placebo). The discontinuation rate due to adverse events was low for zumilokibart -exposed patients (2.4%). There were no injection site reactions in the zumilokibart treated group. In addition, improvement in asthma and sinusitis, as measured by improvements in ACQ-5 and SNOT-22 in patients with comorbid asthma or sinusitis, was observed, which reflect zumilokibart's potential to broadly impact Type 2 inflammatory disease.

All Part A patients that benefited from treatment in the induction arm received the opportunity to continue to zumilokibart maintenance treatment, which evaluated three and six-month dosing intervals. Patients in the placebo arm for the first 16 weeks also received the opportunity to receive an induction regimen of zumilokibart followed by three-month dosing of zumilokibart. A schematic of the Part A trial design is shown in Figure 1 below. We expect to report Part A maintenance data in March 2026.

Figure 1 — APEX Phase 2 Part A trial design evaluating zumilokibart in patients with AD

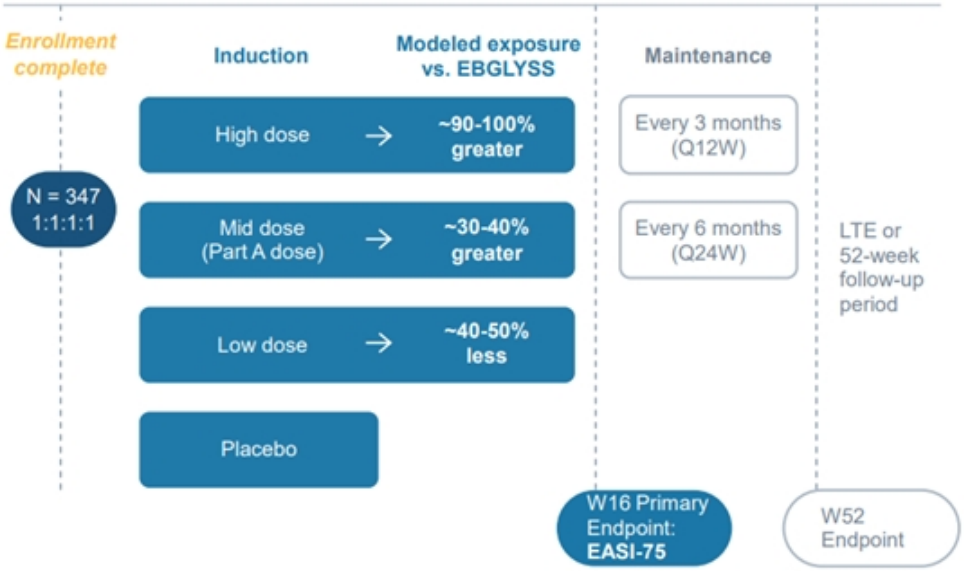


In February 2025, we announced that we had commenced dosing of the Part B portion of the APEX Phase 2 trial. Part B is testing a higher and a lower dose of zumilokibart.

The APEX Part A induction regimen was designed to exceed EBGLYSS exposures by approximately 30% to 40% with potential for improved clinical outcomes and maintenance regimen is designed to equal lebrikizumab's exposures. The results at Week 16 of the Part A study showed that patients in the highest zumilokibart exposure quartile (n=19) achieved the highest clinical response of any quartile in a post hoc exposure-response analysis. These patients had a mean 84.0% reduction in EASI from baseline, 89.5% of patients reaching EASI-75, 63.2% achieving IGA0/1, and 63.2% achieving EASI-90, demonstrating a robust response at the highest exposure level. The highest zumilokibart Part B dose was designed to exceed EBGLYSS exposures by approximately 90 to 100% as show in Figure 2, which is similar to the exposure obtained in the highest quartile of the Part A results.

A schematic of the APEX Part B trial design is shown in Figure 2 below.

Figure 2 — APEX Phase 2 Part B trial design evaluating zumilokibart in patients with AD



In January 2026, we announced that we completed Part B enrollment ahead of schedule and exceeded target enrollment with a total of 347 patients. We expect to report 16-week topline induction data from Part B in the second quarter of 2026. Subject to positive results and regulatory alignment with the U.S. Food and Drug Administration (the "FDA"), we plan to initiate a Phase 3 trial in AD in the second half of 2026, enabling a potential launch of zumilokibart for the treatment of AD in 2029.

Phase 1b Trial in Patients with Asthma

In April 2025, we initiated a Phase 1b trial of zumilokibart (APG777) in patients with mild-to-moderate asthma, and in January 2026, we announced positive interim data from the trial. The trial is a double-blind, placebo-controlled trial evaluating the safety and tolerability of zumilokibart in patients with mild-to-moderate asthma. The trial is designed to also evaluate fractional exhaled nitric oxide ("FeNO") suppression, a biomarker of Type 2 inflammation that has shown the strongest correlation with exacerbations in asthma. The trial enrolled 31 adult patients who were randomized 3:1 to zumilokibart versus placebo and participants received a single dose of 720 mg of zumilokibart or placebo on day 1. Nineteen of the patients with mild-to-moderate asthma had a FeNO baseline ≥25 ppb, representative of asthma with Type 2 inflammation, and as a result met the pre-specified criteria for the analysis population.

In the trial, zumilokibart demonstrated a favorable safety profile and was well-tolerated in all patients. In the 19 patients analysis population, the only TEAEs observed in more than one patient was gastroesophageal reflux disease ("GERD"), which was observed in 2 patients. In the analysis population, there were no Grade 3 or higher TEAEs or serious adverse events observed and no conjunctivitis, injection site reactions, or anti-drug antibodies ("ADAs") were observed. In the full safety population (n=31) that were on treatment (n=23), TEAEs occurring in more than one patient on zumilokibart were upper respiratory tract infection (n=3), nasopharyngitis (n=2), GERD (n=2), and arthralgia (n=2); there were no Grade 3 or higher TEAEs or serious adverse events.

Zumilokibart demonstrated robust and durable suppression of FeNO following a single dose in the analysis population. A maximum absolute mean FeNO reduction of 45 ppb (60% decrease from baseline) after a single dose was observed in the analysis population. Durable FeNO suppression through 16 weeks was observed for all patients in the analysis population. Zumilokibart also demonstrated suppression of FeNO through 32 weeks for those patients in the analysis population with follow up available at the time of the data cut (n=3), supporting the potential for 3- or 6- month dosing. In the trial, positive trends were observed in forced expiratory volume in one second ("FEV1") and across Type 2 biomarkers for all available data in the analysis population. FEV1 is a pharmacodynamic measure of

lung function. Based on these results, we anticipate sharing our plans later in 2026 to further evaluate zumilokibart in the ASPIRE Phase 2 asthma trial.

Expansion Opportunities in Other Indications

We expect that results from the Phase 1b trial of zumilokibart for the treatment of asthma, in addition to topline induction data from the Part B portion of the APEX Phase 2 trial in AD, will allow us to determine dose selections for further expansion indications in 2027 and beyond, including but not limited to asthma and EoE. We expect to announce plans for the Phase 2 trial in EoE in 2026. Based on our clinical data, we expect to further evaluate additional opportunities to develop zumilokibart for other I&I indications, including alopecia areata, chronic rhinosinusitis with nasal polyps ("CRSwNP"), chronic spontaneous urticaria, and prurigo nodularis.

In addition, we plan to evaluate zumilokibart in combination with other investigational therapies within our pipeline to potentially enable greater efficacy for I&I conditions. The first of these combinations is APG279, which combines zumilokibart with APG990, our novel, SQ, half-life extended mAb targeting OX40L. We are also evaluating APG273, which combines zumilokibart with APG333, our novel, SQ, half-life extended mAb targeting thymic stromal lymphopoietin ("TSLP").

APG279 – Combination of zumilokibart (APG777) and APG990 – anti-OX40L antibody

We are developing zumilokibart and APG990 together as APG279, a potential first-in-class coformulation for the treatment of AD by combining deep and sustained inhibition of Type 2 inflammation via zumilokibart's inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990's inhibition of OX40L. APG990 is an SQ extended half-life mAb that utilizes advanced antibody engineering to target OX40L.

In August 2024, we initiated a Phase 1 clinical trial of APG990, which was designed as a double-blind, placebo-controlled, first-in-human, single-ascending dose trial designed to evaluate the safety and PK of APG990 in 40 healthy adult participants across five cohorts. Doses of subcutaneous APG990 evaluated in the study included 75mg, 150mg, 300mg, 600mg and 1,200mg. In March 2025, we announced positive interim safety and PK data from the trial. PK data showed a half-life of approximately 60 days across doses tested. APG990, in single doses up to 1,200mg, was well tolerated and showed a favorable safety profile, consistent with other assets targeting OX40L. The most common (≥10%) TEAEs were headache. 53% of participants observed at least one TEAE and there were no Grade 3 TEAEs related to study drug or severe adverse events. No adverse events led to study discontinuation. There were no cases of pyrexia or chills.

In July 2025, we commenced dosing in the Phase 1b trial of APG279 against DUPIXENT in patients with moderate-to-severe AD, which was upsized from approximately 50 to 80 patients due to a strong patient enrollment, with a data readout expected in the second half of 2026. The initial clinical trial of APG279 is being conducted as a coadministration of zumilokibart and APG990. We plan to advance the development of APG279 in future studies as a coformulation. The PK data for APG990, when considered together with APG279 coformulation data, provides the potential for dosing the combination two to four times per year with a single 2 mL coformulated injection.

APG273 – Combination of zumilokibart (APG777) and APG333 - anti-TSLP antibody

We are developing zumilokibart and APG333 together as APG273, a potential quarterly or less frequently dosed co-formulation for the treatment of asthma and COPD. APG333 is a fully-human mAb against TSLP, an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of people living with asthma and COPD, with the potential for extended half-life and to be used in combination with other mAbs for potentially greater efficacy in broader populations.

In December 2024, we initiated a Phase 1 clinical trial of APG333 in healthy volunteers, and in November 2025, we announced positive interim safety, PK and PD results from the clinical trial. APG333 demonstrated a half-life of approximately 55 days, supporting the potential for every three- and six-month dosing. In addition, key biomarkers of eosinophils and IL-5 showed depth of suppression in line with TSLP analogs and durability out to 6 months (limit of available follow-up).

APG333, with single doses of up to 1,000 mg, was well tolerated across the four cohorts. The most common TEAEs occurring in ≥10% of APG333 treated participants were headache and upper respiratory tract infection. TEAEs were generally mild and self-limited and there were no dose dependent trends in TEAEs seen. There were no Grade 3 TEAEs or severe adverse events; and no adverse events led to study discontinuation.

We plan to announce additional clinical plans for APG273 in 2026 to support advancement into future combination trials in asthma and COPD.

APG808 – anti-IL4Rα antibody

APG808 is an SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight different Type 2 allergic diseases. In March 2024, we commenced dosing of the first healthy volunteers in the APG808 Phase 1 trial, and in September 2024, we commenced dosing of the first asthma patients as a cohort in that Phase 1 trial. In December 2024, we announced positive interim safety, PK and PD data from the Phase 1 trial. APG808 demonstrated a potential best-in-class PK profile, including a half-life of approximately 55 days at projected, clinically relevant steady state exposures, supporting the potential for every two- to three-month maintenance dosing. Single doses of APG808 demonstrated a deep and sustained effect on PD markers out to approximately three months (longest follow-up available at time of data cut). APG808 was well-tolerated across all dose groups.

In May 2025, we announced positive interim results from the Phase 1b trial of APG808 in patients with mild-to-moderate asthma. The trial was a double-blind, placebo-controlled, multiple-dose trial, which evaluated the safety and tolerability of APG808 in 22 adult patients with mild-to-moderate asthma. The trial also evaluated FeNO, thymus and activation-regulated chemokine ("TARC"), and pSTAT6. Participants were randomized 3:1, receiving 600mg of APG808 or placebo on day 1 and day 29.

The results demonstrated that APG808 was well-tolerated, with multiple doses of APG808 resulting in rapid suppression of FeNO, with a maximal robust FeNO decrease from baseline of 53% and sustained FeNO decrease from baseline of 50% at 12 weeks. APG808 also demonstrated sustained and near-complete reduction in pSTAT6 as well as deep reduction of TARC maintained through 12 weeks. The most common TEAEs observed were headache, injection site erythema, and upper respiratory tract infections. There were no Grade 3 TEAEs or severe adverse events, and no adverse events led to study discontinuation.

APG808's optimized PK profile coupled with FeNO suppression out to 12-weeks reinforces the potential for 2-months or longer maintenance dosing, offering a significant advantage compared to the current bi-weekly standard of care.

Our Approach

Our goal is to discover and develop new therapies for a range of I&I indications. We aim to accomplish this goal by focusing on known biologic drivers of disease and utilizing advanced antibody engineering to develop product candidates with optimized properties that have the potential to overcome limitations of existing therapies, both in terms of reduced injection burden, as well as improved efficacy. For instance, each of our product candidates, zumilokibart (APG777), APG990 (as a combination partner with zumilokibart for APG279), APG333 (as a combination partner with zumilokibart for APG273) and APG808, bind to the same epitopes, or binding sites, on IL-13, OX40L, TSLP and IL-4Rα as EBGLYSS (lebrikizumab), amlitelimab, TEZPIRE (tezepelumab), and DUPIXENT (dupilumab), respectively, based on our head-to-head preclinical studies, but are designed to include extended half-life technologies and other optimized properties. When designing our product candidates, we test multiple half-life extension technologies, including YTE and LS amino acid modifications, to identify the optimal candidate to advance against each target. YTE amino acid modifications are a triple modification (M252Y/S254T/T256E) introduced into the antibody, while LS amino acid modifications are a double modification (M428L/N434S). YTE and LS amino acid modifications are proven half-life extension technologies that have the potential to significantly improve the PK profile and reduce injection burden compared to existing agents. In addition to extended half-life, our antibody engineering product candidates are designed to improve antibody candidate attributes, including in vitro potency, bioavailability and decreased PK variability, as well as those attributes essential for manufacturability and high concentration formulation (i.e. viscosity, solubility and stability) to generate optimized antibodies. We believe our approach will

enable us to develop a portfolio of therapies that are differentiated compared to the currently available standards of care and address unmet medical needs for I&I indications, including the potential for improved dosing and/or efficacy.

Our Strategy

Our goal is to become a leader in developing and commercializing novel therapies for I&I indications. Our antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties. The key elements of our strategy include:

- Advancing zumilokibart targeting IL-13 through clinical development, regulatory filings, approval and launch for AD;
- Advancing APG279 for the dual inhibition of OX40L and IL-13;
- Advancing APG273 for the dual inhibition of TSLP and IL-13;
- Maximizing the potential of our programs through indication expansion beyond AD, including asthma, EoE and COPD; and
- Expanding existing and evaluating new collaborations to broaden the impact we can have for patients living with I&I indications.

Overview of AD

Disease Overview

AD, the most common subtype of eczema, is a chronic inflammatory skin disorder that affects individuals of all ages and races. AD affects individuals living in geographic regions worldwide. AD is characterized by pruritic (itchy), erythematous (red) and often excoriated (damaged) skin lesions, which are most often located on the neck, inner elbows and behind the knees. The specific cause of AD is unknown; however, research has shown that genetics, the immune system and the environment all play a role in the disease. AD can significantly impact quality of life, leading to sleep disturbance, psychological distress, elevated infection risk and chronic pain. AD is frequently associated with other atopic manifestations such as food allergy, allergic rhinitis (also known as hay fever) and asthma. AD is characterized by a Th2 response, which describes Th2 cells that produce small proteins called cytokines, like IL-13, which regulate inflammation, immune response and tissue repair.

AD usually begins in childhood; however, patients can become affected with this inflammatory disease at any age. For some people, AD improves by adulthood, but for many, it can be a lifelong illness. It is estimated that 81.6 million people suffer from moderate to severe AD worldwide. Approximately 40% of all AD patients have moderate-to-severe disease. The incidence of AD has increased two- to three-fold in industrialized nations since the 1970s, with approximately 15% to 20% of children and 1% to 3% of adults affected worldwide.

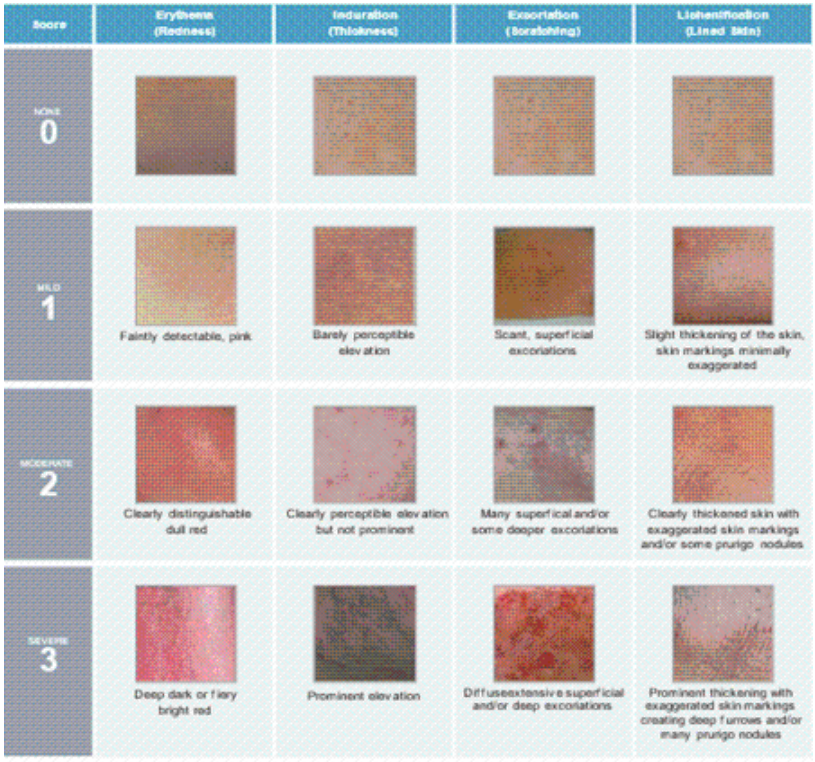
Overview of Current Treatment Options

There is no cure for AD and many people have difficulty controlling the disease. AD patients work with a dermatologist to determine treatment options that can bring their symptoms under control. For less extensive disease (i.e., mild-to-moderate AD), treatment is primarily topical corticosteroids and targeted topical treatments (e.g., a topical JAK inhibitor). For more extensive disease (i.e., moderate-to-severe AD), mAbs have emerged as the preferred frontline therapy in most adult and pediatric patients that is not controlled by topical therapies. Avoiding environmental and stress triggers, increased skin care regimen and dietary and lifestyle changes may also be part of the treatment recommendations.

Treatment of AD is specific to severity of disease. The primary goal of AD management is to control symptoms and prevent flares. Outcomes in AD are primarily reported using two measures: EASI and IGA. Other measures are used as well to gain a comprehensive understanding of a treatment's impact on AD patients.

EASI assesses key signs of eczema over four natural anatomic divisions of the body (the head and neck, the trunk, the upper extremities and the lower extremities) across the parameters of erythema (redness), induration (thickness), excoriation (scratching), lichenification (lined skin) and percentage of the region affected. The EASI score range is from 0 to 72 with 72 being the most severe. Zero is considered clear, 0.1 to 1.0 is considered almost clear, 1.1 to 7.0 is considered mild, 7.1 to 21.0 is considered moderate, 21.1 to 50.0 is considered severe and above 50.1 is considered very severe. Proportion of patients achieving EASI-75, an improvement of at least 75% from baseline on the EASI, or EASI-90, an improvement of at least 90% from baseline on the EASI, are key outcome measures in clinical trials of patients with moderate-to-severe AD. The extent and severity of AD as measured by the EASI is shown in Figure 3 below.

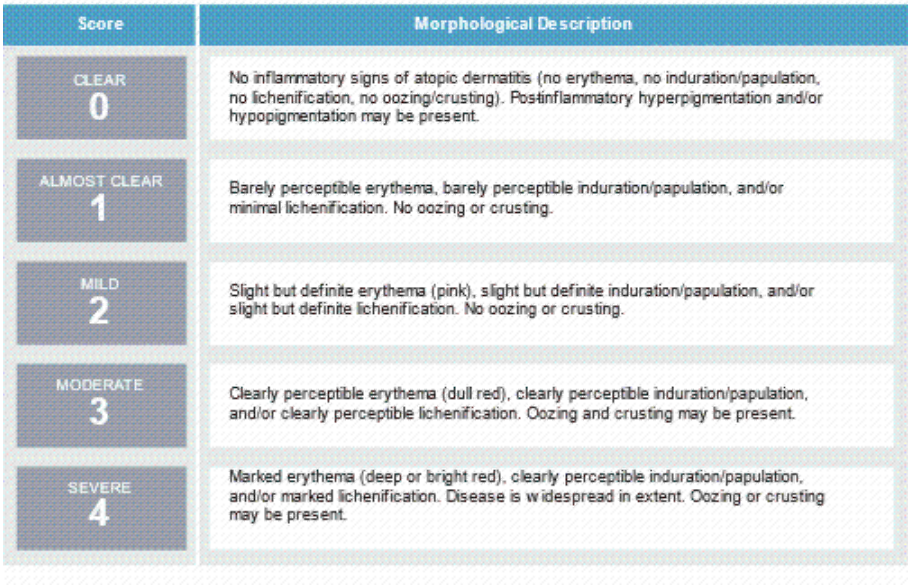
Figure 3 — Eczema Area and Severity Index



Source: Harmonising Outcome Measures for Eczema (HOME). EASI Guidance (presentation). Accessed April 28, 2023.

As shown in Figure 4 below, IGA is a five-point scale (scale 0 to 4) that uses clinical characteristics to assess overall disease severity at any given timepoint. Typical enrollment for clinical trials for moderate-to-severe AD patients requires an IGA score of three or four. As an outcome measure, IGA is looked at as the number of patients achieving an IGA score of 0 or 1 with at least a two-point decrease in IGA from baseline, referred to as proportion of patients with IGA 0/1.

Figure 4 — Investigator's Global Assessment



For patients with mild-to-moderate AD, topically applied corticosteroids and emollients are the mainstay of therapy with the exact regimen based on severity, body area involved and degree of skin inflammation. Options include topical corticosteroids, topical calcineurin inhibitors (tacrolimus or pimecrolimus), crisaborole or topical ruxolitinub.

AD patients with persistent moderate-to-severe disease may require systemic treatment. mAbs have emerged as the preferred frontline therapy in most adult and pediatric patients with moderate-to-severe AD that is not controlled by topical therapies. There are four FDA approved mAbs, DUPIXENT, ADBRY, EBGLYSS, and NEMLUVIO, labeled to treat moderate-to-severe AD that is inadequately controlled by topical corticosteroids.

For patients for which biologics such as DUPIXENT, ADBRY, EBGLYSS, or NEMLUVIO do not provide adequate control of moderate-to-severe AD, systemic JAK inhibitors may be recommended. RINVOQ (upadacitinib) or CIBINQO (abrocitinib) are both FDA-approved treatments for AD that may be prescribed to patients who do not respond to topical prescription treatments or systemic drugs, including biologics. Despite their effectiveness and convenient oral administration, these therapies are associated with serious risk of life-threatening side effects and carry boxed warnings. FDA labels for these therapies require patients to step-through (prove non-responsive or inability to tolerate) a biologic before systemic JAK inhibitors are indicated. Serious side effects can include infections, mortality, malignancies, cardiovascular events, thrombosis, hypersensitivity, gastrointestinal perforation, various lab abnormalities and embryo-fetal toxicity. These toxicity challenges have limited clinical use of systemic JAK inhibitors for AD where patients are generally healthy and young. In 2025, systemic JAK inhibitors represented approximately 10% of the AD market based on revenue.

An emerging mechanism in treatments for AD is targeting OX40L, which occurs higher up in the inflammatory pathway than IL-13 or IL-4Rα and potentially broadens the impact on the inflammatory cascade. OX40L is the ligand for OX40. For additional information on AD treatments currently available or in development, see the section titled "—Competition" below.

Addressing the Limitations of Current Biologics

Despite recent advancements in AD treatment, a significant number of patients continue to suffer from active disease. Today's treatments are associated with many challenges, including a high frequency of injections that may lead to poor patient compliance. The dosing schedule of current biologics is driven by the short half-life for these agents, which provides a meaningful opportunity for a new treatment option with improved administration due to less frequent dosing.

High injection burden coupled with needle fatigue reported in adult patients has impacted the use of currently approved AD biologics. Based on a peer-reviewed third-party study of real-world use published in the Journal of the American Academy of Dermatology, more than 20% of patients discontinue treatment with DUPIXENT within six months of starting therapy. Pediatric patients in particular often suffer from fear of needles, which limits the use of current biologics in a large and growing patient population.

In 2025, we conducted, through an independent third-party, a blinded market research survey of 75 practicing healthcare professionals ("HCPs") comprised of dermatologists, allergists, and immunologists in the United States.

HCPs surveyed were screened for years of experience in the field, number of AD patients treated, and experience prescribing biologic therapies in AD. The HCPs that responded to the survey had an average of 16 years in practice, treated an average of 100 AD patients per month and treated a mix of both adult and adolescent patients.

The research included a survey aimed at understanding HCP perceptions and preferences on the current AD biologic market as well as a potential new treatment option with every three-month dosing in maintenance. We created a blinded Target Product Profile ("TPP") comprised of a potential indication statement and, dosing regimen, as well as efficacy and safety outcomes based the on zumilokibart (APG777) APEX Part A 16-week induction data.

Respondents were presented with TPPs for each of the currently marketed AD biologic treatments as well as a blinded TPP for zumilokibart. The blinded zumilokibart TPP was ranked as the most preferred biologic treatment by 60% of the respondents, and 79% of respondents indicated they would consider the blinded zumilokibart TPP their biologic of choice for the treatment of their moderate to severe AD patients. For those patients treated with the leading currently approved biologic for the treatment of moderate to severe AD and not well-controlled, 79% of HCPs expressed they were likely to prescribe the blinded zumilokibart TPP.

In 2025, we also conducted an independent blinded market research survey of 90 moderate to severe AD patients in the United States. The respondent pool consisted of 30 patients who had never been treated with a biologic, 30 biologic-treated AD patients that were well controlled, and 30 biologic-treated patients that were not well controlled on their current treatment. All patients had to be pharmacologically treated for at least four months by a dermatologist, allergist or immunologist for their AD.

The research included a survey aimed at understanding patient perceptions of the current AD treatment options and what dosing, clinical, and safety attributes are most important in a treatment. Similar to the HCP research, we created and presented a blinded TPP comprised of a potential indication statement and dosing regimen, as well as efficacy and safety outcomes based on the zumilokibart APEX Part A 16-week induction data.

The biologic naïve patient subgroup was asked about their likelihood of starting a biologic treatment if the blinded zumilokibart TPP was available on the market. 67% of the biologic naïve patients expressed a likelihood of starting biologic treatment. The biologic treated subgroups (well controlled and not well controlled), were asked about their likelihood of switching to the blinded zumilokibart TPP from their current medication if it were available on the market. 97% of the not well controlled patient respondents expressed they were likely to switch, and 90% of the well-controlled patient respondents expressed they were likely to switch. Patient respondents highlighted perceived efficacy data on skin clearance and itch, side effect profile, and once every three months maintenance dosing as reasons to consider starting or switching to the blinded zumilokibart TPP.

Overview of Asthma

Disease Overview

Asthma is one of the most common non-communicable diseases and, for a substantial number of patients, has an impact on quality of life. Asthma is estimated to affect 40 million adults and 12 million children in the United States, France, Germany, Italy, Japan, Spain and the United Kingdom, with prevalence rates of 5% to 8% in many countries. The global asthma biologics market is forecasted to grow to approximately $16B by 2028. Asthma is a complex multifactorial disease, attributed to interactions between genetic susceptibility, host factors and environmental exposures, which result in airway inflammation, control of airway tone and reactivity. The resulting clinical presentation can vary, but can result in shortness of breath, chest tightness or pain, coughing and wheezing. In the United States, asthma accounts for approximately five million physician visits, one million emergency room visits and thousands of deaths annually.

We believe asthma to be an important expansion opportunity for zumilokibart given the significant overlap with AD (31% according to third-party market research studies) and unmet need for extended dosing biologics that do not sacrifice clinical benefit. Patients with moderate-to-severe asthma who qualify and require biologic treatment have a serious condition that, when not treated appropriately, can lead to additional exacerbations and unnecessary emergency room and hospital visits. Extended duration therapies may lead to increased adherence rates with better control and outcomes for these patients.

Eosinophilic asthma is a recognized subtype associated with increased severity and late-onset asthma. IL-13 can induce immune activation and eosinophilic response broadly, and in the case of asthma, contribute to inflammation, airway hyperreactivity and recruitment of eosinophils to lung tissues. Further, in third-party clinical studies, IL-13 and eosinophils have been shown to be positively correlated in airway lumen. Thus, we believe targeting IL-13 in eosinophilic asthma is a compelling approach.

Overview of Current Treatment Options

Treatment of asthma focuses on control of asthma symptoms and reduction of asthma exacerbations. Exact treatments are based on severity and can include short-acting inhalers (e.g., short-acting beta agonists) used as needed, long-acting inhalers (e.g., long-acting beta agonists, inhaled corticosteroids) given daily or systemic medications, such as biologics.

Biologics, specifically, have begun to play an important role in the treatment of moderate-to-severe asthma, largely as an add-on to inhaled medication. XOLAIR was the first biologic approved for asthma in 2003 and subsequently, an additional five biologics have been approved since 2015 (NUCALA, CINQAIR, FASENRA, DUPIXENT, TEZSPIRE and EXDENSUR). For additional information on asthma treatments that are currently available or in development, see the section titled "—Competition" below.

Overview of Eosinophilic Esophagitis

Disease Overview

EoE is a chronic inflammatory condition of the esophagus, with the hallmark histological finding being eosinophilic infiltrates (i.e., presences of eosinophils in the tissue). When not treated appropriately, EoE progresses to cause scarring and strictures of the esophagus, which gives patients significant trouble with eating and drinking and potential nutritional compromise. Once considered a rare condition, incidence and prevalence rates have rapidly increased with EoE now being the most common cause of upper-gastrointestinal morbidity. The overall prevalence in the United States is approximately 1 in 700, up from 1 in 2,000 in 2014, with more than 400,000 Americans currently suffering from the condition.

Overview of Current Treatment Options

The only available biologic for the treatment of EoE is DUPIXENT, which was first approved for this indication in 2022 and later approved for patients aged 1 and older in 2024, and requires weekly dosing.

Overview of COPD

Disease Overview

COPD is a heterogenous, progressive respiratory condition characterized by cough, dyspnea and airflow obstruction. It is estimated that approximately 10% of the global population 40 years of age and older have COPD, and as of 2024, COPD was the fourth leading cause of death worldwide according to the World Health Organization. In the United States, over 150,000 people die of COPD each year.

Overview of Current Treatment Options

For stable COPD, inhaled bronchodilators (drugs that increase the size of the airways) are the mainstay of treatment. These include short-and long-acting beta-agonists (e.g., albuterol, salmeterol and formoterol), muscarinic agonists (e.g., tiotropium and aclidinium), and inhaled glucocorticoids (e.g., fluticasone and budesonide). For patients with refractory COPD, treatment options include chronic antibiotic use and DALIRESP (roflumilast).

The only available biologics for the treatment of COPD are DUPIXENT and NUCALA, which was approved in 2024. For additional information on COPD treatments that are currently available or in development, see the section titled "—Competition" below.

Additional Expansion Opportunities

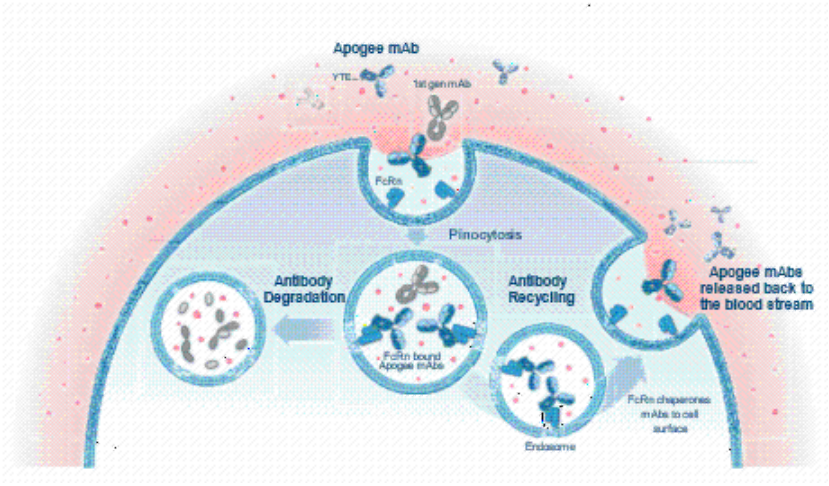
We believe that each of our product candidates has the potential to treat multiple additional I&I indications beyond AD, asthma, EoE and COPD, including Alopecia Areata, CRSwNP, Chronic Spontaneous Urticaria, and Prurigo Nodularis. Initial structured indication prioritization has identified asthma as a leading expansion opportunity given the significant overlap with AD and the clinical unmet need for extended dosing biologics that do not sacrifice clinical benefit. We may expand into additional I&I indications that are implicated in the disease pathways targeted by our current or future product candidates.

We do not yet have clinical data showing the ability of our product candidates to treat indications beyond AD and asthma and there can be no assurance that our product candidates will have similar or comparable results to any products or later-stage product candidates for these indications.

Half-Life Extension and Antibody Engineering Technologies

Our antibody engineering product candidates are designed to improve antibody candidate attributes, including half-life extension, in vitro potency, bioavailability and decreased PK variability, as well as those attributes essential for manufacturability and high concentration formulation (i.e. viscosity, solubility and stability) to generate optimized antibodies. Each of our product candidates utilize YTE or LS amino acid modifications and are designed to significantly extend the half-life of antibodies by supercharging the body's innate recycling mechanism for antibodies. Antibodies in circulation are naturally taken up by cells and degraded, which limits the half-life in circulation. Cells have evolved a mechanism to spare certain antibodies from degradation and return them to circulation, thus extending their half-life. This recycling mechanism works via the neonatal Fc receptor ("FcRn"). Antibodies are internalized into a cell via pinocytosis, the process of extracellular fluid and substances (including antibodies), being invaginated, or brought into, the cell resulting in an internalized vesicle. The process of pinocytosis is nonspecific, meaning uptake of fluid and substances is not regulated in any way. The internal vesical, or endosome, fuses with lysosomes, the specialized organelle or area in the cell that is able to break down and digest biomolecules. When antibodies are taken up by lysosomes, they can bind to FcRn on the membrane surface of the endosome in the acidic conditions within the lysosomes, which spares them from degradation. The antibody can then be returned to the cell surface with the membrane of the endosome and released back into circulation. This process is shown in Figure 5 below.

Figure 5 — Our half-life extended mAbs are designed to be recycled back into circulation more readily so drug exists at much higher levels for longer duration of effect



This natural mechanism of antibody recycling has been exploited by antibody engineers. Specifically, modifications to antibodies that increase the affinity for FcRn were developed in the early 2000s. One such modification was to the fragment crystallizable region ("Fc region") of antibodies in the form of a triple modification: M252Y/S254T/T256E. Referred to as "YTE amino acid modifications" due to the three amino acid changes, this triple modification has been observed to result in an approximately ten-fold increase in binding affinity of antibodies to FcRn compared to antibodies without YTE amino acid modifications in third-party studies. The increased affinity of antibodies with YTE amino acid modification for FcRn results in increased antibody recycling (i.e., less lysosomal degradation) and a prolonged half-life. LS is a double amino acid modification (M428L/N434S) that works similarly to YTE amino acid modifications and increases the antibodies affinity for FcRn, which leads to a prolonged half-life compared to wild type counterparts.

There is the potential for at least two significant benefits to antibodies that are engineered with a half-life extension amino acid modification:

- **Significantly increased half-life, leading to the potential for greater duration of effect.** The typical half-life for an IgG antibody is typically 11 to 30 days. By contrast, IgG antibodies with half-life extension amino acid modifications, such as YTE, have the potential to increase human half-life several fold compared to non-YTE mAbs, with half-lives for our first four YTE mAb product candidates having demonstrated to range from 55 days to 77 days. The half-life extension allows the drug to remain in the body for a longer period of time and therefore have additional action. The prolonged half-life results in more sustained concentrations, or levels of drug in the blood stream, often measured in area under the curve (AUC) between two time points.
- **Decreased variability in drug exposure from person to person, leading to the potential for more consistent clinical outcomes.** The magnitude of half-life extension that YTE amino acid modification confers has been observed to be relatively consistent from person to person in third-party trials. For this reason, the typical factors that can vary amongst different people and give rise to variability in drug exposure from person to person have less of an impact for YTE antibodies. Decreased variability in exposure from one person to the next means the amount of drug in the body is more similar from one person to the next, which could help to better predict how people respond to the drug.

Half-life extension amino acid modifications, such as YTE and LS amino acid modifications, have been introduced to monoclonal IgG1 in a wide variety of human therapeutics.

Zumilokibart (APG777)

Zumilokibart leverages YTE amino acid modifications half-life extension technology and is an SQ mAb targeting IL-13.

Zumilokibart 's target, IL13, has no known non-disease function

Zumilokibart's target, IL-13, is a cytokine with no known non-disease function such as growth or metabolism. IL-13 is a cytokine primarily produced by activated Th2 cells. Its primary role in normal physiology is to generate a Th2 response to parasitic infection. While increased IL-13 production has been implicated in a variety of indications, such as AD, asthma and certain types of cancer, the absence of IL-13 in animal models has not been tied to disease. In third-party studies, mice that lacked IL-13 (IL-13−/− knockout mice) were observed to be healthy and exhibited normal behavior under typical laboratory conditions.

IL-13 signaling begins with the binding of IL-13 to IL-13Rα1, forming an inactive complex that then binds to IL-4Rα to form the complete, active receptor heterodimer. The active receptor recruits members of the JAK family of enzymes, triggering a signaling cascade that results in the expression of pro-inflammatory cytokines and leads to an immune response by the body.

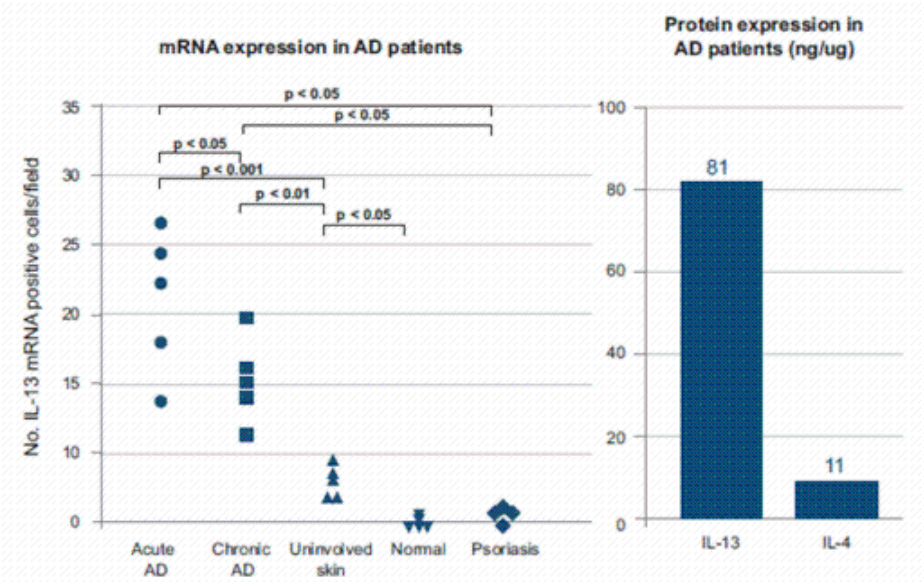
IL-13 is a known driver of AD pathogenesis and broader I&I indications

The pathogenesis, or underlying molecular cause of the disease, of AD involves both genetic and environmental factors that interact to produce a complex immune response. Genetic factors associated with AD include variations in genes that regulate the immune response, such as those encoding for IL-4, IL-13 and IL-31.

AD is characterized by a Th2 response, which describes Th2 cells, a subset of white blood cells, that produce small proteins called cytosine, like IL-13, which regulate inflammation, immune response and tissue repair. Overactivation of Th2 cells contributes to several allergic diseases, including AD, and chronic dysregulation of cytokine production and signaling leads to chronic inflammation and skin barrier dysfunction in AD.

More specifically, IL-4, IL-5 and IL-13 are all associated with Th2 response and IL-4 and IL-13 play a key role in the impairment of the skin barrier in AD, which leads to transepidermal water loss and susceptibility to irritants and allergens, creating an inflammatory positive feedback loop that is characteristic of AD. In third-party studies, IL-13 was observed to be elevated in skin lesions of patients with both acute and chronic AD compared to uninvolved skin and normal skin (see left panel of Figure 6 below) and was shown to be elevated to a greater extent than IL-4 in the skin of AD patients (see right panel of Figure 6 below).

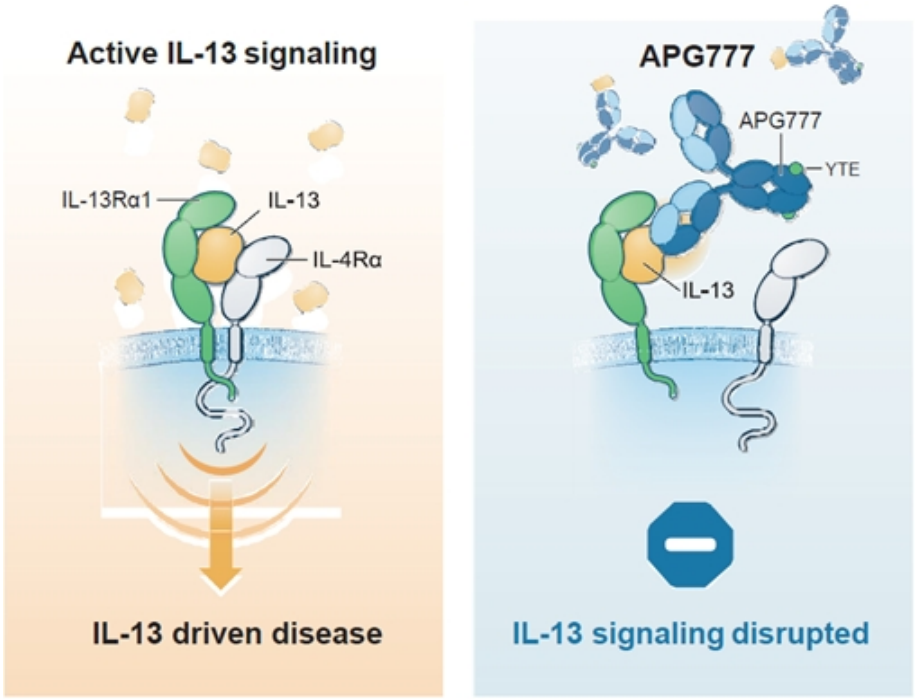
Figure 6 — Cytokine expression in AD and Non-AD skin samples in third-party studies



Sources: Hamid Q et al. J Allergy Clin Immunol. 1996 Jul;98(1). Koppes SA et al. Int Arch Allergy Immunol. 2016;170(3).

IL-13 signals through the formation of the IL-13Rα1-IL4Rα heterodimer. In turn, the active IL-13Rα1-IL4Rα heterodimer, through a signaling cascade, leads to skin barrier defects, immune cell recruitment, tissue inflammation, lichenification (skin thickening) and pruritis (skin itching). Zumilokibart is designed to interrupt the heterodimer formation and thus disrupt IL-13 signaling as shown in Figure 7 below.

Figure 7 — Zumilokibart is designed to disrupt IL-13 signaling by preventing the formation of the IL-13Rα1-IL4Rα heterodimer



APG279

We are developing zumilokibart and APG990 together as a potential first-in-class coformulation combining deep and sustained inhibition of Type 2 inflammation via zumilokibart's inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990's inhibition of OX40L. APG990 is an SQ extended half-life mAb targeting OX40L.

OX40L is the ligand for OX40 expressed on antigen presenting cells. Its interaction with OX40 causes the accumulation of T cells by providing a survival signal. T cells are important types of white blood cells of the immune system that play a central role in the immune response. OX40L, by playing a role in activating T cells and reprogramming them into inflammatory subsets, contributes to immune overactivation in AD and other inflammatory conditions. OX40-OX40L interaction has been implicated in a broad range of inflammatory and autoimmune diseases, including Inflammatory Bowel Disease, asthma, diabetes, arthritis, atherosclerosis, transplant rejection, GVHD and Systemic Lupus Erythematosus. Additionally, OX40L activation of OX40 inhibits the expression of FOXP3 and the inhibitory function of regulatory T (Treg) cells. Treg cells can suppress the immune response that leads to worsening symptoms in inflammatory conditions.

OX40L blockade therefore has two mechanisms by which it might have impact on the pathology associated with inflammatory conditions, first by suppressing inflammatory T cell activation, and second by increasing the proliferation of Treg cells, which can serve to further reduce effector T cell function.

Currently, there are three mechanisms of action targeted by approved biologic agents in atopic dermatitis, IL-13, IL-4Rα, and IL-31R. Targeting OX40L could represent an additional mechanism of action. OX40L, which is positioned further upstream in the inflammatory pathway than IL-13, may allow for a potentially broader impact on the inflammatory cascade by inhibiting Type 1, Type 2, and Type 3 pathways.

Potential clinical benefit of targeting both IL-13 and OX40L

In preclinical studies, the combination of APG279 has been shown to drive closer to JAK-like inhibition of Type 1, 2, and 3 signaling compared to approved or in-development biologics, with the potential for best-in-class dosing and better tolerability in AD and a variety of other I&I diseases. We are currently testing the clinical benefit of APG279 as a coformulation in the Phase 1b trial of APG279 against DUPIXENT in patients with moderate-to-severe AD.

APG273

We are developing zumilokibart and APG333 together as APG273, a potential quarterly or less frequently dosed co-formulation for the treatment of asthma and COPD.

APG333 is a fully-human mAb against TSLP. TSLP is an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of people living with asthma and COPD. APG333 has the potential to be used in combination with other mAbs for potentially greater efficacy in broader populations.

TSLP is a cytokine belonging to the alarmin family that is involved in the activation and modulation of the immune system. TSLP is primarily produced by epithelial cells in response to tissue damage by a variety of agents (allergens, viruses, bacteria, etc.) and functions as a potent immune activator by agonizing a heterodimeric complex composed of the TSLPR and IL-7Ra. Formation of the TSLP-TSLPR-IL7Rα heterocomplex activates downstream signaling pathways that regulate a wide array of immune functions, including epithelial barrier dysfunction, dendritic cell activation, and type 2 ILC2s activation/survival. TSLP signaling also drives the recruitment of immune cells, the induction of Th2 responses, and the regulation of B cell function, explaining its involvement in tissue homeostasis, host defense, and the pathophysiology of allergic and inflammatory diseases including asthma and COPD.

TSLP plays important roles in Type 2 and Type 3 inflammation and TSLP inhibition has shown clinical benefit in both eosinophilic and non-eosinophilic asthma. TSLP inhibition has been clinically validated, with the only approved product on the market for the treatment of severe asthma without biomarker or phenotype restrictions. Currently, other mechanisms targeted by approved biologic agents in asthma include IL-4Ra, IL-5, IL-5R and IgE. Mechanisms of approved biologic agents in COPD are IL-4Ra and IL-5.

Potential clinical benefit of targeting both IL-13 and TSLP

In preclinical studies, the combination of zumilokibart and APG333 has been shown to drive both inhibition of inflammation centrally and local airway responses compared to approved or in-development biologics, which only target central or local inflammation, with the potential for a significantly less frequent dosing schedule.

APG808

APG808 is an SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight different Type 2 allergic diseases. By blocking IL-4Rα, we believe APG808 will prevent formation of the IL-13Rα1-IL-4Rα heterodimer, which is understood to be a key pathogenic step in multiple Th2-driven diseases such as AD, asthma, COPD and CRSwNP. Preventing the formation of the IL-13Rα1-IL-4Rα heterodimer in turn prevents recruitment of members of the JAK family of enzymes and prevents the signaling cascade that results in the expression of pro-inflammatory cytokines and leads to an immune response by the body in these diseases.

Our Collaboration, License and Services Agreements

Paragon Option Agreements

In February 2022, we entered into an antibody discovery and option agreement with Paragon, which was subsequently amended in November 2022 (as amended, the "2022 Option Agreement"). Under the terms of the 2022 Option Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. The 2022 Option Agreement initially included two selected targets, IL-13 and IL-4Rα, and was subsequently amended in November 2022 to include an additional selected target, OX40L. Under the

2022 Option Agreement, we have the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets (each, an "Option"). From time to time, we can choose to add additional targets to the collaboration by mutual agreement with Paragon.

Pursuant to the terms of the 2022 Option Agreement, the parties initiated certain research programs that generally focused on a particular target (each, a "Research Program"). Each Research Program is aimed at discovering, generating, identifying and/or characterizing antibodies directed to the respective target. For each Research Program, the parties established a research plan that sets forth the activities that will be conducted, and the associated research budget (each, a "Research Plan"). Upon execution of the 2022 Option Agreement, we agreed with Paragon on an initial Research Plan that outlined the services that will be performed commencing at inception of the arrangement related to IL-13 and IL-4Rα. The Research Plan for OX40L was agreed to prior to December 31, 2022. Our exclusive option with respect to any future Research Program is exercisable at our sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Plan activities (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the 2022 Option Agreement.

In consideration for the exclusive options granted under the 2022 Option Agreement, we paid an upfront cash amount of $1.3 million and issued 1,250,000 common units to Paragon. Paragon was also entitled to up to an additional 3,750,000 of common units in exchange for the rights granted under the 2022 Option Agreement, which were issued in connection with the closings of the additional tranches of the Series A preferred unit ("Series A Preferred Unit") financing. Under the 2022 Option Agreement, on a Research Program-by-Research Program basis following the finalization of the Research Plan for each respective Research Program, we are required to pay Paragon a nonrefundable fee in cash of $0.5 million. We are also obligated to compensate Paragon on a quarterly basis for its services performed under each Research Program based on the actual costs incurred.

In November 2023, we entered into an additional antibody discovery and option agreement with Paragon (the "2023 Option Agreement" and together with the 2022 Option Agreement, collectively, the "Option Agreements"). Under the terms of the 2023 Option Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. The 2023 Option Agreement initially includes one target, TSLP. Under the 2023 Option Agreement, we have the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets. From time to time, we can choose to add additional targets to the collaboration by mutual agreement with Paragon.

Pursuant to the terms of the 2023 Option Agreement, the parties may initiate Research Programs. Each Research Program will be aimed at discovering, generating, identifying and/or characterizing antibodies directed to the respective target. For each Research Program, the parties must establish a Research Plan. In January 2024, we agreed on an initial Research Plan with Paragon that outlined the services that would be performed commencing at inception of the arrangement related to TSLP. Our exclusive option with respect to each Research Program is exercisable at our sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Plan activities. There is no payment due upon exercise of an Option pursuant to the 2023 Option Agreement.

Under the 2023 Option Agreement, on a Research Program-by-Research Program basis following the finalization of the Research Plan for each respective Research Program, we are required to pay Paragon a nonrefundable fee in cash of $2.0 million. We are also obligated to compensate Paragon on a quarterly basis for its services performed under each Research Program based on the actual costs incurred. We expense the service fees as the associated costs are incurred when the underlying services are rendered. In January 2024, we finalized the Research Plan with Paragon related to the TSLP target. As such, we made a one-time non-refundable payment of $2.0 million to Paragon in the first quarter of 2024.

Unless terminated earlier, the Option Agreements shall continue in force on a Research Program-by-Research Program basis until the earlier of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by us; and (ii) the effective date of the license agreement for such Research Program if we exercise our Option with respect to such Research Program (the "Term"). Upon the expiration of the Term for all then-existing Research Programs, the applicable Option Agreement will automatically expire in its entirety. We may terminate either Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that we must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Each party has the right to terminate either Option Agreement or any Research Program upon (i) 30 days' prior written notice of the other party's material breach that remains uncured for the 30-day period and (ii) the other party's bankruptcy.

Paragon License Agreements

In November 2022, we exercised our option available under the 2022 Option Agreement with respect to the IL-13 Research Program. Upon such exercise, the parties entered into an associated license agreement (the "IL-13 License Agreement"). In April 2023, we exercised our option available under the 2022 Option Agreement with respect to the IL-4Rα Research Program and the OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the "IL-4Rα License Agreement" and the "OX40L License Agreement," respectively). In August 2024, we exercised our option available under the 2023 Option Agreement with respect to the TSLP Research Program and entered into the associated license agreement (the "TSLP License Agreement," and collectively with the IL-13 License Agreement, the IL-4Rα License Agreement and the OX40L License Agreement, the "License Agreements"). Under the terms of the License Agreements, Paragon granted to us an exclusive, worldwide, royalty-bearing, sublicensable right and license with respect to certain information, patent rights and sequence information related to antibodies directed at the respective target to use, make, sell, import, export and otherwise exploit the antibodies directed at the respective target. Pursuant to the License Agreements, we granted to Paragon a similar license (except that such license we granted to Paragon is non-exclusive) to the respective licenses with respect to multispecific antibodies that are directed at the respective targets and one or more other antibodies. We were also granted a right of first negotiation with Paragon concerning the development, license and grant of rights to certain multispecific antibodies associated with each respective license. We are solely responsible for the continued development, manufacture and commercialization of products at our own cost and expense for each licensed target.

Under the IL-13 License Agreement, the IL-4Rα License Agreement and the OX40L License Agreement, we are obligated to pay Paragon up to $3.0 million upon the achievement of specific development and clinical milestones for the first product under each of the License Agreements that achieves such specified milestones, including a payment of $1.0 million upon the nomination of a development candidate and $2.0 million upon the first dosing of a human patient in a Phase 1 trial. Under the TSLP License Agreement, we are obligated to pay Paragon up to $28.0 million upon the achievement of specific development and clinical milestones for the first product, including a payment of $3.0 million upon the nomination of a development candidate and $5.0 million upon the first dosing of a human patient in a Phase 1 trial.

Upon execution of the IL-13 License Agreement, we paid Paragon a $1.0 million fee for the nomination of a development candidate. In August 2023, we announced the dosing of our first participant in the Phase 1 trial of zumilokibart (APG777) and made a milestone payment of $2.0 million in the fourth quarter of 2023. In November 2023, we finalized the nomination of a development candidate under the IL-4Rα License Agreement and made a milestone payment of $1.0 million to Paragon in the fourth quarter of 2023. In March 2024, we announced the dosing of our first participant in a Phase 1 trial of APG808 and made a milestone payment of $2.0 million to Paragon in the first quarter of 2024. In May 2024, we finalized the nomination of a development candidate under the OX40L License Agreement and made a milestone payment of $1.0 million to Paragon in the second quarter of 2024. In August 2024, we announced the dosing of our first participant in the Phase 1 trial of APG990 and made a milestone payment of $2.0 million in the third quarter of 2024. In October 2024, we finalized the nomination of a development candidate under the TSLP License Agreement and made a milestone payment of $3.0 million to Paragon in the fourth quarter of 2024. In December 2024, we announced the dosing of our first participant in the Phase 1 trial of APG333 and made a milestone payment of $5.0 million in the fourth quarter of 2024.

We are also obligated to pay royalties to Paragon equal to a low-single digit percentage of net sales of any products under each of the respective License Agreements, and Paragon has a similar obligation to pay royalties to us with respect to each of the multispecific licenses. Royalties are due on a product-by-product and country-by-country basis beginning upon the first commercial sale of each product and ending on the later of (i) 12 years after the first commercial sale of such product in such country and (ii) expiration of the last valid claim of a patent covering such product in such country.

Unless earlier terminated, the License Agreements remain in effect until the expiration of the last-to-expire Royalty Term for any and all products associated with the respective license. We may terminate the agreement in its entirety or on a country-by-country or product-by-product at any time for any or no reason upon 60 days' advance written notice to Paragon, and either party may terminate for (i) the other party's material breach that remains uncured for 90 days (or 30 days with respect to any failure to make payments) following notice of such breach and (ii) the other party's bankruptcy. Upon any termination prior to the expiration of a License Agreement, all licenses and rights granted pursuant to such License Agreement will automatically terminate and revert to the granting party and all other rights and obligations of the parties will terminate.

Biologics Master Services Agreement — WuXi Biologics (Hong Kong) Limited

In June 2022, Paragon and WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") entered into a biologics master services agreement (the "WuXi Biologics MSA"), which was subsequently novated to us by Paragon in the second quarter of 2023. The WuXi Biologics MSA governs all development activities and GMP manufacturing and testing for zumilokibart (APG777), APG990, APG333 and APG808, as well as potential future product candidates, on a work order basis. Under the WuXi Biologics MSA, we are obligated to pay WuXi Biologics a service fee and all non-cancellable obligations in the amount specified in each work order associated with the agreement for the provision of services.

The WuXi Biologics MSA terminates on the later of (i) June 20, 2027 or (ii) the completion of services under all work orders executed by the parties prior to June 20, 2027, unless terminated earlier. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier. We can terminate the WuXi Biologics MSA or any work order at any time upon 30 days' prior written notice and immediately upon written notice if WuXi Biologics fails to obtain or maintain required material governmental licenses or approvals. Either party may terminate a work order (i) at any time upon six months' prior notice with reasonable cause, provided however that if WuXi Biologics terminates a work order in such manner, no termination or cancellation fees shall be paid by us and (ii) immediately for cause upon (a) the other party's material breach that remains uncured for 30 days after notice of such breach, (b) the other party's bankruptcy or (c) a force majeure event that prevents performance for a period of at least 90 days.

Cell Line License Agreement — WuXi Biologics (Hong Kong) Limited

In June 2022, Paragon and WuXi Biologics entered into a cell line license agreement (the "Cell Line License Agreement"), which was subsequently novated to us by Paragon in the second quarter of 2023. Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used to manufacture zumilokibart (APG777), APG990, APG333 and APG808.

In consideration for the license, we have paid WuXi Biologics a non-refundable license fee of $150,000. Additionally, if we manufacture all of our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the "Royalty"). If we manufacture part of our commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Master Services Agreement and Project Specific Agreements — Samsung Biologics Limited

In March 2025, we entered into a Master Services Agreement (the "Samsung Biologics MSA"), made effective as of February 28, 2025, with Samsung Biologics Co., Ltd. ("Samsung Biologics"), pursuant to which Samsung Biologics will manufacture and supply us with zumilokibart (APG777) drug substance (the "Samsung Biologics Product") for clinical development and commercial sale, if approved. We are obligated to pay Samsung Biologics service fees for each manufactured batch, as well as the costs of materials purchased by Samsung Biologics and expenses including testing and storage, which such costs and fees will be specified in Project Specific Agreements (each a "PSA").

Also in March 2025, we entered into a PSA (the "Initial PSA") with Samsung Biologics, made effective as of February 28, 2025, pursuant to which Samsung Biologics will produce clinical batches of the Samsung Biologics Product at its facility in Incheon, South Korea, perform process characterization and validation, and manufacture process performance qualification lots of the Samsung Biologics Product. Under the Initial PSA, we must purchase certain minimum quantities of the Samsung Biologics Product and have agreed to pay Samsung Biologics as determined pursuant to the terms of the Initial PSA.

The Samsung Biologics MSA will terminate in February 2035, or, if a PSA is still in effect, when such PSA terminates, and may be extended upon mutual agreement of the parties. The Initial PSA will terminate in December 2034. We or Samsung Biologics may terminate the Samsung Biologics MSA or the Initial PSA in the event of an uncured material breach by, insolvency of or inability to perform due to a force majeure event by the other party. In the event all applicable PSAs have been terminated, Samsung Biologics has agreed to provide assistance with certain technology transfer matters, subject to exceptions. If we terminate the Samsung Biologics MSA or Initial PSA without cause, we will generally be responsible for paying the purchase price for our aggregate product commitment for the remainder of the term, less any amounts we have already paid.

In February 2026, the Company entered into a separate PSA with Samsung that would provide for the commercial manufacture of zumilokibart drug substance should the program eventually receive regulatory approval. If specific circumstances render Apogee unable to proceed with commercial distribution, the PSA provides for Samsung to receive compensation, including for contractually obligated expenses, and an exit fee in the high single-digit millions.

For additional detail regarding the agreements described above, see the section titled "Notes to Consolidated Financial Statements—Other Significant Agreements" included elsewhere in this Annual Report.

Competition

The biotechnology and biopharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, development experience and scientific knowledge provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Many of the companies with which we are currently competing or will complete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, clinical and management personnel, establishing clinical trial sites, patient

enrollment for clinical trials as well as in acquiring technologies complementary to, or necessary for, our programs. Key competitive factors affecting the success of all our product candidates that we develop, if approved, are likely to be efficacy, safety, convenience, presentation, price, the level of generic competition and the availability of reimbursement from government and other third-party payors. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, there are several companies, including major pharmaceutical companies, developing or marketing treatments that may be approved for the same indications and/or disease as our product candidates. We are early in the clinical development stage of our product candidates and there can be no assurance that our product candidates will have similar or comparable results.

Over time, I&I markets have developed with a general increasing number of competitors, improved efficacy and improved dosing intervals (i.e. less frequent dosing). Psoriasis is one example of how an I&I market has developed. ENBREL was first approved for psoriasis in 2004 with an every week maintenance dosing schedule. Four years after ENBREL's approval for psoriasis, HUMIRA was approved in 2008 for psoriasis with an every other week dosing schedule. STELARA was approved a year later with similar Phase 3 data, as measured by the percentage of patients achieving PASI-75 (change in psoriasis area and severity index ("PASI") score from baseline of at least 75%), but with a significantly improved dosing schedule of every twelve weeks. A number of psoriasis drugs have been approved since 2009 that demonstrated higher PASI-75 or PASI-90 scores in their pivotal studies as compared to STELARA, but have a more burdensome dosing schedule and have not been able to attain the same level of estimated psoriasis annual sales. Among those drugs are COSENTYX and TALTZ, which have dosing schedules of every four weeks. The only drug in the psoriasis market that is projected to achieve similar estimated psoriasis annual sales to STELARA is SKYRIZI, which has a similar dosing schedule of every twelve weeks, but also provided modest improvements in outcomes, as evidenced by higher PASI-75 scores in clinical trials. While the AD market has shown similarities to the psoriasis market to date, there can be no assurance that the AD market will develop in a similar or comparable manner to psoriasis.

There are several approved products for moderate-to-severe AD, such as dupilumab, an IL-4Rα mAb marketed as DUPIXENT by Sanofi/Regeneron, lebrikizumab, an IL-13 mAb marketed as EBGLYSS by Lilly, tralokinumab-ldrm, an IL-13 mAb marketed as ADBRY by LEO Pharmaceuticals, and nemolizumab, an anti-IL-31Rα mAb marketed as NEMLUVIO in the U.S. and the European Union ("EU") by Galderma and MITCHGA in Japan by Maruho Co., Ltd. There are several approved treatments that target JAK1 and/or JAK2 to treat AD, including abrocitinib, marketed as CIBINQO by Pfizer, and upadacitinib, marketed as RINVOQ by AbbVie.

We are also aware of several product candidates in clinical development for AD, including but not limited to:

- ***Phase 3***: Amlitelimab, an OX40L mAb, by Sanofi; and rocatinlimab, a T-cell rebalancing mAb that targets the OX40 receptor, by Kyowa Kirin Co., Ltd.; and
- ***Phase 2***: rezpegaldesleukin, an anti-IL-2, by NEKTAR; temptokibart, an anti-IL-22R, by LEO Pharma; KT-621, an oral STAT6 degrader, by Kymera; GHZ339, an anti-IL-13/IL-18, by Novartis; EVO756, an MRGPRX2 inhibitor, by Evommune; PF-08049820, a STAT6 inhibitor, by Pfizer; lunsekimig, an anti-IL-13/TSLP nanobody, by Sanofi; IMG-007, an anti-OX40, by InmageneBio; and galvokimig an anti-IL-13/IL-17AF, by UCB; EVO301, an anti-IL-18 fusion protein, by Evommune; camoteskimab, an anti-IL-18, by Apollo; donzakimig, an anti-IL-13/IL-22, by UCB.

Advanced therapy penetration in AD is currently expected to ramp up from 8% in 2022 to approximately 25% by 2032. With more convenient and patient-friendly dosing, and potentially better efficacy, we believe that the market for future penetration of biologics could expand even beyond the projected 25%.

There are several approved products for the treatment of asthma, including dupilumab, an IL-4Rα mAb marketed as DUPIXENT by Sanofi/Regeneron, omalizumab, an anti-IgE mAb marketed as XOLAIR by Genentech/Novartis, mepolizumab, an anti-IL-5 mAb marketed as NUCALA by GSK, reslizumab, an anti-IL-5 mAb marketed as CINQAIR by Teva, benralizumab, an anti-IL-5Rα mAb marketed as FASENRA by AstraZeneca,

tezepelumab, an anti-TSLP mAb marketed as TEZSPIRE by Amgen/AstraZeneca, and depemokimab, an anti-IL-5 mAb marketed as EXDENSUR by GSK.

We are also aware of several product candidates in clinical development for asthma, including but not limited to:

- ***Phase 3***: GB-0895, a TSLP mAb, by Generate Bio; and
- ***Phase 2***: Lunsekimig, a IL-13/TSLP nanobody, by Sanofi, PF-07275315, an anti-IL-4/IL-13/TSLP multispecific, by Pfizer, amlitelimab, an anti-OX40L mAb, by Sanofi, verekitug, an anti-TSLPR mAb, by Upstream Bio, rocatinlimab, an anti-OX40 mAb, by Amgen, BEL512, an anti-IL-13/TSLP bispecific, by Bellenos Bio, WIN378, an anti-TSLP mAb, by Winward Bio, solrikitug, a anti-TSLP mAb, by Uniquity, KT-621, an oral STAT6 degrader, by Kymera Therapeutics, rademikibart, an anti-IL-4Rα mAb, by Connect Bio, atuliflapon, an oral FLAP inhibitor, by AstraZeneca, povorcitinib, an oral JAK1 inhibitor, by Incyte.

The only available biologic for the treatment of EoE is DUPIXENT. There are several approved products for COPD, including DUPIXENT, NUCALA and OHTUVAYRE (ensifentrine), a PDE3/PDE4 inhibitor from Verona Pharma.

We are aware of several other biologics in development that are implicated in the disease pathways targeted by our current product candidates, including but not limited to:

- ***Phase 3***: mepolizumab, an anti-IL-5 mAb from GSK; itepekimab, an anti-IL-33 mAb from Sanofi/Regeneron; tozorakimab, an anti-IL-33 mAb from AstraZeneca; benralizumab, an anti-IL-5R mAb, from AstraZeneca; tezepelumab, a anti-TSLP mAb from AstraZeneca/Amgen; and astegolimab, an anti-ST2 mAb from Roche.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. All of our preclinical and clinical drug supply development, manufacturing, storage, distribution and testing are outsourced to third-party manufacturers and facilities. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development, and commercialization of our product candidates rather than diverting resources to internally develop and maintain manufacturing facilities. As our product candidates advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our supply needs.

With our contract development and manufacturing organizations, we have developed, or expect to develop, high yield, industry standard mAb drug manufacturing processes suitable for preclinical supply, as well as clinical and commercial scale manufacturing. We have developed, or expect to develop, industry standard sterile liquid drug product formulations, presentations, and manufacturing processes to enable SQ delivery of all of our planned clinical development candidates. We have successfully manufactured zumilokibart (APG777) drug substance at commercial scale for clinical trial use, and we have successfully manufactured zumilokibart drug product at clinical scale with acceptable yields for near-term, planned clinical trials. Our formulation for zumilokibart is suitable for SQ injection. By the time of commercialization, we expect zumilokibart to be administered via a pre-filled syringe and/or autoinjector. We use a similar approach to the development and supply for the following product candidates: APG990 (as a combination partner with zumilokibart for APG279), APG333 (as a combination partner with zumilokibart for APG273), and APG808. APG990, APG333, and APG808 drug substance and drug product have been successfully manufactured at clinical scale with acceptable yields for use in our planned clinical trials.

While we expect to continue to devote significant resources to process development, scale-up, manufacturing resupply and registration-enabling validation activities for zumilokibart, we believe the manufacturing processes for mAbs such as zumilokibart are well established and should not create meaningful impediments to either clinical development or commercial launch. We have created redundancy in our clinical supply by contracting with second source drug substance and drug product manufacturers. We currently have two sources for our preclinical and clinical supply of zumilokibart drug substance and drug product, and have entered into agreement for the commercial supply

of zumilokibart drug substance should the product candidate eventually receive regulatory approval, and we are working to finalize the terms of our potential commercial supply arrangement for zumilokibart drug product. We have a sole source relationship for our preclinical and clinical supply of APG990 (as a combination partner with zumilokibart for APG279), APG333 (as a combination partner with zumilokibart for APG273), and APG808 drug substance and drug product. We will continue to identify additional drug substance and drug product contract manufacturers to ensure that we will have sufficient capacity as well as redundancy within our supply chain to avoid product shortages in the future due to geopolitical uncertainties and other risks. We will also continue to invest in development activities to ensure an acceptable cost of goods. We will also continue to apply mitigation strategies to ensure minimal disruption to our manufacturing supply due to any future global raw material supply chain shortages. We believe there are multiple sources for the raw materials required for the manufacture of our product candidates. While any reduction or halt in the supply of raw materials, drug substance or drug product could limit our ability to develop our product candidates until a replacement supplier or contract manufacturer is found and qualified, we believe that we have or will be able to manufacture sufficient clinical supply of zumilokibart, APG990 (as a combination partner with zumilokibart for APG279), APG333 (as a combination partner with zumilokibart for APG273), and APG808, as well as future pipeline products, to support our planned clinical trials, and have access to sufficient manufacturing capacity to support our planned clinical development program.

In light of the BIOSECURE Act, which prohibits federal agencies from entering into procurement contracts with an entity that uses biotechnology equipment or services from a biotechnology company of concern, we continue to take risk mitigation measures to reduce our supply chain risk in the event that WuXi Biologics, Samsung Biologics or one of our other manufacturers or other supply chain vendors is impacted, including by continuing to identify and select additional source suppliers, including those based in the U.S. and EU, for our contract development, manufacturing, testing, and storage needs. We will also continue to closely monitor geopolitical risk and implement additional mitigation plans and supply chain redundancies, as needed. See the section titled, Risk Factor - Risks Related to Our Reliance on Third Parties - "*We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our programs.*"

Intellectual Property

Overview

We strive to protect the proprietary product candidates and technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technologies, diagnostics, and other inventions.

Patent Rights Relating to Our IL-13 Program

As of January 31, 2026, we own eight patent families directed to antibodies that target IL-13, including zumilokibart (APG777), pharmaceutical formulations and compositions, and methods of using those antibodies. The first patent family is directed to compositions of matter and includes patent applications filed in the U.S. and in foreign jurisdictions including Europe, Japan and China. A U.S. patent in this family issued on July 15, 2025; it is U.S. Patent No. 12,358,979. We expect this patent to expire on June 16, 2043, absent any applicable patent term extension. If other patents issue from this family we would expect these patents to expire in 2043, absent any applicable patent term extensions. The second patent family is directed to methods of using zumilokibart and includes patent applications filed in the U.S. and in foreign jurisdictions, including Europe, Japan and China. If any of these patent applications mature into one or more issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. The third patent family is directed to pharmaceutical formulations containing zumilokibart and includes a Patent Cooperation Treaty ("PCT") application. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. The fourth patent family is directed to other zumilokibart compositions and includes a PCT application and applications filed in Argentina and Taiwan. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, or the Argentina or Taiwan applications mature into one or more issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. The fifth patent family is directed to methods of administering zumilokibart and includes a PCT

application. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The sixth patent family is directed to compositions of zumilokibart in combination with hyaluronidase or a variant thereof and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The seventh patent family is directed to the administration of zumilokibart to treat asthma and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, we would expect those patents to expire in 2046, absent any applicable patent term extensions. The remaining patent family is directed to compositions of anti-IL-13 antibodies and, as of January 31, 2026, includes one provisional application. If this provisional application is pursued non-provisionally and matures into one or more issued patents, we would expect those patents to expire in 2046, absent any applicable patent term extensions.

Patent Rights Relating to Our OX40L Program

As of January 31, 2026, we own four patent families directed to antibodies that target OX40L, including APG990, and methods of using those antibodies and formulations thereof. The first patent family has applications pending in the U.S. and in foreign jurisdictions including Europe, Japan and China. If any of these applications matures into one or more issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. The second patent family is directed to methods of administering anti-OX40L antibodies and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The third patent family is directed to compositions of APG990 in combination with hyaluronidase or a variant thereof and includes a U.S. application. If the U.S. application matures into an issued patent, we would expect that patent to expire in 2045, absent any applicable patent term extensions. The fourth patent family is directed to pharmaceutical formulations including APG990 and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions.

Patent Rights Relating to Our TSLP Program

As of January 31, 2026, we have licensed one patent family from Paragon directed to antibodies that target TSLP that have half-life extending mutations made to the Fc region of the antibody. This family includes applications in the U.S., Europe, Japa and China. If these applications are pursued and mature into one or more issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. We have also licensed one patent family from Paragon directed to antibodies that target TSLP, including APG333, and methods of using those antibodies. This family includes a PCT application and applications filed in Argentina and Taiwan. If this PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, or the Argentinian or Taiwanese applications are pursued and mature into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. We also own two patent families directed to anti-TSLP antibodies, including APG333. One family is directed to methods of administering anti-TSLP antibodies, including APG333, and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The other family is directed to compositions of anti-TSLP antibodies such as APG333 in combination with hyaluronidase or a variant thereof and includes a U.S. application. If the U.S. application matures into an issued patent, we would expect that patent to expire in 2045, absent any applicable patent term extensions.

Patent Rights Relating to Our IL-4Ra Program

As of January 31, 2026, we own four patent families directed to antibodies that target IL-4Ra, including APG808, and methods of using those antibodies. The first patent family includes applications filed in the U.S. and in foreign jurisdictions including Europe, Japan and China. If any of these applications matures into one or more issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. The second patent family is directed to methods of using APG808 and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The third patent family is directed to

compositions of APG808 in combination with hyaluronidase or a variant thereof and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The fourth patent family is directed to combinations of anti-IL-4Ra and anti-TSLP or anti-TSLPR antibodies and, as of January 31, 2026, includes two provisional applications. If these provisional applications are pursued non-provisionally and mature into one or more issued patents, we would expect those patents to expire in 2046, absent any applicable patent term extensions.

Patent Rights Relating to Our Combination Programs

As of January 31, 2026, we own seven patent families directed to combinations of zumilokibart, APG990 (as a combination partner with zumilokibart for APG279), APG333 (as a combination partner with zumilokibart for APG273), and/or APG808, methods of administration and/or pharmaceutical formulations and compositions thereof. The first family is directed to combinations of anti-IL-13 antibodies and anti-OX40L antibodies and includes a PCT application, as well as applications in Argentina and Taiwan. If the PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, or if the Argentinian or Taiwanese applications mature into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The second family is directed to combinations of anti-IL-4Ra antibodies and anti-OX40L antibodies and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The third family is directed to co-formulations of anti-IL-13 antibodies such as zumilokibart and anti-OX40L antibodies such as APG990 and includes a PCT application. If the PCT application is pursued in the U.S. or any foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The fourth family is directed to combinations of anti-IL-13 antibodies such as zumilokibart and anti-TSLP antibodies such as APG333 in further combination with hyaluronidase or a variant thereof and includes a PCT application. If the PCT application is pursued in the U.S. or a foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent applicable patent term extensions. The fifth family is directed to combinations of anti-IL-4Ra antibodies such as APG808 and anti-TSLP antibodies such as APG333 in further combination with hyaluronidase or a variant thereof and includes a PCT application. If the PCT application is pursued in the U.S. or a foreign jurisdiction and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The sixth family is directed to combinations of anti-OX40L antibodies such as APG990 and anti-TSLP antibodies such as APG333 in further combination with hyaluronidase or a variant thereof and includes a U.S. application. If the U.S. application is pursued and matures into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions. The seventh family is directed to methods of administering anti-IL-13 antibodies such as zumilokibart in combination with anti-OX40L antibodies such as APG990 and, as of January 31, 2026, includes three provisional applications. If these provisional applications are pursued non-provisionally and mature into one or more issued patents, we would expect those patents to expire in 2046, absent any applicable patent term extensions. We have also licensed three patent families from Paragon directed to combinations of APG333 with zumilokibart, APG808 and APG990 and methods of using those combinations. Each of the three families includes a PCT application, as well as applications in Argentina and Taiwan. If the PCT application is pursued in the U.S. or a foreign jurisdiction and matures into one or more issued patents, or if the Argentinian or Taiwanese patent applications mature into one or more issued patents, we would expect those patents to expire in 2045, absent any applicable patent term extensions.

In addition, we have four other patent families that are directed to half-life-extended antibodies to different targets. As of January 31, 2026, each of these four patent families has between one and two provisional applications filed. If these provisional applications are pursued non-provisionally and mature into one or more issued patents, we would expect those patents to expire in 2046, absent any applicable patent term extensions.

As indicated above, some of our owned and licensed patent applications are provisional patent applications. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent

applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Moreover, the patent application and approval processes are expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the future, if and when our product candidates receive approval from the FDA or foreign regulatory authorities, we expect to apply for patent term extensions in applicable jurisdictions on issued patents we may obtain in the future covering those products, depending upon the length of the clinical trials for each product and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our owned and licensed pending patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated, infringed or circumvented. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information, see the section titled "Risk Factors — Risks Related to Intellectual Property".

Other IP Rights

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, that such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see the section entitled "Risk Factors — Risks Related to Intellectual Property".

Trademark Rights Relating to the Apogee Therapeutics Name and Logo

As of January 31, 2025, we own a U.S. trademark registration for the Apogee logo and the mark APOGEE THERAPEUTICS for research and development services of new pharmaceutical products. We also obtained a Statement of Grant of Protection in the UK for the APOGEE THERAPEUTICS mark for research and development services of new pharmaceutical products. The Apogee logo and the APOGEE THERAPEUTICS mark are also pending registration in several other countries.

Employees and Human Capital Resources

As of December 31, 2025, we had 261 full-time employees, 57 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 191 employees are engaged in research and development. We also retain independent contractors as needed to support our organization's needs. None of our employees are represented by labor unions or covered under collective bargaining agreements. We consider our relationship with our employees to be good.

We believe our employees are critical to our success and ability to achieve our business objectives. To that end, we are focused on retaining, developing and engaging our existing employees, and attracting high performing talent to join our team. Our rewards package (cash and equity-based compensation, 401(k) and health and welfare benefits plans) is a key tool in retaining, engaging and rewarding our team. We are also committed to the continued learning and development of our employees, which we believe will enable us to do our best work for patients. We encourage our team members to attend conferences and seminars and take continuing education courses to further their development.

We expect to continue to build our team to ensure we can effectively execute against our clinical plans. As we grow, we strive to retain the fast-paced, psychologically safe and entrepreneurial culture that embodies our four C.O.R.E. values: **C**aring, **O**riginal, **R**esilient and **E**goless.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, or a small molecule drug candidate's quality, safety and efficacy, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our company and our products or product candidates.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local 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 following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with cGMPs;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies ("NAMs"). An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive

clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a Data Safety Monitoring Board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results

as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate 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 Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan ("PSP") within 60 days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted, except that the PREA will apply to an original BLA for a new active ingredient that is orphan-designated if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a risk evaluation and mitigation strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and 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 also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if there is evidence it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Combination Therapy

Combination therapy is a treatment modality that involves the use of two or more drugs to be used in combination to treat a disease or condition. If those drugs are combined in one dosage form, such as one pill, that is known as a fixed dose combination product and it is reviewed pursuant to the FDA's Combination Rule at 21 CFR 300.50. The rule provides that two or more drugs may be combined in a single dosage form when each component contributes to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug.

But not all combination therapy falls under the category of a fixed dose combination. For example, the FDA recognizes that two drugs in separate dosage forms and in separate packaging, that otherwise might be administered as monotherapy for an indication, also may be used in combination for the same indication. In 2013, the FDA issued guidance to assist sponsors that were developing the range of combination therapies that fall outside the category of fixed dose combinations. That guidance provides recommendations and advice on such topics as: (1) assessment at the outset whether two or more therapies are appropriate for use in combination; (2) guiding principles for nonclinical and clinical development of the combination; (3) options for regulatory pathways to seek marketing approval of the combination; and (4) post-marketing safety monitoring and reporting obligations. Given the wide range of potential combination therapy variations, the FDA indicated it intends to assess each potential combination on a case-by case basis and encouraged sponsors to engage in early and regular consultation with the relevant review division at the agency throughout the development process for its proposed combination.

Regulation of Combination Products

Certain therapeutic products are comprised of multiple components, such as drug components, biologic components, and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug/biologic-device combination product is attributable to the drug or biological product, the FDA center responsible for premarket review of the drug or biological product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the biologic component generally would be reviewed and approved pursuant to the biologic approval processes set forth in the FDCA. In reviewing the BLA for such a product, however, FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products with both device and drug/biologic components are subject to cGMP requirements applicable to both drugs and devices, including the Quality Management System Regulation applicable to medical devices.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the

product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented.

FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved 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, is generally 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. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The FDA has issued guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. 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 impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

As discussed below, the Inflation Reduction Act of 2022 (the "IRA") is a law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common commercial activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, for persons in a position to refer or recommend federally reimbursable healthcare business may be alleged to be intended to induce prescribing, purchasing or recommending, and may be subject to scrutiny if they do not qualify for an exception or regulatory safe harbor. Qualifying for a statutory exception or regulatory safe harbor requires satisfying all of the criteria for the exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS, but it does increase the risk of regulatory scrutiny. Ultimately, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The FCA, which can be enforced through civil whistleblower or qui tam actions, prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act.

We are also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners.

For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations impose data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information ("PHI") for or on behalf of such covered entities. These requirements imposed by HIPAA and HITECH on covered entities and business associates include entering into agreements that require business associates to protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act, Washington's My Health My Data Act, and the Connecticut Data Privacy Act (as amended by Public-Act 23-145) that govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state attorneys general, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal

information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household and is included under a new category of personal information, "sensitive personal information", which is offered greater protection. The CCPA and numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, exempt PHI that is subject to HIPAA; and others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, our use of artificial intelligence ("AI") and machine learning may be subject to laws and evolving regulations regarding the use of AI and machine learning, controlling for data bias, and antidiscrimination.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a list of 15 additional Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new “inflation rebate” covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar’s market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA’s impact on commercialization and competition remains largely uncertain.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, 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. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. 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 product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress. In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In May 2025, the Trump Administration renewed the idea of international reference pricing through an executive order entitled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which, among other things, directs the HHS and other agencies to communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for U.S. patients in line with comparably developed nations and to facilitate direct-to-consumer purchasing programs. The HHS subsequently issued guidance indicating the MFN target price will be the lowest price paid in an Organisation for Economic Co-operation and Development country with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capital. In addition, in December 2025, CMS proposed new drug payment models to lower drug prices for Medicare beneficiaries; under the models, CMS would explore potential adjustments to Medicare drug inflation rebate calculations by comparison to international drug pricing information. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect government authorities to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The processing of personal data, including health-related personal data in the European Economic Area(“EEA”) is mainly governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (“GDPR”), and related data protection laws in individual EEA countries. In the United Kingdom, the processing of personal data is mainly governed by the GDPR as incorporated into UK law pursuant to the European Union (Withdrawal) Act 2018 (the “UK GDPR”). The GDPR and UK GDPR imposes a number of strict obligations and requirements for the processing, including collecting, analyzing and transferring, of personal data of individuals in the EEA or in the UK, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR and UK GDPR include requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and obligations relating to the security and confidentiality of the personal data.

EEA countries may also impose additional requirements in relation to the processing of health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EEA that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on the appropriate safeguards, data exporters, with the assistance of the data importers, are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the safeguards in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework.

With regard to the transfer of data from the EEA to the UK, based on the EC's adequacy decision of June 28, 2021 and subsequent renewals, personal data may continue to flow freely from the EEA to the UK on the basis that the UK is deemed to provide an adequate level of data protection until December 27, 2031. The adequacy decisions will automatically expire unless renewed.

With respect to transfers from the UK to other countries, these transfers are also subject to specific transfer rules under the UK regime. These UK international transfer rules broadly mirror the EU GDPR rules.

On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers ("UK Addendum") and a document setting out transitional provisions. The IDTA and UK Addendum came into force on March 21, 2022 and are the primary UK-approved mechanisms for putting in place appropriate safeguards for UK restricted transfers, subject to transitional arrangements for legacy SCCs. Regarding transfers from the UK to the EEA, the UK Information Commissioner's Office ("ICO") guidance indicates that organizations do not need new arrangements. With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the UK Extension to the EU-US Data Privacy Framework, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the recipient is a U.S. organization certified to the EU-US Data Privacy Framework and participating in the UK Extension to the EU-US Data Privacy Framework.

Failure to comply with the requirements of the GDPR or UK GDPR and the related national data protection laws of the EEA countries may result in significant monetary fines for noncompliance of up to €20 million or £17.5 million (as applicable), 4% of the total worldwide annual turnover (for higher-tier infringements). This is enforced by ICO and is entirely separate from fines under EU GDPR. In addition, violations of national laws can trigger additional, administrative penalties, investigations, corrective orders, temporary or definitive bans, and, in some jurisdictions, and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed.

Data protection authorities from the different EEA countries may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EEA.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU Clinical Trials Regulation No. 536/2014 ("CTR"), European Medicines Agency ("EMA") disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization ("MA") for human medicines in the EU/EEA must have been carried out in accordance with EU regulations. This means that clinical trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EEA, including adhering to international good clinical practice and the Declaration of Helsinki. The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the CTR, a sponsor is able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the "Clinical Trials Information System" or "CTIS"). One national regulatory authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application consult and coordinate with the other concerned EU Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU Member States. However, a concerned EU member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU database, including a layperson's summary. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory and CTIS serves as the single entry point for submission of clinical trial-related information and data. As of January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive need to comply with the CTR and have to be transitioned to CTIS.

Under the CTR, national laws, regulations, and the applicable GCP and GLP standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki. Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the National Competent Authority and to the Ethics Committees of the EU member state where they occur.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party ("SAWP"). A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain an MA of a drug under EU regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

To be used or sold in the UK, a drug must have an effective MA granted by the Medicines and Healthcare Products Regulatory Agency ("MHRA") under the Human Medicines Regulations 2012 (SI 2012/1916), as amended. MA applications are submitted electronically via the MHRA Submissions Portal. Under the MHRA's national assessment procedure, the MHRA generally aims to reach a decision within 210 "clock-on" days, excluding any "clock-stops" while the applicant prepares responses to MHRA questions.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Recognition Procedure ("IRP") for MAAs. The IRP has applied since January 1, 2024 and replaces existing EU reliance procedures to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic,

FDA, EMA, among others). The IRP allows medicinal products approved in other jurisdictions that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the EMA that is valid for all EU Member States as well as in the three additional EEA Member States (Norway, Iceland and Liechtenstein). The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy, or tissue engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

Under the centralized procedure, the CHMP is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure

Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization:

(i) they can be authorized under the centralized procedure if they concern a significant therapeutic, scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state; or (iii) they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national MA (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned member states, are subsequently required to grant a MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA, subject only to limited redactions.

MA Validity Period

MAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA. Following Windsor Framework changes, which became effective January 1, 2025, European Commission Union authorizations are no longer valid in Northern Ireland and centrally authorized products are instead authorized by the MHRA under UK-wide marketing authorizations; existing licenses for product licensed by the MHRA that covers Great Britain only become geographically valid UK-wide while retaining their license number/prefix.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on December 31, 2020 (the Brexit Transition Period) will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining member states of the EU, the three year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including advanced therapy medicinal products ("ATMPs") are subject to extensive pre-and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to Regulation (EC) No 1394/2007, the Committee for Advanced Therapies ("CAT") is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Exceptional Circumstances/Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU in exceptional circumstances. A conditional MA can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. Once a conditional MA has been granted, the MA holder must fulfil specific obligations within defined timelines. A conditional MA is valid for one year and must be renewed annually, but it can be converted into a standard MA once the MA holder fulfils the obligations imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. Innovative medicinal products, referred to as New Chemical Entities ("NCE") approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product's first MA in the EU. After eight years, a generic product application may be submitted, and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one-year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the EU's regulatory authorities to include a NCE. Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation and negotiations are still ongoing. The timing for finalization of these negotiations and entry into force are unclear.

The current drafts envisage:

- a shortening of the periods of data exclusivity from eight to six years(with transferable vouchers for an additional year of market protection as an incentive for the development of new antibiotics);
- earlier regulatory guidance and extension of market exclusivity for orphan medicines (depending on certain conditions);

- four-year data exclusivity for additional indications of existing products; and
- rules governing the availability of products (including shortage prevention plans and some supply obligations for manufacturers).

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. The EMA grants orphan drug designation if the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU (prevalence criterion). In addition, Orphan Drug Designation can be granted if, for economic reasons, the medicinal product would be unlikely to be developed without incentives and if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. An application for orphan drug designation (which is not a MA, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for MA of the medicinal product is submitted. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MA is submitted, and sponsors must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional MA.

The EMA's Committee for Orphan Medicinal Products ("COMP") reassesses the orphan drug designation of a product in parallel with the review for a MA; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of MA review by the EMA and approval by the EC. Additionally, any MA granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of a MA, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, the regulatory authorities of the EU Member States and the EMA may not accept applications for MA, accept an application to extend an existing MA or grant a MA for other similar medicinal products for the same therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity for an orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics ("SmPC") addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, i.e. the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a MA may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

In the UK, following the post-Brexit transition period, a system for incentivizing the development of orphan medicines was introduced. Overall, the requirements for orphan designation largely replicate the requirements in the EU and the benefit of market exclusivity has been retained. Products with an orphan designation in the EU can be considered for an orphan MA in Great Britain and, marketing authorizations granted for products that fulfil UK orphan criteria are valid UK-wide regardless of whether there is an EU orphan designation. The MHRA will review applications for orphan designation at the time of a MA, and will offer incentives, such as market exclusivity and full or partial refunds for MA fees to encourage the development of medicines in rare diseases. Separately, the MHRA has stated that it is considering updating its licensing framework for orphan medicines, with a draft framework expected by spring 2026.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee ("PDCO"). Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has published guidance on the procedures for UK PIPs which, where possible, mirror the submission format and requirements of the EU system. From January 1, 2025, EU pediatric requirements are addressed via Windsor Framework categorization: for Category 2 products, both UK and EU pediatric requirements apply, and an EU-agreed PIP must also be in place (unless waived).

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small-and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from CAT are appointed facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and MAs. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation

of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of a MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of Periodic Safety Update Reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

On October 27, 2025, the Council of the European Union approved a framework for compulsory licensing of crisis-relevant products (including medicinal products) in crisis situations. While the proposal focuses on voluntary agreements with intellectual property rights holders, it includes rules on compulsory licensing as a measure of last resort upon activation / declaration of a crisis or emergency mode. The European Parliament has not yet voted on the proposal.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent

regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the MA granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals. EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the Hazardous Material Regulations. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK-based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed.

The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement, which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 ("MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Regulation

In addition to the foregoing, local, state and federal laws, including in the United States and Israel, regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

General Information

Our internet address is www.apogeetherapeutics.com. No portion of our website, or any other website that may be referenced, is incorporated by reference into this Annual Report.

You are advised to read this Annual Report in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission ("SEC"). The SEC maintains information for electronic filers (including Apogee) at its website at www.sec.gov. We make our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports, available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this Annual Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and related notes. We believe the risks described below are the risks that are material to us as of the date of this Annual Report. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risk Factor Summary

Below is a summary of the material risks to our business, our operations and an investment in our common stock. This summary does not address all of the risks that we face. Risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report in its entirety before making investment decisions regarding our common stock.

- We are a clinical stage biotechnology company with a limited operating history, we are currently conducting clinical trials, and we have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts.
- We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products approved for sale, have not generated any revenue from our programs and may never generate revenue or become profitable.
- We face competition from entities that have developed or may develop programs for the diseases addressed by our programs.
- Our programs are in clinical and preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability.
- We are substantially dependent on the success of our programs, zumilokibart (APG777), APG279, APG273, APG990, APG333 and APG808, and our ongoing and anticipated clinical trials of such programs may not be successful.
- Our approach to the discovery and development of our programs is unproven, and we may not be successful in our efforts to build a pipeline of programs with commercial value.
- Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.
- If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We rely on collaborations and licensing arrangements with third parties. If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.

- We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our programs.
- We currently rely, and expect to rely in the future, on the use of manufacturing suites in third-party facilities or on third parties to manufacture our products, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.
- We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We are a clinical stage biotechnology company with a limited operating history, we are currently conducting clinical trials, and we have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical stage biotechnology company with limited operating history. Since our inception in 2022, we have incurred significant operating losses and have utilized substantially all of our resources to date in-licensing and developing our programs, organizing and staffing our company and providing other general and administrative support for our operations. We have limited experience as a company in initiating, conducting or completing clinical trials. In part because of this limited experience, we cannot be certain that our planned clinical trials will begin or be completed on time, if at all, or that our ongoing clinical trials will be completed on time, if at all. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We continue to work to transition from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts.

Developing biotechnology products is a very long, time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our programs, zumilokibart, APG279, APG273, APG990, APG333 and APG808, and any future programs and product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we are currently conducting or anticipate.

Because the design of our planned and anticipated clinical trials, as well as the outcome of our ongoing, planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any program we develop. Our future capital requirements depend on many factors, including but not limited to:

- the rate of progress in the development of our zumilokibart, APG279, APG273, APG990, APG333 and APG808 programs, including for expansion indications beyond AD, asthma and EoE;
- the scope, progress, results and costs of preclinical studies and clinical trials for any other current and future programs;
- the number and characteristics of programs and technologies that we develop or may in-license;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs necessary to obtain regulatory approvals, if any, for any approved products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including claims of infringement, misappropriation or other violation of third-party intellectual property;
- the continuation of our existing collaborations and licensing and other arrangements and entry into new collaborations and licensing and other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the costs we incur in maintaining business operations;
- the costs of hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the costs of adding operational, financial and management information systems and personnel;
- global macroeconomic conditions;
- the costs associated with being a public company;
- the costs and timing of future laboratory facilities;
- the revenue, if any, received from commercial sales of our products for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for programs.

Accordingly, we will require substantial additional funding to continue our operations. Based on our current operating plan, we estimate that our existing cash, cash equivalents, and marketable securities will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the second half of 2028. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently anticipate.

We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt

covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through strategic collaborations, licensing arrangements, royalty financings or other collaborations with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. Our ability to raise additional capital may be adversely impacted by global macroeconomic conditions and volatility in the credit and financial markets in the United States and worldwide, including resulting from tariffs and trade restrictions, public health crises, the conflict between Russia and Ukraine or the conflicts in the Middle East. For example, escalating trade tensions, uncertainty around interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries, which such volatility can have an adverse effect on the ability to raise capital. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may be required to delay, limit, suspend or terminate our product development programs. Our failure to raise capital as and when needed or on acceptable terms could also have a negative impact on any future commercialization efforts or we may be required to grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products approved for sale, have not generated any revenue from our programs and may never generate revenue or become profitable.

Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risks that any program will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of any approved products, we may be unable to continue operations without additional funding.

We have incurred significant net losses in each period since we commenced operations in February 2022. We generated net losses of $255.8 million and $182.1 million for the years ended December 31, 2025 and 2024. As of December 31, 2025, we had an accumulated deficit of $561.8 million. We expect to continue to incur significant losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance our existing and future programs through preclinical and clinical development, including expansion into additional indications;
- seek to identify additional programs and additional product candidates;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek regulatory and marketing approvals for our programs;
- seek to identify, establish and maintain additional collaborations and license agreements;
- make milestone payments to Paragon under the Option Agreements and licensing and royalty payments to WuXi Biologics under the Cell Line License Agreement and under any additional future collaboration or license agreements that we enter into;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which we may obtain marketing approval, either by ourselves or in collaboration with others;
- generate revenue from commercial sales of product candidates for which we receive marketing approval;

- hire additional personnel including research and development, clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-license products, intellectual property and technologies;
- develop and manufacture our clinical supplies and access commercial-scale current good manufacturing practices ("cGMP") capacity and capabilities through third parties or our own manufacturing facility; and
- continue to operate as a public company.

In addition, our expenses will increase if, among other things, we are required by the FDA or other regulatory authorities to perform trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in completing our clinical trials or the development of any of our programs, or there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Our failure to become profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Risks Related to Discovery, Development and Commercialization

We face competition from entities that have developed or may develop programs for the diseases addressed by our product candidates.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our competitors have developed, are developing or will develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that are in development and approved following the launch of our products. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success could be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if biosimilars enter the market more quickly than we do and are able to gain market acceptance. See the section titled "Business—Competition" in this Annual Report for a more detailed description of our competitors and the factors that may affect the success of our programs.

In addition, because of the competitive landscape for I&I indications, we may also face competition for clinical trial enrollment. Patient enrollment will depend on many factors, including if potential clinical trial patients choose to undergo treatment with approved products or enroll in competitors' ongoing clinical trials for product candidates that are under development for the same indications as our product candidates. An increase in the number of approved products for the indications we are targeting with our programs may further exacerbate this competition. Our inability to enroll a sufficient number of patients could, among other things, delay our development timeline, which may further harm our competitive position.

Our programs are in clinical and preclinical stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and we have not completed any pivotal clinical trials. As a result, we expect it will be many years before we commercialize any product candidate, if ever. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have not yet demonstrated our ability to complete any pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our programs and future product candidates.

We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or any future product candidates, including:

- regulators or institutional review boards ("IRBs"), the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocols or dropping out of a trial;
- clinical trials of any programs may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any programs may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators amend clinical trial protocols, which could extend the development timeline of our programs;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;

- the cost of clinical trials of any of our programs may be greater than we anticipate;
- the quality of our programs or other materials necessary to conduct clinical trials of our programs may be inadequate to initiate or complete a given clinical trial;
- we may be unable to manufacture sufficient quantities of our drug products for use in clinical trials, or there may be delays in manufacturing or distribution;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our programs;
- we may fail to establish an appropriate safety profile for a program based on clinical or preclinical data for such programs as well as data emerging from other therapies in the same class as our programs; and
- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to proceed with proposed clinical trial.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND or similar clinical trial application. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing future clinical trials, the start of such clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any future clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including the United Kingdom ("UK") and countries in the European Union ("EU").

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a program if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates. We or our current or future collaborators' inability to complete development of, or commercialize our product candidates, or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the success of our product candidates, zumilokibart, APG279, APG273, APG990, APG333 and APG808 and our ongoing and anticipated trials may not be successful.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our product candidates, including zumilokibart, APG279, APG273, APG990, APG333 and APG808. We are investing a majority of our efforts and financial resources into the research and development of these product candidates and currently have ongoing clinical trials in zumilokibart, APG279, APG990, APG333, and APG808. The success of our product candidates is substantially dependent on observing a longer half-life of our product candidates in humans than other mAbs currently marketed and in development as we believe this longer half-life has the potential to result in a more favorable dosing schedule for our product candidates, assuming they successfully complete clinical development and obtain marketing approval. This is based in part on the assumption that the longer half-life we have observed in non-human primates ("NHPs") will translate into an extended half-life of our product candidates in humans. To the extent we do not observe this extended half-life when we dose humans with our product candidates or if there are unexpected tolerability issues, including when dosed in combination, it would significantly and adversely affect the clinical and commercial potential of our product candidates.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these product candidates, or any other product candidates, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these products, even if approved. If we are not successful in commercializing zumilokibart, APG279, APG273, APG990, APG333, and APG808 including potential combinations of certain of our product candidates, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and our expenses may increase and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement, receipt of interim results or completion of scientific studies and clinical trials, such as the expected timing for Phase 2 APEX Part A maintenance data and Phase 2 APEX Part B topline data, initiation of the Phase 3 trial of zumilokibart for AD, initiation of clinical trials of zumilokibart for asthma and EoE, and the Phase 1b head-to-head clinical trial of APG279 against DUPIXENT in AD, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. For example, we plan to conduct clinical trials in asthma and EoE with trial designs informed by the Phase 2 APEX Part B clinical trial of zumilokibart, as well as the Phase 1b clinical trial of zumilokibart in asthma, which will result in a delay to the previously communicated initiation timing of the zumilokibart Phase 2b clinical trials in asthma and EoE. This change in milestone timing and any inability to not meet other milestones as publicly announced, or at all, may delay the commercialization of our product candidates or commercialization may never be achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Our approach to the discovery and development of our programs is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value.

Our approach to the discovery and development of our programs leverages clinically validated mechanisms of action and incorporates advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. Our programs are purposefully designed to improve upon existing product candidates and products while maintaining the same, well-established mechanisms of action. However, the scientific research that forms the basis of our efforts to develop programs using half-life extension technologies, including YTE and LS amino acid modification, is ongoing and may not result in viable product candidates. We have limited clinical data on product candidates utilizing YTE and LS half-life extension technologies, especially in I&I indications, demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of these technologies and the extended half-life and exposure profile of our product candidates compared to currently approved products is unknown.

In addition, we may in the future seek to discover and develop programs that are based on novel targets and technologies that are unproven. If our discovery activities fail to identify novel targets or technologies for drug discovery, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs. We and our existing or future collaborators may never receive approval to market and commercialize any program. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from our programs prove to be ineffective, unsafe or commercially unviable, our programs and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our programs, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such program.

Before obtaining marketing approval from regulatory authorities for the sale of any product, we must complete preclinical studies and conduct extensive clinical trials to demonstrate the safety and efficacy of our program in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of NHPs to conduct certain preclinical studies that we are required to complete prior to submitting an IND or foreign equivalent prior to initiating clinical development, and prior to submitting a marketing application. During the past several years, there was a global shortage of NHPs available for drug development. If the shortages occur in the future, this could cause significantly increased costs of obtaining or decreased availability of NHPs for our future preclinical studies. This could also result in delays in our development and approval timelines.

Furthermore, a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Our clinical trials are subject to significant risk factors that can have a material and negative impact on outcomes, many of which are beyond our control. Such factors include unexpectedly high placebo rates, safety limitations and/or tolerability concerns. Other factors that can impact our clinical trial results include, without limitation, patient baseline demographics, clinical protocol adherence, and physician and patient scored outcome measures, among others. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. In addition, we expect to rely on patients to provide feedback on measures such as itch and quality of life, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular patient, and from patient to patient and from site to site within a clinical trial.

We cannot be sure that the FDA will agree with our clinical development plan. We used the data from our Phase 1 trial of zumilokibart in healthy volunteers to support our Phase 2 trial in AD and plan to use such data to support Phase 2 trials in other I&I indications. If the FDA requires us to conduct additional trials, enroll additional patients, or imposes trial enrollment restrictions for zumilokibart or any of our other programs, our development timelines may be delayed. We cannot be sure that submission of an IND, biologics license application ("BLA") or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in 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 clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; challenges and delays in activating planned clinical trial sites globally due to the impact of geopolitical tensions; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our programs for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements ("GCPs") or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO") and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board or equivalent body, if any, for such clinical trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the programs, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our programs beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our programs, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We anticipate developing certain product candidates for use in combination with one or more of our other product candidates, and regulatory or safety issues with combination therapies may delay or prevent development and approval of our product candidates.

We anticipate developing certain product candidates for use in combination with one or more of our other product candidates, which may present challenges that are not faced for single agent product candidates. For example, our plans to evaluate current or future product candidates in combination with other product candidates may result in adverse effects based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in clinical trials. In addition, the FDA or comparable foreign regulatory authorities may require us to conduct additional unplanned clinical trials, or to use more complex clinical trial designs in order to evaluate the contribution of each product candidate to any observed effects.

Further, none of our product candidates have been approved by the FDA. If we develop a combination therapy with two of our product candidates and only one product candidate is approved, we will not be able to market and sell that product candidate in combination with the unapproved product candidate for the combination indication if the unapproved product candidate does not ultimately obtain marketing approval either alone or in combination with the approved product candidate.

If the FDA or comparable foreign regulatory authorities do not approve each of, or revoke the approval of any of, the product candidates involved in our combination therapies, or if safety, efficacy, quality, manufacturing or supply issues arise with the any of the product candidates involved in our combination therapies we develop, we may be unable to obtain approval of or market such combination therapy.

If we encounter difficulties enrolling patients in our current and future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our current and future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients in current or future trials for any of our programs will depend on many factors, including if patients choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for programs that are under development for the same indications as our programs, and patients instead enroll in such clinical trials. Also, if we are unable to enroll a sufficient number of patients with the necessary baseline characteristics, our placebo rates, clinical trial results and the patient population indicated on the label approved by the FDA could be impacted. Additionally, the number of patients required for clinical trials of our programs may be larger than we anticipate, especially if regulatory bodies require the completion of non-inferiority or superiority trials. Even if we are able to enroll a sufficient number of patients for our current or future clinical trials, we may have difficulty maintaining patients in our clinical trials. Our inability to enroll or maintain a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether.

Preliminary, "topline" or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

Any preliminary or topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular program and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our current and future clinical trials or those of our future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of our product candidates.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our preclinical studies in NHPs and those of our clinical trials for which we have disclosed data have not shown any such characteristics to date, we cannot assure you that the results of our clinical trials will not reveal such characteristics. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more programs altogether. For example, certain drugs targeting IL-13, including zumilokibart, in the Part A portion of our APEX Phase 2 clinical trial, or IL-4Rα have demonstrated increased conjunctivitis in patients with AD. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend any clinical trials of any program at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies and trials have later been found to cause side effects that prevented their further development. Other potential products have shown side effects in preclinical studies, which side effects do not present themselves in clinical trials in humans. Even if the side effects do not preclude the program from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. TEAEs could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our programs may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our programs may not be normally encountered in the general patient population and by medical personnel. In addition, safety issues associated with competing products that target similar pathways could result in the FDA or comparable foreign regulatory authorities imposing restrictions on our clinical trials or product labeling or denying approval of our products. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

In addition, even if we successfully advance our programs or any future program through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our programs will not be uncovered when a significantly larger number of patients are exposed to the program after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our programs over a multi-year period.

If any of the foregoing events occur or if one or more of our programs prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue a particular program and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected programs.

For example, we are initially focused on our current programs, zumilokibart, APG279, APG273, APG990, APG333 and APG808, alone or in combination. As a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular program, we may relinquish valuable rights to that program through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such program.

Any approved products resulting from our current programs or any future program may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product gains payor access, can be sold at a competitive price and will otherwise be accepted in the market.

For example, there are several approved products and product candidates in later stages of development for the treatment of AD, including DUPIXENT, EBGLYSS, ADBRY and NEMLUVIO in the United States and EU; all approved treatments for moderate-to-severe AD. However, our programs in development for AD incorporate advanced antibody engineering to optimize half-life of antibodies targeting IL-13 and OX40L; to date, no such antibody has been approved by the FDA for the treatment of AD. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates half-life extension for our targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. An extended half-life may make it more difficult for patients to change treatments and there is a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Market acceptance of our programs will depend on many factors, including factors that are not within our control.

Sales of medical/pharmaceutical products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other HCPs, government agencies or private insurers will determine that our product is safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If any current or future program is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that program and may not become or remain profitable.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing monotherapy and combination programs which may compete with one another. For example, we are developing zumilokibart and APG279 for the same indication: AD, and may in the future develop our programs for other I&I indications. Each such program targets single or multiple mechanisms that could provide differentiation from standard of care or each other. Based on the distinct mechanisms of action, we are developing zumilokibart as a frontline treatment for patients with moderate-to-severe AD who have failed or have an inadequate response to topical corticosteroids. APG279 may serve as alternative treatments for frontline patients and/or patients who have failed or have inadequate responses to other treatment options. However, developing multiple programs for a single indication may negatively impact the commercial success of each individual program if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple programs are approved for the same indication, they may compete for the same patients, which could impact our product development timelines and limit our future revenue.

We are conducting and may conduct future clinical trials for our programs at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are conducting ongoing clinical trials, which include sites outside the United States, and we may choose to conduct one or more of our future clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions and guidance imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. 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. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Further, conducting international clinical trials presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Risks Related to Our Reliance on Third Parties

We rely on collaborations and licensing arrangements with third parties, including our collaboration with Paragon. If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.

We currently rely on our collaborations and licensing arrangements with third parties, including Paragon, for a substantial portion of our discovery capabilities and in-licenses. We consider Paragon to be a related party because Fairmount Funds Management LLC, which beneficially owns more than 5% of Paragon, beneficially owns more than 5% of our capital stock and has two seats on our Board of Directors (the "Board").

Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our collaborators or licensors experiences delays in performance of, or fails to perform its obligations under their agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, our pipeline and programs and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be

able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our programs and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or provide development or commercialization capabilities that complement our own. We may not realize the benefits of such collaborations, alliances or licensing arrangements. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

We may face significant competition in attracting appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we only control certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, and in some instances GLP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our programs in clinical development. If we or any of these third parties fail to comply with applicable GCP or GLP regulations, 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 by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may be involved in mergers, acquisitions or similar transactions and may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our current or future product candidates. If these third parties 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates.

Our reliance on foreign CMOs may expose us to supply chain disruption, delays in our clinical development programs, regulatory risks and increased costs, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We currently rely on foreign CMOs, including WuXi Biologics and Samsung Biologics, and will likely continue to rely on foreign CMOs in the future. Foreign CMOs may be subject to U.S. legislation, including the BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Since February 2025, the United States government has imposed various tariffs on imports from China, South Korea and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China, South Korea or impose other restrictions on companies' ability to work with Chinese and South Korean biotechnology companies. To the extent these or future tariffs are applicable to the material we import from China, South Korea and other countries, our financial condition could be adversely affected.

Further, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the U.K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs.

We currently rely and expect to rely in the future on the use of third-party facilities and on third parties to manufacture and test our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or testing facilities or if the third-party manufacturers encounter difficulties in production.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on CMOs for developing, manufacturing and testing our product candidates. While we have manufactured zumilokibart drug substance at commercial scale, it has only been for use in clinical trials, and we have not yet demonstrated the ability to manufacture zumilokibart drug product or any of our other product candidates on a commercial scale and may not be able to successfully manufacture any of our product candidates for commercialization, if approved. We currently have two sources for our preclinical and clinical supply of zumilokibart drug substance and drug product and have entered into an agreement for the commercial supply of zumilokibart drug substance should the product candidate eventually receive regulatory approval, and we are working to finalize the terms of our potential commercial supply arrangement for zumilokibart drug product.We have a sole source relationship for our preclinical and clinical supply of APG990, APG333, and APG808 drug substance and drug product. If there should be any disruption in our supply arrangements, including any adverse events affecting our sole suppliers, it could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify alternate supply sources. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our

product candidates. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and other qualified personnel. 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 approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, human capital constraints or as a result of labor disputes or unstable political environments, including tariffs and restrictions imposed by the United States government and potential retaliatory measures by foreign governments, which impact goods required for the operation of their business. If any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs and other vendors are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention, refusal to permit the import or export of products or increased costs as a result of tariffs on imports imposed by the United States government. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, resulting in higher costs or adversely impacting commercialization of our products. See the section titled “Business-Manufacturing and Supply” in this Annual Report for a more detailed description of our manufacturing and supply plans and assumptions and the factors that may affect the success of our product candidates.

We intend to deliver our product candidates via a pre-filled syringe, autoinjector or other drug delivery device presentation that will have its own regulatory, development, supply and other risks.

We intend to deliver our product candidates via a pre-filled syringe, autoinjector or other drug delivery device presentation. There may be unforeseen technical complications related to the development activities required to bring such a product to market. Our product candidates may not be approved or may be substantially delayed in receiving approval if the device presentations do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device presentation is sought under a single application, the increased complexity of the review process may delay approval. In addition, our drug delivery device presentation for zumilokibart is provided by a single-source unaffiliated third-party. We are dependent on the sustained cooperation and effort of that third-party and any other third-party companies we may contract with in the future, both, to supply the device presentation and, in some cases, to conduct the studies required for approval or other regulatory clearance of the device presentation. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the device presentation, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the device presentation could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

Risks Related to Our Business and Operations

In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.

We expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical drug development, technical operations, clinical operations, regulatory

affairs and commercial operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. We are dependent on the experience of our management team, who have only worked together for a limited time in managing a public company with such anticipated growth, and we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, Chief Medical Officer, Chief Financial Officer and other key members of our leadership team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments may disrupt the global supply chain for biopharmaceutical products. If tariffs, trade restrictions, or other trade related measures are ultimately applied to materials used in our clinical development programs or commercial supply chain, our cost on development and commercialization may increase, our ability to source critical CMOs to manufacture product candidates may be limited, and our clinical development timeline may be delayed.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or

other improper activities. While we have adopted a code of conduct, it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants, third party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, "sensitive information").

We may implement a variety of security measures designed to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, including attacks enhanced or facilitated by AI, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Our remote workforce may create additional risks for our information technology systems and data because a majority of our employees work remotely and utilize network connections, computers, and devices working at home, while in transit and in public locations. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, deter new customers from products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We, and third parties who we work with are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations. See the section titled "Business—Government Regulation—Data Privacy and Security" in this Annual Report for a more detailed description of the laws that may affect our ability to operate.

Additionally, our employees and personnel have begun to use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits and has the potential to result in bias, miscalculations, data errors and other unintended consequences. Furthermore, any confidential information that is disclosed to a third-party generative AI platform or vendor that uses generative AI could be leaked or disclosed to others, including sensitive information that is used to train the third parties' model, which may impact our ability to realize the benefits of our intellectual property. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. Our vendors may also incorporate generative AI tools into their offerings, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection. If any of our vendors experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules governing U.S. federal, state and local income taxation are constantly under review and modification by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws, including those with potential retroactive application, could adversely affect us or our stockholders. We regularly assess the potential impact of various tax reform proposals and modifications to existing tax treaties in jurisdictions where we have operations to understand their potential effect on our business and any assumptions we have made about our future taxable income. However, we cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals may have on our tax positions, financial conditions or our stockholders, if they were to be enacted.

For example, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to immediately deduct research and development expenditures and instead requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. On July 4, 2025, the U.S. Congress enacted the OBBBA, which includes a provision restoring the immediate deductibility of domestic research and development expenditures. Although the impact of the OBBBA has been immaterial to our business to date, we have no assurance as to whether, when and how this provision may be subject to further amendment or repeal. These and other changes in tax laws or in how they are interpreted may adversely affect our effective tax rate, results of operation and financial condition.

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

We may acquire additional businesses 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 programs or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Risks Related to Intellectual Property

Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our programs and technologies and to prevent third parties from competing with us. Our success depends in large part on our ability to obtain and maintain patent protection for our technologies, programs and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. We own and have licensed rights to pending patent applications and expect to continue to file patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business.

However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on programs worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications.

Our intellectual property portfolio is at an early stage and we currently own one issued patent. Our pending and future patent applications may not result in additional patents being issued. Any issued patents may not afford sufficient protection of our programs or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or programs. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our programs could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our programs under patent protection could be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage.

In addition to seeking patents for some of our technology and programs, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could expose us to patent infringement allegations and enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors.

These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Lastly, if our trademarks and trade names are not registered or adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We may not be successful in obtaining or maintaining necessary rights to our programs through acquisitions and in-licenses.

Because our development programs currently do and may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our programs. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our programs, there may be times when the filing and prosecution activities for patents and patent applications relating to our programs are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our programs, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those programs may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, programs, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected programs, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, programs, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and the priority of invention of patented technology.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third party rights. If certain of our programs advance to commercialization, patent rights held by third parties, if found to be valid and enforceable, could be alleged to render one or more of our programs infringing. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected program and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g. patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of our common stock.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if our programs are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biotechnology industry, in addition to our employees, we engage the services of consultants to assist us in the development of our programs. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets

or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our programs, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act") could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, in 2023, the United States Supreme Court in Amgen, Inc. v. Sanofi held that Amgen's patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement where the patent specification provided twenty-six exemplary antibodies, but the claimed class of antibodies covered a "vast number" of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in Amgen or other recent precedential court decisions. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing

patents could change in ways that could have a material adverse effect on our patent rights and weaken our ability to protect, defend and enforce our patent rights in the future.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In addition, a European Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the EU. This enables third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Although we do not currently own any European patents, if we obtain such patents in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our programs, our competitive position would be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our programs in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we

may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue or will be maintained in a validity proceeding with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs or as a result of questions regarding co-ownership of potential joint inventions.

Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our programs for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our programs are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new programs, patents protecting such programs might expire before or shortly after such programs are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our technology licensed from various third parties may be subject to retained rights.

Our future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from

research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the programs involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our products, if approved, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates; 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; and 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. In addition, the FDA and comparable foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations or revise existing regulations, or take other actions, such as those implemented by the Department of Government Efficiency, which may impact our clinical development plans or prevent or delay approval of our product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product

candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be materially impaired.

Disruptions at the FDA and other government agencies could negatively affect the review and approval of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel, disruptions caused by government shutdowns and public health crises. There have been mass layoffs of federal employees since the start of the current presidential administration in January 2025, the full impact of which is unclear at this time. In addition, over the last several years, the U.S. federal government has shut down several times, including as recently as October 2025, and certain regulatory agencies, such as the FDA, have furloughed critical government employees and stopped critical activities. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, the presidential administration has made and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA. Such changes could result in the imposition of additional requirements upon our business, including in connection with our planned and ongoing clinical trials, that could delay our submissions to the FDA and ability to obtain approvals and increase the costs of compliance.

We are unable to predict the extent to which the current or future presidential administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting the review and approvability of our submissions and our business and operations. It is unclear how executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or manufacturing of our current product candidates or future product candidates, which could have a material adverse effect on our business.

We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient or drug substance, developing an acceptable formulation, performing tests to adequately characterize the product, documenting a repeatable manufacturing process, meeting facility, process and testing validation requirements, and demonstrating that our drug products meet standards for parenteral administration as well as stability requirements. Meeting these chemistry, manufacturing and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing and control requirements, we may not be successful in getting our products approved.

Our programs for which we intend to seek approval as biologics may face competition sooner than anticipated.

The ACA, includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the

reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our programs approved as biologics under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened or changed due to congressional action or otherwise, or that the FDA will not consider our programs to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified patient subpopulations, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve our product candidates, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. See the section titled "Business—Government Regulation—Healthcare Reform" in this Annual Report for a more detailed description of healthcare

reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products, if approved. See the section titled "Business—Government Regulation—Other Healthcare Laws and Compliance Requirements" in this Annual Report for a more detailed description of the laws that may affect our ability to operate.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Even if we are able to commercialize any product candidates, due to potential unfavorable pricing regulations and/or third-party coverage/access and reimbursement policies, we may not be able to realize access to products or appropriate pricing, which would seriously harm our business.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement and distribution for these product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers, health maintenance organizations, group purchasing organizations and pharmacy benefit managers, decide which medications they will pay for and establish reimbursement levels.

Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off-label uses of those product candidates, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See the sections titled "Business—Government Regulation—Coverage and Reimbursement" and "Business—Other Government Regulation Outside of the United States—Regulation in the European Union" in this Annual Report for a more detailed description of the government regulations and third-party payor practices that may affect our ability to commercialize our product candidates.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as

amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue and/or our ability to gain access to our products, if any.

In some countries, particularly member states of the EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation for one or more of our programs. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular program is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Additionally, changes in the leadership of the FDA and other actions taken by the presidential administration, including mass layoffs within the federal government, may impose constraints on the FDA's ability to engage in activities in the normal course and may result in reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to take advantage of the benefits for the Fast Track Designation and progress development of our programs or obtain regulatory approval for our programs. See the section titled "Business—Government Regulation—Expedited Development and Review Programs" in this Annual Report for a more detailed description of the process for seeking Fast Track Designation.

Risks Related to Our Common Stock

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The price of our stock has fluctuated in the past and may continue to be volatile, and you could lose all or part of your investment.

The trading price of our common stock has fluctuated in the past, and is likely to continue to fluctuate substantially in response to various factors, some of which are beyond our control, including the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report. The realization of any of these factors could have a dramatic and adverse impact on the market price of our common stock.

In addition, the stock market in general, and the market for biotechnology and biopharmaceutical companies in particular, have historically been particularly volatile and experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors, including developments related to the products and product candidates of our competitors, may negatively affect the market price of our common stock, regardless of our actual operating performance or clinical trial results. For example, our stock price experienced volatility around the release of positive 16-week data from APEX Part A of our Phase 2 trial of zumilokibart for AD. In addition, escalating trade tensions, uncertainty around interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries. If the market price of our common stock does not exceed the price at which you purchase your shares, you may not realize any return on your investment in us and may lose some or all of your investment. Securities class action litigation is often initiated against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would materially adversely affect our business, financial condition and results of operation.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding voting common stock and all of our outstanding non-voting common stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to entrench management or impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

A sale of a substantial number of shares of our common stock may cause the market price of our common stock to drop significantly, even if our business is doing well.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of a substantial number of shares of our common stock in the public market, including shares sold by holders of 5% or more of our capital stock and their respective affiliates or shares issued through our at-the-market facility or upon exercise of outstanding options or other

equity awards, could reduce the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

In addition, certain holders of our shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have filed a registration statement under the Securities Act to register the shares of our common stock reserved for issuance under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our Board that our stockholders might consider favorable. At any time while at least 6,061,821 shares of non-voting common stock remain issued and outstanding, we may not consummate a Fundamental Transaction (as defined in our amended and restated certificate of incorporation) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of non-voting common stock. All of the outstanding shares of non-voting common stock are held by entities affiliated with two stockholders. This provision of our amended and restated certificate of incorporation may make it more difficult for us to enter into any of the aforementioned transactions.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. See the section titled “Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law” in our Description of Securities filed as Exhibit 4.4 to this Annual Report.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for certain actions, in all cases subject to the court’s having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the “Securities Act”) but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These exclusive forum provisions may impose additional costs on stockholders in pursuing any such claims or limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits. There is uncertainty as to whether a court would enforce such provisions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other

jurisdictions, which could materially adversely affect our business. See the section titled "Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law" in our Description of Securities filed as Exhibit 4.3 to this Annual Report.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

General Risk Factors

We may become exposed to costly and damaging liability claims, either when testing our programs in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the use of our product candidates in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, HCPs, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or

any prospects for commercialization of our products. Although we currently maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal information, contractual relations with collaborators and licensors and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, and we may not have adequate insurance coverage in the event these risks materialize, which may cause a material adverse effect on our business, financial condition, results of operations or cash flows.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us or our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts continue coverage of us or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, our stock price could be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our clinical trials or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

We will continue to incur increased costs as a result of operating as a public company, and our management will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social and governance focused disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. Our management and other personnel will continue to devote a substantial amount of time to these compliance initiatives, and we will continue to incur increased legal and financial compliance costs. For example, maintaining customary public company director and officer liability insurance requires substantial expenditures. The impact of these legal and financial requirements could make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our product candidates, once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. We are also required to have an audit of the effectiveness of our internal

control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the conflict between Russia and Ukraine, and Israel and Hamas or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, especially in light of recent comments and executive orders made by the current presidential administration, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), government shutdowns, tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers. Since February 2025, the United States government has imposed various tariffs on imports from most countries, including tariffs on imports from China and South Korea. In September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products that are intended for use in

clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. There still remains substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. Historically, tariffs have led to increased trade and political tensions and foreign countries' retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, which could materially adversely affect global economic conditions and the stability of global financial markets. In addition, the Federal Reserve raised interest rates multiple times in response to concerns about inflation and, although it has lowered interest rates, there is no guarantee that it will not raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, geopolitical uncertainties and international conflicts, including the ongoing military conflicts between Russia and Ukraine and in the Middle East and rising tensions with China, have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented and utilize a risk-based approach that incorporates various information security processes designed to assess, identify and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity and availability of information technology systems and the data residing therein. The critical data contained on our information systems include intellectual property, confidential information that is proprietary, strategic or competitive in nature, and sensitive, personal information that we collect, use, store and transmit digitally in the ordinary course of our business. These processes are managed and monitored by a dedicated information technology team, which is led by our Senior Vice President of Information Technology, and include mechanisms, controls, technologies, systems, and other processes designed to monitor and evaluate our threat environment, prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. Our cybersecurity program is informed in part by certain industry standards and best practices as outlined by the National Institute of Standards and Technology ("NIST") Cybersecurity Framework. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence. We use email security tools, managed detection and response, third party managed security services, regular vulnerability scans and threat intelligence feeds. We also have an incident response plan designed to mitigate and remediate identified cybersecurity incidents and escalate certain incidents as appropriate to management and the Audit Committee. We assess third-party service providers with a cyber security questionnaire and a follow up meeting or audit based upon the risk profile of the third party with access to personal, confidential or proprietary information to implement and maintain cybersecurity practices intended to be consistent with applicable legal standards and industry best practices.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality

of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share. To mitigate the aforementioned consequences of cybersecurity incidents, we carry cyber attack insurance. In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors," under the heading "Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants, third party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations."

Our Senior Vice President of Information Technology, a certified CISSP, who reports directly to the Chief Financial Officer and has over 25 years of experience managing information technology and cybersecurity, is responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which comprises solely independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Senior Vice President of Information Technology. The Board also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

Item 2. Properties.

We maintain a corporate headquarters in Waltham, Massachusetts, laboratory and office space in Boston, Massachusetts, office space in San Francisco, California and otherwise operate virtually in the United States. Our corporate headquarters in Waltham, Massachusetts, consists of 1,087 square feet of leased office space under a lease agreement that expires in September 2026. We also lease a laboratory facility located in Boston, Massachusetts, which consists of 17,685 square feet of R&D laboratories and office space under a lease agreement that expires in November 2026, with the option to extend for one year. In September 2024, the Company entered into a lease agreement for 15,710 square feet of office space in San Francisco, California. The lease expires in September 2029 with two one-year options to extend. We believe these arrangements support our current needs. If we require additional space, we believe that we will be able to obtain such space on acceptable, commercially reasonable terms.

Item 3. Legal Proceedings.

We are not party to any material legal proceedings at this time. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

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 trades on the Nasdaq Global Market under the symbol "APGE".

Holders

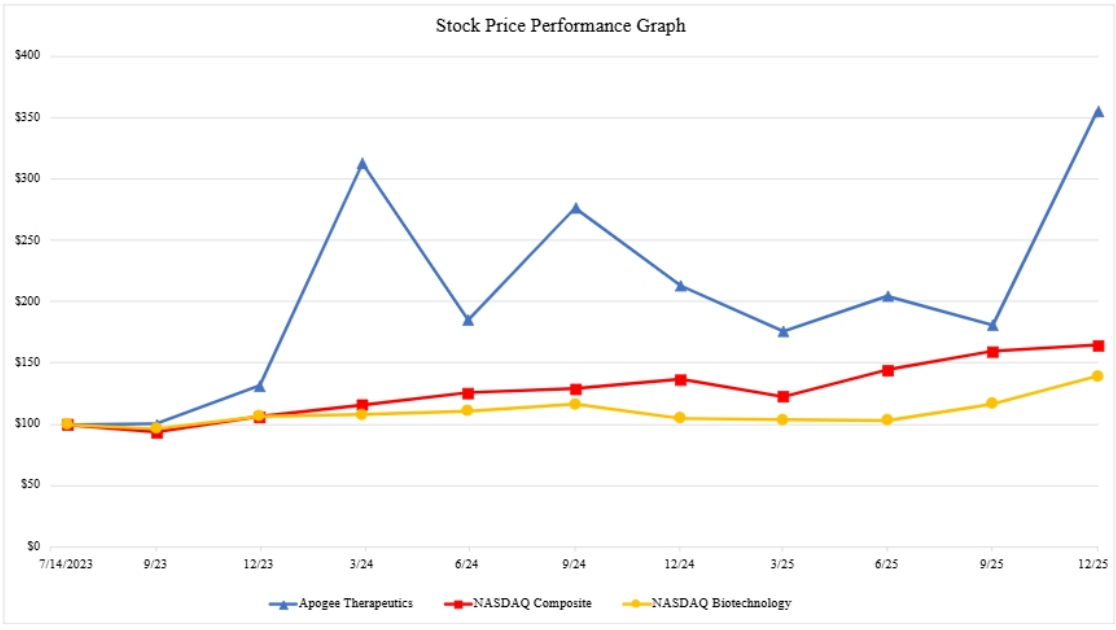
As of February 23, 2026, we had approximately 6 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

Dividend Policy

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the operations and the further development and expansion of our business. We have no present intention to pay cash dividends on our common stock or non-voting common stock. Any determination to pay dividends to holders of our common stock or non-voting common stock will be at the discretion of our Board and will depend on many factors, including our financial condition, results of operations, liquidity, earnings, projected capital and other cash requirements, legal requirements, restrictions in the agreements governing any indebtedness we may enter into, our business prospects and other factors that our Board deems relevant.

Stock Performance Graph and Cumulative Total Return

The following stock performance graph compares our total stock return with the total return for (i) the Nasdaq Composite Index and (ii) the Nasdaq Biotechnology Index for the period from July 14, 2023 through December 31, 2025. The figures represented below assume an investment of $100 in our common stock and in the Nasdaq Composite Index and the Nasdaq Biotechnology Index and the reinvestment of dividends into shares of common stock. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our common stock.



	Ticker	7/14/2023	9/30/2023	12/31/2023	3/31/2024	6/30/2024	9/30/2024	12/31/2024	3/31/2025	6/30/2025	9/30/2025	12/31/2025
Apogee Therapeutics, Inc	APGE	$ 100.00	$ 100.33	$ 131.61	$ 313.00	$ 185.35	$ 276.68	$ 213.38	$ 175.98	$ 204.57	$ 180.97	$ 355.53
NASDAQ Composite	^IXIC	$ 100.00	$ 93.66	$ 106.36	$ 116.05	$ 125.64	$ 128.88	$ 136.82	$ 122.57	$ 144.33	$ 159.40	$ 164.68
NASDAQ Biotechnology	^NBI	$ 100.00	$ 96.40	$ 106.56	$ 108.01	$ 110.82	$ 116.25	$ 105.10	$ 103.49	$ 103.08	$ 116.84	$ 139.15

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Use of Proceeds from IPO

In July 2023, we completed our IPO pursuant to which we issued and sold an aggregate of 20,297,500 shares of our common stock, including the full exercise of the underwriters' option to purchase up 2,647,500 additional shares, at the IPO price of $17.00 per share. The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File Nos. 333-272831 and 333-273236), which was declared effective on July 13, 2023. Jefferies, TD Cowen, Stifel and Guggenheim Securities acted as joint book-running managers for the IPO. Wedbush PacGrow acted as lead manager for the IPO. We received gross proceeds from our IPO of approximately $345.1 million, and net proceeds of approximately $315.4 million, after deducting underwriting discounts and commissions and other offering expenses. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

The net proceeds from the IPO have been used and are expected to be used, primarily to fund our clinical trials, and manufacturing of our zumilokibart (APG777) product candidate, fund our preclinical studies, clinical trials and manufacturing of our APG808 program, fund our preclinical studies, clinical trials and manufacturing of our APG990 program and fund our preclinical studies of other programs. We intend to use the remainder for our additional research and development activities, as well as for capital expenditures, working capital and general corporate purposes. There has been no material change in our intended use of proceeds from our IPO as described in the final prospectus for our IPO filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 17, 2023.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations in conjunction with the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K (this "Annual Report"). The following discussion contains forward-looking statements that reflect our current plans, forecasts, estimates and beliefs and involve risks and uncertainties. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Our actual results, outcomes and the timing of events could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in the section titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors." We urge you to consider these factors carefully in evaluating the forward-looking statements contained in this Annual Report. Forward-looking statements are not historical facts, reflect our current views with respect to future events, and apply only as of the date made. We do not intend, and undertake no obligation, to update these forward-looking statements, except as required by law. Unless the context requires otherwise, references to "we," "us," "our," "Apogee" or "the Company" refer to Apogee Therapeutics, Inc. and its subsidiaries.

Overview

We are a clinical stage biotechnology company advancing optimized, novel biologics with the potential for differentiated efficacy and dosing in the largest inflammatory and immunology ("I&I") markets, including for the treatment of atopic dermatitis ("AD"), asthma, eosinophilic esophagitis ("EoE"), chronic obstructive pulmonary disease ("COPD"), and other I&I indications. Our antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties.

Our pipeline comprises multiple antibody programs being developed initially for the treatment of I&I indications as monotherapies and combinations, including zumilokibart (APG777), APG279 (zumilokibart + APG990), APG273 (zumilokibart + APG333), and APG808 (each, a "program" or "product candidate"). With four validated targets in our portfolio, we are seeking to achieve best-in-class efficacy and dosing through monotherapies and combinations of our novel antibodies. Based on a broad pipeline and depth of expertise, we believe we can deliver value and meaningful benefit to patients underserved by today's standard of care. We believe each of our product candidates has potential for broad application across multiple I&I indications.

Recent Developments

The following is a summary of key developments affecting our business for the year ended December 31, 2025, except for updates related to our programs, which are discussed in "Item 1. Business" included in this Annual Report.

Equity Offerings

On October 10, 2025, pursuant to our Registration Statement on Form S-3, which became effective in August 2024 (File No 333-281503), we issued and sold an aggregate of 8,048,782 shares of common stock (inclusive of 1,097,561 shares of common stock pursuant to the exercise in full of the underwriters' option to purchase additional shares) at a public offering price of $41.00 per share, and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to 365,853 shares of common stock at a public offering price of $40.99999 per pre-funded warrant (the "October 2025 Offering"). The pre-funded warrants have an exercise price of $0.00001 per share and are exercisable immediately. The aggregate net proceeds from the offering were $324.1 million after deducting underwriting discounts and commissions, and estimated offering expenses payable by us.

ATM Facility

During the year ended December 31, 2025, we sold 1,175,701 shares of common stock under our at the market offering program ("ATM Facility") for gross proceeds of $67.6 million, less commissions and other offering expenses of $2.0 million.

Net Loss

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of any programs we may develop. We generated a net loss of $255.8 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $561.8 million. We expect to continue to incur significantly increased expenses for the foreseeable future if and as we continue to operate our business.

Macroeconomic Conditions

The global macroeconomic environment is uncertain, and could be negatively affected by, among other things, financial market volatility and uncertainty, inflation, interest rate fluctuations, changing tariff policies and trade restrictions, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, instability in the global banking system, cybersecurity events, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. We closely monitor the impact of these factors on all aspects of our business, including the potential impacts on our clinical trial trials, supply chain, regulatory interactions, employees, third-party partners, suppliers, and vendors. The ultimate impact of global and domestic economic conditions on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. As a result, we are subject to continuing risks and uncertainties and continue to closely monitor the impact of the current conditions on our business. For more information regarding these risks and uncertainties, see the section titled “Risk Factors” in this Annual Report.

Overview of Financial Results

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our programs are successful and result in regulatory approval or collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements that we may enter into with third parties, or any combination thereof.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the development and research of our programs. These expenses include:

- the cost of developing and validating our manufacturing process for use in our preclinical studies and current and future clinical trials;
- expenses incurred in connection with continuing our current research programs and preclinical development of any programs we may identify, including under agreements with third parties, such as consultants and contractors;
- costs of funding research performed by third parties, including Paragon, that conduct research and development and preclinical or clinical activities on our behalf;
- the cost to acquire in-process research and development, with no alternative future use associated with asset acquisitions, such as the Option Agreements, and License Agreements;
- expenses incurred under agreements with clinical trial sites and clinical research organizations (“CROs”) that conduct research and development activities on our behalf, including clinical trial execution, project management, data management and related outsourced services;

- costs related to production of clinical supplies and preclinical materials, including fees paid to contract manufacturers; and
- personnel-related expenses, including salaries, bonuses and equity-based compensation expense.

We measure and recognize asset acquisitions or licenses to intellectual property that are not deemed to be business combinations based on the cost to acquire or license the asset or group of assets, which includes transaction costs. In an asset acquisition or license to intellectual property, the cost allocated to acquired in-process research and development, with no alternative future use is recognized as research and development expense on the acquisition date.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our primary focus since inception has been the identification and development of our pipeline programs. Our research and development costs primarily consist of external costs, including CRO fees and fees paid to Paragon under the Option Agreements and the License Agreements. We do not separately track or segregate the amount of costs incurred under the Option Agreements due to the early-stage and discovery nature of the services. We do not allocate personnel-related costs by program because these resources are used and these costs are deployed across multiple programs under development, and, as such, are not separately classified.

We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities for our programs, and any potential future programs, including investments in clinical trials and manufacturing. The success of programs we may identify and develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies;
- effective Investigational New Drug applications (“INDs”) or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any programs we may develop;
- successful enrollment and completion of clinical trials;
- positive results from our future clinical trials that support a finding of safety and effectiveness, acceptable PK profile, and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any products we may develop; and
- maintenance of a continued acceptable safety, tolerability and efficacy profile of any programs we may develop following approval.

Any changes in the outcome of any of these variables with respect to the development of programs that we may identify could mean a significant change in the costs and timing associated with the development of such programs. For example, if the U.S. Food and Drug Administration (“FDA”) or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a program, or if we experience significant delays in our clinical trials due to patient enrollment, macroeconomic events or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our programs.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, and equity-based compensation, for individuals in our executive, finance, legal, IT, operations, human resources, business development, commercial and other administrative functions. Other significant general and administrative expenses include legal fees relating to corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and recruiting costs. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates, if approved. We also expect to continue incurring expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other Income (Expense), Net

Interest Income

Interest income consists of interest income earned from our cash, cash equivalents, and marketable securities and amortization of investment discounts.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits generated in each period as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss ("NOL") carryforwards and the vast majority of our tax credit carryforwards will not be realized.

As of December 31, 2025, we had U.S. federal NOL carryforwards of approximately $250.7 million, which may be available to reduce future taxable income and have an indefinite carryforward period but are limited in their usage to an annual deduction equal to 80% of annual taxable income. We also had state net operating loss carryforwards of approximately $94.3 million, which will begin to expire in 2043 for state tax purposes. As of December 31, 2025, we also had U.S. federal and research and development tax credit carryforwards of approximately $16.7 million, which may be available to reduce future tax liabilities. We also had California research and development credit carryforwards of approximately $2.9 million. Additionally, we had Massachusetts research and development credit carryforwards of approximately $1.7 million. The U.S. federal and Massachusetts research and development tax credit carryforwards expire at various dates beginning in 2042 and the California research and development tax credit carryforwards do not expire. We have recorded a full valuation allowance against our net deferred tax assets at the balance sheet date.

Results of Operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2025 compared to the year ended December 31, 2024 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2024 compared to the year ended December 31, 2023 can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025.

Comparison of the Year Ended December 31, 2025 and Year Ended December 31, 2024

The following table summarizes our consolidated statements of operations for the periods presented (in thousands):

	YEAR ENDED DECEMBER 31,		
	2025	2024	$ CHANGE
Operating expenses:			
Research and development	$ 214,712	$ 167,865	$ 46,847
General and administrative	70,883	49,005	21,878
Total operating expenses	285,595	216,870	68,725
Loss from operations	(285,595)	(216,870)	(68,725)
Other income, net:			
Interest income	30,030	34,742	(4,712)
Total other income, net	30,030	34,742	(4,712)
Net loss before taxes	(255,565)	(182,128)	(73,437)
Provision for income taxes	(278)	(18)	(260)
Net loss after taxes	$ (255,843)	$ (182,146)	$ (73,697)

Research and Development Expense

The following table summarizes our research and development expenses incurred for the periods presented (in thousands):

	YEAR ENDED DECEMBER 31,	
	2025	2024
External research and development costs by program:		
Zumilokibart (APG777)	$ 76,441	$ 49,241
APG990/APG279	16,250	20,000
APG333/APG273	5,257	28,095
APG808	3,136	10,311
Unallocated research and development costs:		
External-discovery related costs and other	22,469	11,064
Personnel-related (excluding equity-based compensation)	68,490	39,013
Equity-based compensation	22,381	9,964
Depreciation expense	288	177
Total research and development expenses	$ 214,712	$ 167,865

Research and development expenses for the years ended December 31, 2025 and 2024 were $214.7 million and $167.9 million, respectively. The increase of $46.8 million was primarily driven by further development of our zumilokibart (APG777) program, increases in personnel costs and equity-based compensation, associated with the growth in our research and development team, and increases in external-discovery related costs and other expenses, partially offset by decreases in expenses related to our APG990/APG279, APG333/APG273 and APG808 programs.

Research and development expense related to the zumilokibart (APG777) program increased by $27.2 million in the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily driven by increases in clinical trial-related expenses and clinical manufacturing activities to support our ongoing clinical trials. Research and development expense related to the APG990/APG279 program decreased by $3.8 million in the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to a reduction in clinical manufacturing activities and a decrease in expenses incurred under the Option Agreements and License Agreements, which included milestone payments of $1.0 million and $2.0 million to Paragon, related to the nomination of a development candidate in May 2024 and the first dosing of human participants in a Phase 1 clinical trial in August 2024, respectively, partially offset by an increase in clinical trial expenses. Research and development expense related to the APG333/APG273 program decreased by $22.8 million in the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to a reduction in clinical manufacturing activities and a decrease in

expenses incurred under the Option Agreements and License Agreements, which included a $2.0 million research initiation fee and milestone payments of $3.0 million and $5.0 million to Paragon related to the nomination of a development candidate in October 2024 and the first dosing of a human patient in a Phase 1 clinical trial in December 2024, respectively. Research and development expense related to the APG808 program decreased by $7.2 million in the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily driven by decreases in clinical trial expenses, expenses incurred under the Option Agreements and License Agreements, including a milestone payment of $2.0 million to Paragon in March 2024 for the first dosing of a human patient in a Phase 1 trial, and a decrease in clinical manufacturing expenses.

External-discovery related costs and other expenses increased by $11.4 million in the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to increases in professional service fees and non-program specific research and development expense. Personnel-related expenses and equity-based compensation increased by $29.5 million and $12.4 million, respectively, in the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to increased headcount and an increase in the fair value of equity awards granted.

General and Administrative Expense

The following table summarizes our general and administrative expenses for the periods presented (in thousands):

	YEAR ENDED DECEMBER 31,	
	2025	2024
Personnel-related (excluding equity-based compensation)	$ 26,740	$ 16,935
Equity-based compensation	23,896	13,368
Legal and professional fees	4,315	6,451
Depreciation expense	1,130	—
Other	14,802	12,251
Total general and administrative expenses	$ 70,883	$ 49,005

General and administrative expenses for the year ended December 31, 2025 were $70.9 million, compared to $49.0 million for the year ended December 31, 2024. The increase of $21.9 million was primarily due to increases of $9.8 million and $10.5 million in personnel-related expense and equity-based compensation, respectively, primarily driven by increased headcount and an increase in the fair value of equity awards granted.

Other Income, Net

Interest income decreased $4.7 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, which was primarily related to interest on our cash, cash equivalents and marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses. We have not yet commercialized any of our programs, which are in various phases of early-stage and late-stage development, and we do not expect to generate revenue from sales of any of our programs for several years, if at all. To date, we have financed our operations from the proceeds from the issuance of preferred units and the sale of common stock in our IPO, our March 2024 Offering (as defined below), our ATM Facility and our October 2025 Offering. As of December 31, 2025, we had cash and cash equivalents of $131.5 million, marketable securities of $598.6 million and long-term marketable securities of $172.7 million.

Prior to our IPO, we received gross proceeds of $169.0 million from the sales of our preferred units. In connection with our IPO in July 2023, we issued and sold an aggregate of 20,297,500 shares of common stock (inclusive of 2,647,500 shares of common stock pursuant to the exercise in full of the underwriters' option to purchase

additional shares) at a price of $17.00 per share for net proceeds of $315.4 million, after deducting underwriting discounts and commissions, and other offering expenses.

In March 2024, we issued and sold an aggregate of 7,790,321 shares of common stock (inclusive of 1,016,128 shares pursuant to the exercise in full of the underwriters' option to purchase additional shares) at a public offering price of $62.00 per share, for net proceeds of $450.0 million after deducting underwriting discounts and commissions, and other offering expenses (the **"**March 2024 Offering**"**).

In August 2024, we entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC (the "Sales Agent"), pursuant to which we may offer and sell shares of common stock up to a maximum aggregate offering price of $300.0 million, from time to time, through an ATM Facility. During the year ended December 31, 2024, we sold 926,049 shares of common stock under the ATM Facility for gross proceeds of $44.9 million, less commissions and other offering expenses of $1.4 million. During the year ended December 31, 2025 we sold 1,175,701 shares of common stock under the ATM Facility for gross proceeds of $67.6 million, less commissions and other offering expenses of $2.0 million. As of December 31, 2025, $187.5 million remained available for sale under the Sale Agreement.

In connection with our October 2025 Offering, we issued and sold an aggregate of 8,048,782 shares of common stock (inclusive of 1,097,561 shares of common stock pursuant to the exercise in full of the underwriters' option to purchase additional shares) at a public offering price of $41.00 per share, and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to 365,853 shares of common stock at a public offering price of $40.99999 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.00001 per share and are exercisable immediately. The aggregate net proceeds from the offering were $324.1 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Future Funding Requirements

To date, we have not generated any revenue from product sales. We do not expect to generate revenue from product sales unless and until we successfully complete preclinical and clinical development of, receive regulatory approval for, and commercialize a product candidate and we do not know when that will occur, if at all. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical and clinical activities. In addition, if we obtain regulatory approval for any product candidates, we expect to incur significant expenses related to product sales, marketing, and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. We expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on the factors set out above. For more information, see the section titled "Risk Factors—Risks Related to Our Limited Operating History, Financial Position and Capital Requirements."

Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the rate of progress in the development of our zumilokibart (APG777), APG279, APG273, and APG808 programs;
- the scope, results and costs of preclinical studies and clinical trials for any other current and future programs;
- the number and characteristics of programs and technologies that we develop or may in-license;
- the costs and timing of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs necessary to obtain regulatory approvals, if any, for any approved products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including claims of infringement, misappropriation or other violation of third-party intellectual property;
- the continuation of our existing licensing arrangements and entry into new collaborations and licensing arrangements;
- the costs we incur in maintaining business operations;
- the costs of hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the costs of adding operational, financial and management information systems and personnel;
- adverse global macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), government shutdowns, volatility in financial markets and other challenges in the global economy;
- the costs associated with being a public company;
- the costs and timing of future laboratory facilities;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for programs.
- Identifying potential programs and product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests could be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect our stockholders' rights.

Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, and may require the issuance of warrants, which could potentially dilute our stockholders' ownership interests.

If we raise additional funds through strategic collaborations, licensing arrangements, royalty financings or other collaborations with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our business.

If we are unable to raise additional funds when needed or on acceptable terms, we may be required to delay, limit, suspend, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

As of December 31, 2025, we had $131.5 million of cash and cash equivalents, $598.6 million of marketable securities and $172.7 million of long-term marketable securities. Based on our current operating plan, as of the date of this Annual Report, we estimate that our existing cash, cash equivalents, marketable securities and long-term marketable securities will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the issuance of our consolidated financial statements included elsewhere in this Annual Report. Moreover, based on our current operating plan, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the second half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Cash Flows

The following table provides information regarding our cash flows for the periods presented (in thousands):

	YEAR ENDED DECEMBER 31,	
	2025	2024
Net cash, cash equivalents, and restricted cash provided by (used in):		
Operating activities	$ (227,450)	$ (171,174)
Investing activities	(179,574)	(300,462)
Financing activities	396,490	495,109
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (10,534)	$ 23,473

Net Cash used in Operating Activities

Net cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of operating assets and liabilities, which are generally attributable to timing of payments, and the related effect on certain account balances, operational and strategic decisions and contracts to which we may be a party.

For the year ended December 31, 2025, operating activities used $227.5 million of cash, primarily due to a net loss of $255.8 million, net changes in our operating assets and liabilities of $15.5 million and amortization of discounts on marketable securities of $7.5 million. This was partially offset by non-cash charges of $46.3 million for equity-based compensation and $3.7 million related to lease expense.

For the year ended December 31, 2024, operating activities used $171.2 million of cash, primarily due to a net loss of $182.1 million and amortization of discounts on marketable securities of $12.2 million. This was partially offset by non-cash charges of $23.3 million for equity-based compensation and $1.7 million related to lease expense.

Net Cash used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 was $179.6 million, primarily related to the $642.3 million purchase of marketable securities and $5.1 million purchase of property and equipment. This was partially offset by the maturities of $467.9 million of marketable securities.

Net cash used in investing activities for the year ended December 31, 2024 was $300.5 million, primarily related to the $649.5 million purchase of marketable securities and $1.1 million purchase of property and equipment. This was partially offset by the maturities of $350.1 million of marketable securities.

Net Cash provided by Financing Activities

For the year ended December 31, 2025, financing activities provided $396.5 million of cash, primarily related to the issuance and sale of common stock from our October 2025 Offering, net of paid issuance costs, and the issuance of common stock under our ATM Facility.

For the year ended December 31, 2024, financing activities provided $495.1 million of cash, primarily related to the issuance and sale of common stock from our March 2024 Offering, net of paid issuance costs, and the issuance of common stock under our ATM Facility in December 2024.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for preclinical research studies and testing, clinical trials, manufacturing and other services. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs. The exact amounts of such obligations are dependent on the timing of termination and the terms of the associated agreement. Accordingly, these payments are not disclosed as the amount and timing of such payments are not known.

Our agreements to license intellectual property include potential milestone payments that are dependent upon the development of products using the intellectual property licensed under the agreements and contingent upon the achievement of specific development and clinical milestones. As of December 31, 2025, we have incurred $17.0 million of the maximum aggregate potential milestone payments. We are also obligated to pay royalties to (i) Paragon at a royalty rate of a low single-digit percentage based on net sales of any products under the License Agreements, once commercialized and (ii) WuXi Biologics at a royalty rate of a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer.

We do not have any off-balance sheet arrangements that are material or reasonably likely to become material to our financial condition or results of operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us 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 consolidated financial statements, as well as the reported revenues recognized and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that are most critical to the judgments and estimates used in the preparation of our consolidated financial statements. While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies used in preparation of our consolidated financial statements require the most significant judgments and estimates.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, overhead costs, contract services and other related costs. The value of goods and services received from CROs and CMOs in the reporting period are estimated based on the level of services performed, and progress in the period in cases when we have not received an invoice from the supplier. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense. When billing terms under these contracts do not coincide with the timing of when the work is performed, we are required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including our knowledge of the progress towards completion of the specific tasks to be performed, invoicing to date under the contracts, communication from the vendors of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts.

Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by us.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued accounting standards and have determined that, other than as disclosed in Note 2 to our consolidated financial statements included elsewhere in this Annual Report, such standards are not expected to have a material impact on our consolidated financial statements or do not otherwise apply to our operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents, short-term and long-term marketable securities of $902.9 million as of December 31, 2025, which consisted primarily of U.S. Treasury Securities, Commercial Paper, U.S. Government Bonds, and Corporate Securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short and intermediate-term duration, according to our audit committee-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. Our primary exposure to market risk is interest income volatility, which is sensitive to changes in the general level of interest rates; however due to the low risk profiles of our investments, we do not anticipate a significant exposure to interest rate risk on the fair market value of our investments. We believe the effect of a hypothetical 10% change in market interest rates would not have had a material impact on our historical consolidated financial statements for the periods presented.

Foreign Currency Risk

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities primarily associated with a limited number of clinical and manufacturing activities. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments or transactions are made. We believe the effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have had a material impact on our historical consolidated financial statements for the periods presented.

Inflation Risk

Although we do not believe that inflation has had a material effect on our business, financial position or results of operations to date, we may experience some effect due to an impact on the costs to conduct clinical trials, manufacturing and supply costs, labor costs, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

Item 8. Financial Statements and Supplementary Data

Apogee Therapeutics, Inc.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Apogee Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Apogee Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 2, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

We have audited the accompanying consolidated balance sheets of Apogee Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 2, 2026 expressed an unqualified opinion thereon.

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 consolidated 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.

Accrued and Prepaid Clinical Expenses and Estimates

Description of the Matter	As of December 31, 2025, the Company's accrued clinical expenses balance and prepaid clinical expenses balance was $9.2 million and $0.6 million, respectively. As discussed in Note 2 to the consolidated financial statements, the Company estimates the value of clinical services received in the reporting period based on the level of services performed and the progress in the period in cases when the Company has not received an invoice from the supplier. The Company makes these estimates based on a number of factors, including the Company's knowledge of progress towards completion of certain tasks to be performed, invoicing to date under the contracts, communication from vendors of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred. Auditing the Company's accrued and prepaid clinical expenses was complex in the context of our audit due to the volume of the Company's clinical activities. Furthermore, due to the duration of the Company's clinical programs, and the timing of information received from third parties, the actual amounts incurred may not be known at the time the consolidated financial statements are issued.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accrued and prepaid clinical expense process. For example, we tested controls over management's review of the costs incurred for each vendor and the invoices received to develop estimated balances for accrued and prepaid clinical expenses. To evaluate accrued and prepaid clinical expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used by management to determine the accruals or prepaids. We evaluated the progress of clinical activities through discussion with the Company's personnel that oversee the Company's programs and inspected the Company's contracts with third parties and any pending change orders to assess the impact on amounts recorded. In addition, we compared management's assessment of costs incurred to date to confirmations obtained directly from third parties. We also analyzed fluctuations in accruals by vendor and by program throughout the period subject to audit and tested subsequent invoices received from third parties.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2023.

Boston, Massachusetts

March 2, 2026

PART I – FINANCIAL INFORMATION

APOGEE THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	DECEMBER 31, 2025	DECEMBER 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 131,549	$ 141,789
Marketable securities	598,643	378,864
Prepaid expenses and other current assets	11,166	9,060
Total current assets	741,358	529,713
Long-term marketable securities	172,730	210,416
Property and equipment, net	5,688	1,959
Right-of-use asset, net	8,687	11,365
Other non-current assets	8,671	498
Total assets	$ 937,134	$ 753,951
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,221	$ 1,071
Lease liability	3,504	3,234
Accrued expenses and other current liabilities	23,181	24,255
Total current liabilities	27,906	28,560
Long-term liabilities:		
Lease liability, net of current	5,345	8,597
Total liabilities	33,251	37,157
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common Stock; $0.00001 par value, 400,000,000 authorized, 69,038,943 issued and 68,401,349 outstanding as of December 31, 2025; 400,000,000 authorized, 59,478,725 issued and 58,062,898 outstanding as of December 31, 2024	1	1
Additional paid-in capital	1,464,561	1,021,794
Accumulated other comprehensive income	1,080	915
Accumulated deficit	(561,759)	(305,916)
Total stockholders’ equity	903,883	716,794
Total liabilities and stockholders’ equity	$ 937,134	$ 753,951

The accompanying notes are an integral part of these consolidated financial statements.

APOGEE THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Operating expenses:			
Research and development [1]	$ 214,712	$ 167,865	$ 68,424
General and administrative	70,883	49,005	24,579
Total operating expenses	285,595	216,870	93,003
Loss from operations	(285,595)	(216,870)	(93,003)
Other income, net:			
Interest income, net	30,030	34,742	9,018
Total other income, net	30,030	34,742	9,018
Net loss before taxes	(255,565)	(182,128)	(83,985)
Provision for income taxes	(278)	(18)	—
Net loss after taxes	$ (255,843)	$ (182,146)	$ (83,985)
Net loss per share, basic and diluted	$ (4.22)	$ (3.30)	$ (3.36)
Weighted-average common shares outstanding, basic and diluted	60,690,820	55,193,971	25,005,774

(1) Includes related party amounts of $2,186 for the year ended December 31, 2025, $19,179 for the year ended December 31, 2024 and $26,285 for the year ended December 31, 2023.

The accompanying notes are an integral part of these consolidated financial statements.

APOGEE THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Net loss	$ (255,843)	$ (182,146)	$ (83,985)
Unrealized gains on marketable securities, net of tax	165	586	329
Comprehensive loss	$ (255,678)	$ (181,560)	$ (83,656)

The accompanying notes are an integral part of these consolidated financial statements.

APOGEE THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF PREFERRED UNITS AND STOCKHOLDERS' EQUITY/MEMBERS' DEFICIT

(In thousands, except unit/share data)

	SERIES A PREFERRED UNITS		SERIES B PREFERRED UNITS		COMMON UNITS		INCENTIVE UNITS		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY/MEMBERS' DEFICIT
	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2022	20,000,000	$ 28,971	45,089,212	$ 148,496	5,000,000	$ 2,251	1,625,086	$ 2,142	—	$ —	$ —	$ (39,785)	$ —	$ (35,392)
Vesting of incentive units	—	—	—	—	—	—	922,338	—	—	—	—	—	—	—
Conversion of preferred, common, and incentive units into common stock	(20,000,000)	(28,971)	(45,089,212)	$ (148,496)	(5,000,000)	(2,251)	(2,547,424)	(4,686)	27,597,438	—	184,404	—	—	177,467
Common stock issued in IPO, net of issuance costs of $29,666	—	—	—	—	—	—	—	—	20,297,500	—	315,391	—	—	315,391
Vesting of restricted stock	—	—	—	—	—	—	—	—	443,831	—	—	—	—	—
Equity-based compensation expense	—	—	—	—	—	—	—	2,544	—	—	3,559	—	—	6,103
Unrealized gain on marketable securities, net of tax	—	—	—	—	—	—	—	—	—	—	—	—	329	329
Net loss	—	—	—	—	—	—	—	—	—	—	—	(83,985)	—	(83,985)
Balance at December 31, 2023	—	$ —	—	$ —	—	$ —	—	$ —	48,338,769	$ —	$ 503,354	$ (123,770)	$ 329	$ 379,913

APOGEE THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2023	48,338,769	$ —	$ 503,354	$ (123,770)	$ 329	$ 379,913
Common stock issued, net of issuance costs of $33,045	7,790,321	1	449,954	—	—	449,955
Common stock issued, net of issuance costs of $1,386, under the at the market ("ATM") equity offering program	926,049	—	43,528	—	—	43,528
Vesting of restricted stock	937,083	—	—	—	—	—
Issuance of common stock upon exercise of stock options	43,025	—	852	—	—	852
Issuance of common stock under employee stock purchase plan	27,651	—	774	—	—	774
Equity-based compensation expense	—	—	23,332	—	—	23,332
Change in unrealized gain on marketable securities, net of tax	—	—	—	—	586	586
Net loss	—	—	—	(182,146)	—	(182,146)
Balance at December 31, 2024	58,062,898	$ 1	$ 1,021,794	$ (305,916)	$ 915	$ 716,794
Common stock and pre-funded warrants issued, net of issuance costs of $20,948	8,048,782	—	324,052	—	—	324,052
Vesting of restricted stock	850,110	—	—	—	—	—
Common stock issued, net of issuance costs of $2,025, under the ATM offering program	1,175,701	—	65,582	—	—	65,582
Issuance of common stock upon exercise of stock options	222,104	—	5,300	—	—	5,300
Issuance of common stock under employee stock purchase plan	41,754	—	1,556	—	—	1,556
Equity-based compensation expense	—	—	46,277	—	—	46,277
Unrealized gain on marketable securities, net of tax	—	—	—	—	165	165
Net loss	—	—	—	(255,843)	—	(255,843)
Balance at December 31, 2025	68,401,349	$ 1	$ 1,464,561	$ (561,759)	$ 1,080	$ 903,883

The accompanying notes are an integral part of these consolidated financial statements.

APOGEE THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Cash flows from operating activities:			
Net loss	$ (255,843)	$ (182,146)	$ (83,985)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation expense	1,418	189	—
Equity-based compensation expense	46,277	23,332	6,103
Amortization of discounts on marketable securities	(7,501)	(12,241)	(3,071)
Non-cash lease expense	3,677	1,694	87
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(2,106)	(6,080)	(2,785)
Other assets	(8,467)	(97)	(107)
Accounts payable	150	(1,072)	1,613
Operating lease liability	(3,981)	(1,045)	(270)
Accrued expenses	(1,074)	6,292	7,654
Net cash used in operating activities	(227,450)	(171,174)	(74,761)
Cash flows from investing activities:			
Purchases of marketable securities	(642,300)	(649,450)	(303,743)
Maturities of marketable securities	467,873	350,140	30,000
Purchases of property and equipment	(5,147)	(1,152)	(167)
Net cash used in investing activities	(179,574)	(300,462)	(273,910)
Cash flows from financing activities:			
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	324,052	449,955	315,391
Proceeds from issuance of common stock under ATM equity offering program, net of issuance costs	65,582	43,528	—
Proceeds from exercise of options and employee stock purchase plan purchases	6,856	1,626	—
Net cash provided by financing activities	396,490	495,109	315,391
(Decrease) increase in cash, cash equivalents and restricted cash	(10,534)	23,473	(33,280)
Cash, cash equivalents and restricted cash, beginning of period	142,083	118,610	151,890
Cash, cash equivalents and restricted cash, end of period	$ 131,549	$ 142,083	$ 118,610
Supplemental disclosures of non-cash activities:			
Exchange of 72,636,636 preferred, common, and incentive units in connection with the Reorganization (Note 1)	$ —	$ —	$ 184,404
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ 999	$ 10,842	$ 2,304
Deferred financing issuance costs in accounts payable and accrued expenses	$ —	$ 30	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 619	$ 210
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 131,549	$ 141,789	$ 118,316
Restricted cash	—	294	294
Total	$ 131,549	$ 142,083	$ 118,610

The accompanying notes are an integral part of these consolidated financial statements.

APOGEE THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business

Apogee Therapeutics, Inc., together with its consolidated subsidiary (collectively, "Apogee" or the "Company"), a successor to Apogee Therapeutics, LLC, is a clinical stage biotechnology company advancing optimized, novel biologics with the potential for differentiated efficacy and dosing in the largest inflammatory and immunology ("I&I") markets, including for the treatment of atopic dermatitis ("AD"), asthma, eosinophilic esophagitis ("EoE"), chronic obstructive pulmonary disease ("COPD"), and other I&I indications. Apogee's antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties.

On July 13, 2023, the Company completed a reorganization, pursuant to which the members of Apogee Therapeutics, LLC contributed their units in Apogee Therapeutics, LLC to Apogee Therapeutics, Inc. in exchange for shares of common stock or non-voting common stock of Apogee Therapeutics, Inc. (the "Reorganization"), as follows:

- holders of Series A Preferred Units of Apogee Therapeutics, LLC received 7,678,000 shares of non-voting common stock of Apogee Therapeutics, Inc.;
- holders of Series B Preferred Units of Apogee Therapeutics, LLC received 11,501,108 shares of common stock and 5,808,642 shares of non-voting common stock of Apogee Therapeutics, Inc.;
- holders of common units of Apogee Therapeutics, LLC received 1,919,500 shares of common stock of Apogee Therapeutics, Inc.;
- holders of vested incentive units of Apogee Therapeutics, LLC received 690,188 shares of common stock of Apogee Therapeutics, Inc.; and
- holders of unvested incentive units of Apogee Therapeutics, LLC received 2,779,358 shares of restricted common stock of Apogee Therapeutics, Inc.

In July 2023, the Company completed its IPO, pursuant to which it issued and sold an aggregate of 20,297,500 shares of its common stock (inclusive of 2,647,500 shares pursuant to the exercise of the underwriters' overallotment option in full) at the IPO price of $17.00 per share for net cash proceeds of $315.4 million, after deducting underwriting discounts and commissions and other offering expenses. The shares of Apogee Therapeutics, Inc. began trading on the Nasdaq Global Market on July 14, 2023 under the symbol APGE.

The Company is subject to risks and uncertainties common to early stage companies in the biotechnology industry, including, but not limited to, completing preclinical studies and clinical trials, obtaining regulatory approval for its programs, market acceptance of products, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, and the ability to raise additional capital to fund operations. The Company's programs currently under development, zumilokibart (APG777), APG279 (zumilokibart + APG990), APG273 (zumilokibart + APG333), and APG808, will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales. The Company has primarily funded its operations with proceeds from the sales of preferred units and common stock and has not generated any revenue since inception.

As a result, the Company will need substantial additional funding to support its continued operations and growth strategy. Until such a time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may be unable to raise additional

funds or enter into such other agreements on favorable terms, or at all. If the Company fails to raise capital or enter into such agreements as, and when, needed, the Company may have to significantly delay, scale back or discontinue the development and commercialization of one or more of its programs.

Company Liquidity

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued. The Company had an accumulated deficit of $561.8 million as of December 31, 2025. Further, the Company incurred a net loss of $255.8 million and experienced negative cash flows from operations of $227.5 million for the year ended December 31, 2025. Based on the Company's current operating plan, it estimates that its existing cash and cash equivalents of $131.5 million, marketable securities of $598.6 million and long-term marketable securities of $172.7 million as of December 31, 2025, will be sufficient to enable the Company to fund its operating expenses and capital requirements through at least the next 12 months from the issuance of these consolidated financial statements.

The Company is subject to those risks associated with any biotechnology company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements prior to the Reorganization include the accounts of Apogee Therapeutics, LLC and its wholly-owned subsidiary, Apogee Biologics, Inc. The consolidated financial statements subsequent to the Reorganization include the accounts of Apogee Therapeutics, Inc. and its wholly-owned subsidiaries, Apogee Therapeutics Securities Corporation, formed as a Massachusetts security corporation in September 2024, and Apogee Biologics, Inc. until December 31, 2024, when Apogee Biologics, Inc. merged with and into Apogee Therapeutics, Inc. with Apogee Therapeutics, Inc. surviving the merger.

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates of the Financial Accounting Standards Board ("FASB"). In the Company's management opinion, the information furnished in these consolidated financial statements reflect all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Apogee Therapeutics, Inc. and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of

these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Significant estimates relied upon in preparing the accompanying consolidated financial statements include, among others: research and development expenses and related prepaid or accrued costs, the valuation of equity-based compensation awards and related expense.

Segments

The Company has one operating segment and one reporting unit. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of assessing performance and allocating resources. All of the Company's assets are located in the United States.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures ("ASC 820"), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis as of December 31, 2025 include cash equivalents and marketable securities (Notes 3 and 4). The carrying amounts reflected in the accompanying consolidated balance sheets for prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Property and Equipment, net

Property and equipment are recorded at cost. Depreciation is calculated using the straight-line method over the following estimated useful lives of the assets:

	ESTIMATED USEFUL LIFE
Furniture and fixtures	5 years
Lab equipment	5 years
IT equipment	3 years
Leasehold improvements	Shorter of the lease term or useful life

Upon disposal, retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, overhead costs, contract services and other related costs. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed, and progress in the period in cases when the Company has not received an invoice from the supplier. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the specific tasks to be performed, invoicing to date under the contracts, communication from the vendors of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company.

Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company makes estimates and judgments about future taxable income based on assumptions that are consistent with the Company's plans and estimates. Should the actual amounts differ from these estimates, the amount of the Company's valuation allowance could be materially impacted. Changes in these estimates may result in significant increases or decreases to the tax provision in a period in which such estimates are changed, which in turn would affect net income or loss.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit to the extent that the position is more likely than not to be sustained on examination by the taxing authorities based on the technical merits of the position as well as consideration of the available facts and circumstances. The Company records interest and penalties related to uncertain tax positions, if applicable, as a component of income tax expense.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original final maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in interest-bearing money market funds, U.S. treasury securities, U.S. Government agency securities, and commercial paper.

Marketable Securities

The Company's investments are comprised of U.S. government agency securities, U.S. treasury securities, commercial paper and corporate debt securities. Investments are classified at the time of purchase, based on management's intent, as held-to-maturity, available-for-sale, or trading. All of the Company's marketable security investments are classified as available-for-sale securities and are reported at fair market value using quoted prices in active markets for similar securities. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included as a component of other income within the consolidated statements of operations and comprehensive loss. Unrealized gains and losses are included within the consolidated statements of comprehensive loss.

The Company assesses its available-for-sale securities under the available-for-sale security impairment model in ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Statements as of each reporting date in order to determine if a portion of any decline in fair value below carrying value is the result of a credit loss for its available-for-sale securities. The Company records credit losses for its available-for-sale securities in the consolidated statements of operations and comprehensive loss as credit loss expense, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities. Declines in fair value below carrying value attributable to non-credit related factors are recorded as accumulated other comprehensive loss, which is a separate component of stockholders' equity.

The Company classifies its available-for-sale securities that mature within one year from the balance sheet date as current assets on the consolidated balance sheets. Available-for-sale securities that mature more than one year from the balance sheet date are classified as non-current assets on the consolidated balance sheets.

Leases

The Company determines the initial classification and measurement of its right-of-use assets and lease liabilities at the lease commencement date and thereafter if modified. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its incremental borrowing rate. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

Fixed lease expense for operating leases is recognized on a straight-line basis, unless the right-of-use assets have been impaired, over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the statements of operations and comprehensive loss.

Pre-funded Warrants

The Company evaluates pre-funded warrants under FASB ASC Topic 480, *Distinguishing Liabilities from Equity* and FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815") to determine whether the warrants should be classified as liabilities or equity. Pre-funded warrants are classified as stockholders' equity when they are (i) indexed to the Company's own stock and (ii) meet all equity-classification conditions in ASC 815-40. Proceeds received upon issuance of pre-funded warrants are recorded to additional paid-in capital. Upon exercise, the Company records proceeds to common stock and additional paid-in capital. Because the exercise price is nominal,

equity-classified pre-funded warrants are included in basic and diluted weighted-average shares outstanding beginning on the issuance date but are not reflected as legally outstanding shares until exercised.

Equity-Based Compensation

The Company issues equity-based awards to employees, managers, executives, non-employees and service providers in the form of restricted common stock, restricted stock units, and stock options. The Company accounts for equity-based compensation awards in accordance with FASB ASC Topic 718, Compensation-Stock Compensation.

The fair value of the Company's common stock underlying its equity awards is based on the quoted market price of the Company's common stock on the grant date. The Company estimates the fair value of its stock options using the Black-Scholes option pricing model, which uses as inputs the fair value of the Company's common stock, and certain management estimates, including the expected stock price volatility, the expected term of the award, the risk-free rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information is available. The Company selects companies with comparable characteristics with historical share price information that approximates the expected term of the equity-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period that approximates the calculated expected term of the stock options. The Company will continue to apply this method until a sufficient amount of historical information regarding the volatility of its stock price becomes available. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data. The expected dividend yield is assumed to be zero as the Company has no current plans to pay any dividends on common stock. The fair value of the restricted stock units are based on the Company's stock price on the date of the grant.

The Company generally issues equity awards that are subject to either service-based vesting conditions and in limited instances, service-based and performance-based vesting conditions. Compensation expense for awards issued to grantees with service-based vesting conditions are recognized on a straight-line basis based on the grant date fair value over the associated requisite service period of the award, which is generally the vesting term. Compensation expense for awards to grantees with service-based and performance-based vesting conditions are recognized based on the grant-date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. As of each reporting date, the Company estimates the probability that specified performance criteria will be met and does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company evaluates whether an equity award should be classified and accounted for as a liability award or equity award for all equity-based compensation awards granted. As of December 31, 2025, all of the Company's equity-based awards were equity classified. Forfeitures are recognized as they occur. The Company classifies equity-based compensation expense in the accompanying consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified, as applicable.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially expose the Company to credit risk primarily consist of cash, cash equivalents and marketable securities. The Company's investment portfolio is comprised of money market funds, debt securities issued by U.S. government and corporate debt securities. The Company maintains its deposits with accredited financial institutions and, consequently, the Company does not believe it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. As of December 31, 2025 and December 31, 2024, predominantly all of the Company's primary operating accounts significantly exceeded the FDIC limits.

The Company is dependent on third-party organizations to research, develop, manufacture and process its product candidates for its development programs. In particular, the Company currently relies on a limited number of

third-party manufacturers for preclinical, clinical, and future commercial manufacturing activities. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs could be adversely affected by a significant interruption in the supply of the necessary materials.

Off-Balance Sheet Arrangements

As of December 31, 2025 and December 31, 2024, the Company had no off-balance sheet risks such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and events other than those with stockholders. The Company's unrealized gains and losses on marketable securities represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the consolidated statements of comprehensive loss.

Net Loss Per Share

The Company has two classes of common stock outstanding comprised of voting and non-voting shares. The rights of the holders of voting and non-voting shares are identical, except with respect to voting and conversion. Each share of non-voting stock may be converted into one share of voting stock at any time at the option of the stockholder, subject to certain beneficial ownership limitations. Net loss per share for each class of common stock issued is the same as they are entitled to the same liquidation and dividend rights.

Prior to the Reorganization, the Company calculated basic net loss per common share by dividing net loss by the weighted-average number of common units outstanding for the period. Subsequent to the Reorganization, the Company calculates basic net loss per common share by dividing net loss by the weighted-average number of common shares outstanding for the period, which includes pre-funded warrants to purchase common stock. The Company has generated a net loss in the periods presented so the basic and diluted net loss per unit and net loss per share are the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

For periods presented that include the Reorganization, the weighted-average shares of common stock outstanding include the weighted average number of common units outstanding prior to the Reorganization.

3. Marketable Securities

The following is a summary of the Company's investing portfolio (in thousands):

	AS OF DECEMBER 31, 2025 UNREALIZED			
	COST	GAINS	LOSSES	FAIR VALUE
Marketable securities				
Maturities within one year:				
U.S. treasury securities	$ 221,182	$ 430	$ —	$ 221,612
Debt securities issued by U.S. government agencies	127,796	324	—	128,120
Commercial paper	69,534	22	—	69,556
Corporate debt securities	179,230	136	(11)	179,355
Total maturities within one year	597,742	912	(11)	598,643
Maturities between one and two years:				
U.S. treasury securities	$ 128,396	$ 149	$ —	$ 128,545
Debt securities issued by U.S. government agencies	14,580	16	—	14,596
Corporate debt securities	29,583	16	(10)	29,589
Total maturities between one and two years	172,559	181	(10)	172,730
Total marketable securities	$ 770,301	$ 1,093	$ (21)	$ 771,373

	AS OF DECEMBER 31, 2024 UNREALIZED			
	COST	GAINS	LOSSES	FAIR VALUE
Marketable securities				
Maturities within one year:				
U.S. treasury securities	$ 158,332	$ 469	$ (34)	$ 158,767
Debt securities issued by U.S. government agencies	115,425	169	—	115,594
Commercial paper	35,508	49	—	35,557
Corporate debt securities	68,831	146	(31)	68,946
Total maturities within one year	378,096	833	(65)	378,864
Maturities between one and two years:				
U.S. treasury securities	$ 90,330	$ 109	$ (271)	$ 90,168
Debt securities issued by U.S. government agencies	102,707	470	(75)	103,102
Corporate debt securities	17,232	—	(86)	17,146
Total maturities between one and two years	210,269	579	(432)	210,416
Total marketable securities	$ 588,365	$ 1,412	$ (497)	$ 589,280

As of December 31, 2025, the Company had 22 securities with a total fair market value of $43.7 million in an unrealized loss position. The Company does not intend to sell its investments before recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recorded as of December 31, 2025 and December 31, 2024. Securities are evaluated at the end of each reporting period. The Company did not record any impairment related to its marketable securities during the years ended December 31, 2025, 2024, and 2023.

4. Fair Value Measurements

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

	AS OF DECEMBER 31, 2025			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Cash equivalents:				
Money market funds	$ 86,669	$ —	$ —	$ 86,669
U.S. treasury securities	5,903	—	—	5,903
Commercial paper	—	26,428	—	26,428
Marketable securities:				
U.S. treasury securities	350,157	—	—	350,157
Debt securities issued by U.S. government agencies	—	142,716	—	142,716
Commercial paper	—	69,556	—	69,556
Corporate debt securities	—	208,944	—	208,944
Total	$ 442,729	$ 447,644	$ —	$ 890,373

	AS OF DECEMBER 31, 2024			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Cash equivalents:				
Money market funds	$ 132,491	$ —	$ —	$ 132,491
Marketable securities:				
U.S. treasury securities	248,935	—	—	248,935
Debt securities issued by U.S. government agencies	—	218,696	—	218,696
Commercial paper	—	35,557	—	35,557
Corporate debt securities	—	86,092	—	86,092
Total	$ 381,426	$ 340,345	$ —	$ 721,771

5. Prepaids and Other Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	DECEMBER 31, 2025	DECEMBER 31, 2024
Prepaid clinical	$ 637	$ 552
Prepaid manufacturing	1,090	214
Prepaid other	2,873	1,855
Interest receivable	5,961	4,697
Other current assets	605	1,742
Total	$ 11,166	$ 9,060

As of December 31, 2025, the Company had no restricted cash. As of December 31, 2024, the Company had restricted cash of $0.3 million held as a letter of credit for the benefit of a clinical research organization. The related letter of credit was classified within other non-current assets on the consolidated balance sheet as of December 31, 2024.

As of December 31, 2025, the Company had $8.5 million in long-term prepayments, made in conjunction with the Company's research and development activities, classified within other non-current assets. As of December 31, 2024, the Company had no long-term prepayments.

6. Property and Equipment, net

Property and Equipment, net consisted of the following (in thousands):

	DECEMBER 31, 2025	DECEMBER 31, 2024
Lab equipment	$ 1,469	$ 1,285
Leasehold improvements	3,075	863
Furniture and fixtures	1,760	—
IT equipment	992	—
Less: Accumulated depreciation	(1,608)	(189)
Total	$ 5,688	$ 1,959

The Company recognized $1.4 million and $0.2 million of depreciation expense for the years ended December 31, 2025 and 2024, respectively. The Company recognized an immaterial amount of depreciation expense for the year ended December 31, 2023.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	DECEMBER 31, 2025	DECEMBER 31, 2024
Accrued external research and development expenses	$ 3,231	$ 2,924
Accrued manufacturing expenses	5,889	15,505
Accrued clinical expenses	9,178	2,033
Accrued employee compensation	3,658	1,895
Accrued other	1,225	1,898
Total	$ 23,181	$ 24,255

8. Other Significant Agreements

Paragon Option and License Agreements

For the years ended December 31, 2025, 2024, and 2023, the Company recognized $0.1 million, $19.2 million, and $26.3 million, respectively, of research and development expense in connection with services provided by Paragon under the Option and License Agreements.

For the year ended December 31, 2025, the Company recognized $2.1 million of research and development expense related to an undisclosed target.

Option Agreements

In February 2022, the Company entered into an antibody discovery and option agreement with Paragon, which was subsequently amended in November 2022 (as amended, the "2022 Option Agreement"). Under the terms of the 2022 Option Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. The 2022 Option Agreement initially included two selected targets, IL-13 and IL-4Rα, and was subsequently amended in November 2022 to include an additional selected target, OX40L. Under the 2022 Option Agreement, the Company has the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets (each, an "Option"). From time to time, the Company can choose to add additional targets to the collaboration by mutual agreement with Paragon.

Pursuant to the terms of the 2022 Option Agreement, the parties initiated certain research programs that generally focused on a particular target (each, a "Research Program"). Each Research Program is aimed at discovering,

generating, identifying and/or characterizing antibodies directed to the respective target. For each Research Program, the parties established a research plan that sets forth the activities that will be conducted, and the associated research budget (each, a "Research Plan"). Upon execution of the 2022 Option Agreement, the Company agreed with Paragon on an initial Research Plan that outlined the services that will be performed commencing at inception of the arrangement related to IL-13 and IL-4Rα. The Research Plan for OX40L was agreed to prior to December 31, 2022. The Company's exclusive option with respect to any future Research Program is exercisable at the Company's sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Plan activities (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the 2022 Option Agreement.

In consideration for the exclusive options granted under the 2022 Option Agreement, the Company paid an upfront cash amount of $1.3 million and issued 1,250,000 common units to Paragon. Paragon was also entitled to up to an additional 3,750,000 of common units in exchange for the rights granted under the 2022 Option Agreement, which were issued in connection with the closings of the additional tranches of the Series A Preferred Unit financing. Under the 2022 Option Agreement, on a Research Program-by-Research Program basis following the finalization of the Research Plan for each respective Research Program, the Company is required to pay Paragon a nonrefundable fee in cash of $0.5 million. The Company is also obligated to compensate Paragon on a quarterly basis for its services performed under each Research Program based on the actual costs incurred.

In November 2023, the Company entered into an additional antibody discovery and option agreement with Paragon (the "2023 Option Agreement" and together with the 2022 Option Agreement, collectively, the "Option Agreements"). Under the terms of the 2023 Option Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. The 2023 Option Agreement initially includes one target, TSLP. Under the 2023 Option Agreement, the Company has the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets. From time to time, the Company can choose to add additional targets to the collaboration by mutual agreement with Paragon.

Pursuant to the terms of the 2023 Option Agreement, the parties may initiate Research Programs. Each Research Program will be aimed at discovering, generating, identifying and/or characterizing antibodies directed to the respective target. For each Research Program, the parties must establish a Research Plan. In January 2024, the Company and Paragon agreed on an initial Research Plan with Paragon that outlined the services that will be performed commencing at inception of the arrangement related to TSLP. The Company's exclusive option with respect to each Research Program is exercisable at the Company's sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Plan activities. There is no payment due upon exercise of an Option pursuant to the 2023 Option Agreement.

Under the 2023 Option Agreement, on a Research Program-by-Research Program basis following the finalization of the Research Plan for each respective Research Program, the Company is required to pay Paragon a nonrefundable fee in cash of $2.0 million. The Company is also obligated to compensate Paragon on a quarterly basis for its services performed under each Research Program based on the actual costs incurred. The Company expenses the service fees as the associated costs are incurred when the underlying services are rendered. In January 2024, the Company finalized the Research Plan with Paragon related to the TSLP target. As such, the Company made a one-time non-refundable payment of $2.0 million to Paragon in the first quarter of 2024.

Unless terminated earlier, the Option Agreements shall continue in force on a Research Program-by-Research Program basis until the earlier of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by the Company; and (ii) the effective date of the license agreement for such Research Program if the Company exercises its Option with respect to such Research Program (the "Term"). Upon the expiration of the Term for all then-existing Research Programs, the applicable Option Agreement will automatically expire in its entirety. The Company may terminate the 2023 Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that the Company must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in

connection with its activities under any terminated Research Program. Each party has the right to terminate either Option Agreement or any Research Program upon (i) 30 days' prior written notice of the other party's material breach that remains uncured for the 30-day period and (ii) the other party's bankruptcy.

Paragon License Agreements

In November 2022, the Company exercised its option available under the 2022 Option Agreement with respect to the IL-13 Research Program. Upon such exercise, the parties entered into an associated license agreement (the "IL-13 License Agreement"). In April 2023, the Company exercised its option available under the 2022 Option Agreement with respect to the IL- 4Rα Research Program and the OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the "IL-4Rα License Agreement" and the "OX40L License Agreement," respectively). In August 2024, the Company exercised its option available under the 2023 Option Agreement with respect to the TSLP Research Program and entered into the associated license agreement (the "TSLP License Agreement" and collectively with the IL-13 License Agreement, the IL-4Rα License Agreement and the OX40L License Agreement, the "License Agreements"). Under the terms of the License Agreements, Paragon granted to the Company an exclusive, worldwide, royalty-bearing, sublicensable right and license with respect to certain information, patent rights and sequence information related to antibodies directed at the respective target to use, make, sell, import, export and otherwise exploit the antibodies directed at the respective target. Pursuant to the License Agreements, the Company granted to Paragon a similar license (except that such license the Company granted to Paragon is non-exclusive) to the respective licenses with respect to multispecific antibodies that are directed at the respective targets and one or more other antibodies. The Company was also granted a right of first negotiation with Paragon concerning the development, license and grant of rights to certain multispecific antibodies associated with each respective license. The Company is solely responsible for the continued development, manufacture and commercialization of products at its own cost and expense for each licensed target.

Under the IL-13 License Agreement, the IL-4Rα License Agreement and the OX40L License Agreement, the Company is obligated to pay Paragon up to $3.0 million upon the achievement of specific development and clinical milestones for the first product under each of the License Agreements that achieves such specified milestones, including a payment of $1.0 million upon the nomination of a development candidate and $2.0 million upon the first dosing of a human patient in a Phase 1 trial. Under the TSLP License Agreement, the Company is obligated to pay Paragon up to $28.0 million upon the achievement of specific development and clinical milestones for the first product, including a payment of $3.0 million upon the nomination of a development candidate and $5.0 million upon the first dosing of a human patient in a Phase 1 trial.

Upon execution of the IL-13 License Agreement, the Company paid Paragon a $1.0 million fee for the nomination of a development candidate. In August 2023, the Company announced the dosing of its first participant in the Phase 1 trial of zumilokibart (APG777) and made a milestone payment of $2.0 million in the fourth quarter of 2023. In November 2023, the Company finalized the nomination of a development candidate under the IL-4Rα License Agreement and made a milestone payment of $1.0 million to Paragon in the fourth quarter of 2023. In March 2024, the Company announced the dosing of its first participant in a Phase 1 trial of APG808 and made a milestone payment of $2.0 million to Paragon in the first quarter of 2024. In May 2024, the Company finalized the nomination of a development candidate under the OX40L License Agreement and made a milestone payment of $1.0 million to Paragon in the second quarter of 2024. In August 2024, the Company announced the dosing of its first participant in the Phase 1 trial of APG990 and made a milestone payment of $2.0 million to Paragon in the third quarter of 2024. In October 2024, the Company finalized the nomination of a development candidate under the TSLP License Agreement and made a milestone payment of $3.0 million to Paragon in the fourth quarter of 2024. In December 2024, the Company announced the dosing of its first participant in the Phase 1 trial of APG333 and made a milestone payment of $5.0 million in the fourth quarter of 2024.

The Company is also obligated to pay royalties to Paragon equal to a low-single digit percentage of net sales of any products under each of the respective License Agreements, and Paragon has a similar obligation to pay royalties to the Company with respect to each of the multispecific licenses. Royalties are due on a product-by-product and country-by-country basis beginning upon the first commercial sale of each product and ending on the later of (i) 12 years after the first commercial sale of such product in such country and (ii) expiration of the last valid claim of a patent covering such product in such country (the "Royalty Term").

Unless earlier terminated, the License Agreements remain in effect until the expiration of the last-to-expire Royalty Term for any and all products associated with the respective license. The Company may terminate the agreement in its entirety or on a country-by-country or product-by-product at any time for any or no reason upon 60 days' advance written notice to Paragon, and either party may terminate for (i) the other party's material breach that remains uncured for 90 days (or 30 days with respect to any failure to make payments) following notice of such breach and (ii) the other party's bankruptcy. Upon any termination prior to the expiration of a License Agreement, all licenses and rights granted pursuant to such License Agreement will automatically terminate and revert to the granting party and all other rights and obligations of the parties will terminate.

Biologics Master Services Agreement — WuXi Biologics (Hong Kong) Limited

In June 2022, Paragon and WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") entered into a biologics master services agreement (the "WuXi Biologics MSA"), which was subsequently novated to the Company by Paragon in the second quarter of 2023. The WuXi Biologics MSA governs all development activities and GMP manufacturing and testing for zumilokibart (APG777), APG990, APG333 and APG808, as well as potential future product candidates, on a work order basis. Under the WuXi Biologics MSA, the Company is obligated to pay WuXi Biologics a service fee and all non-cancellable obligations in the amount specified in each work order associated with the agreement for the provision of services.

The WuXi Biologics MSA terminates on the later of (i) June 20, 2027 or (ii) the completion of services under all work orders executed by the parties prior to June 20, 2027, unless terminated earlier. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier. The Company can terminate the WuXi Biologics MSA or any work order at any time upon 30 days' prior written notice and immediately upon written notice if WuXi Biologics fails to obtain or maintain required material governmental licenses or approvals. Either party may terminate a work order (i) at any time upon six months' prior notice with reasonable cause, provided however that if WuXi Biologics terminates a work order in such manner, no termination or cancellation fees shall be paid by the Company and (ii) immediately for cause upon (a) the other party's material breach that remains uncured for 30 days after notice of such breach, (b) the other party's bankruptcy or (c) a force majeure event that prevents performance for a period of at least 90 days.

For the years ended December 31, 2025, 2024, and 2023, the Company recognized $9.3 million, $31.8 million and $20.2 million, respectively, of research and development expense in connection with the WuXi Biologics MSA.

Cell Line License Agreement — WuXi Biologics (Hong Kong) Limited

In June 2022, Paragon and WuXi Biologics entered into a cell line license agreement (the "Cell Line License Agreement"), which was subsequently novated to the Company by Paragon in the second quarter of 2023. Under the Cell Line License Agreement, the Company received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used to manufacture zumilokibart (APG777), APG990, APG333 and APG808.

In consideration for the license, the Company has paid WuXi Biologics a non-refundable license fee of $150,000. Additionally, if the Company manufactures all of its commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, the Company is required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the "Royalty"). If the Company manufactures part of its commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon six months' prior written notice and the payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by the Company that remains uncured for 60 days

after written notice, (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Master Services Agreement and Project Specific Agreements — Samsung Biologics Limited

In March 2025, the Company entered into a Master Services Agreement (the "Samsung Biologics MSA"), made effective as of February 28, 2025, with Samsung Biologics Co., Ltd. ("Samsung Biologics"), pursuant to which Samsung Biologics will manufacture and supply the Company with zumilokibart (APG777) drug substance (the "Samsung Biologics Product") for clinical development and commercial sale, if approved. The Company is obligated to pay Samsung Biologics service fees for each manufactured batch, as well as the costs of materials purchased by Samsung Biologics and expenses including testing and storage, which such costs and fees will be specified in Project Specific Agreements (each a "PSA").

Also in March 2025, the Company entered into a PSA (the "Initial PSA") with Samsung Biologics, made effective as of February 28, 2025, pursuant to which Samsung Biologics will produce clinical batches of the Samsung Biologics Product at its facility in Incheon, South Korea, perform process characterization and validation, and manufacture process performance qualification lots of the Samsung Biologics Product. Under the Initial PSA, the Company must purchase certain minimum quantities of the Samsung Biologics Product and has agreed to pay Samsung Biologics as determined pursuant to the terms of the Initial PSA.

The Samsung Biologics MSA will terminate in February 2035, or, if a PSA is still in effect, when such PSA terminates, and may be extended upon mutual agreement of the parties. The Initial PSA will terminate in December 2034. Either the Company or Samsung Biologics may terminate the Samsung Biologics MSA or the Initial PSA in the event of an uncured material breach by, insolvency of or inability to perform due to a force majeure event by the other party. In the event all applicable PSAs have been terminated, Samsung Biologics has agreed to provide assistance with certain technology transfer matters, subject to exceptions. If the Company terminates the Samsung Biologics MSA or Initial PSA without cause, the Company will generally be responsible for paying the purchase price for the Company's aggregate product commitment for the remainder of the term, less any amounts the Company has already paid.

In February 2026, the Company entered into a separate PSA with Samsung that would provide for the commercial manufacture of zumilokibart drug substance should the program eventually receive regulatory approval. If specific circumstances render Apogee unable to proceed with commercial distribution, the PSA provides for Samsung to receive compensation, including for contractually obligated expenses, and an exit fee in the high single-digit millions.

For the years ended December 31, 2025 and 2024 the Company recognized $12.9 million and $9.9 million, respectively, of research and development expense in connection with the Samsung Biologics MSA. For the year ended December 31, 2023, the Company did not recognize any research and development expense in connection with the Samsung Biologics MSA.

9. Commitments and Contingencies

Other Contracts

Currently, all of the Company's preclinical and clinical drug manufacturing, storage, distribution or quality testing are outsourced to third-party manufacturers. As development programs progress and new process efficiencies are built, the Company expects to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products. Under such agreements, the Company is contractually obligated to make certain payments to vendors upon early termination, primarily to reimburse them for their unrecoverable outlays incurred prior to cancellation as well as any amounts owed by the Company prior to early termination. The actual amounts the Company could pay in the future to the vendors under such agreements may differ from the purchase order amounts due to cancellation provisions.

Indemnification Agreements

The Company enters into standard indemnification agreements and/or indemnification sections in other agreements in the ordinary course of business. Pursuant to the agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. There is no limit to the maximum potential amount of future payments the Company could be required to make under these indemnification agreements. As of December 31, 2025, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company was not aware of any claims under these indemnification arrangements as of December 31, 2025 and December 31, 2024.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of FASB ASC Topic 450, *Contingencies ("*ASC 450*")*. The Company expenses as incurred the costs related to its legal proceedings.

10. Stockholders' Equity

Common Stock

In July 2023, the Company completed its IPO, selling an aggregate of 20,297,500 shares of common stock. All outstanding preferred units were exchanged into 24,987,750 shares of common stock. Following the IPO and as of December 31, 2025, the Company is authorized to issue up to 400,000,000 shares of common stock, par value $0.00001.

In March 2024, the Company issued and sold an aggregate of 7,790,321 shares of its common stock in an underwritten public offering. Net proceeds were $450.0 million after deducting underwriting discounts and commissions and other offering expenses.

In August 2024, the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC (the "Sales Agent"), pursuant to which the Company may offer and sell shares of common stock up to a maximum aggregate offering price of $300.0 million through an at-the-market offering program. In December 2024, the Company sold 926,049 shares of common stock under the ATM for gross proceeds of $44.9 million, less commissions and other offering expenses of $1.4 million. During the year ended December 31, 2025, the Company sold 1,175,701 shares of common stock under the ATM for gross proceeds of $67.6 million, less commissions and other offering expenses of $2.0 million. As of December 31, 2025, $187.5 million remained available for sale under the Sale Agreement.

In October 2025, the Company issued and sold an aggregate of 8,048,782 shares of its common stock in an underwritten public offering and in lieu of common stock to certain investors, pre-funded warrants to purchase up to 365,853 shares of common stock. Net proceeds were $324.1 million, after deducting underwriting discounts and commissions and other offering expenses.

As of December 31, 2025, 69,038,943 and 68,401,349 shares of common stock were issued and outstanding, respectively. The 69,038,943 shares of common stock issued was comprised of 55,552,301 shares of voting common stock and 13,486,642 shares of non-voting common stock. As of December 31, 2025, there were 637,594 shares of unvested restricted common stock included within the shares of common stock issued.

As of December 31, 2024, 59,478,725 and 58,062,898 shares of common stock were issued and outstanding, respectively. The 59,478,725 shares of common stock issued was comprised of 45,992,083 shares of voting common stock and 13,486,642 shares of non-voting common stock. As of December 31, 2024, there were 1,415,827 shares of unvested restricted common stock included within the shares of common stock issued.

Warrants

In October 2025, the Company issued pre-funded warrants to purchase up to 365,853 shares of common stock at an exercise price of $0.00001 per share. The pre-funded warrants were exercisable immediately and are not subject to expiration. As of December 31, 2025, none of the pre-funded warrants have been exercised.

11. Equity-Based Compensation

Restricted Common Stock

The following table provides a summary of the unvested restricted common stock award activity during the year ended December 31, 2025:

	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested restricted common stock as of December 31, 2024	1,415,827	$ 5.30
Vested	(777,736)	$ 4.98
Forfeited	(497)	$ 13.08
Unvested restricted common stock as of December 31, 2025	637,594	$ 5.69

The fair value of restricted common stock awards that vested during the year ended December 31, 2025 was $3.9 million.

Stock Options and Restricted Stock Units

In July 2023, in connection with the IPO, the Company's Board of Directors (the "Board") and stockholders approved the 2023 Equity Incentive Plan (the "2023 Plan"), which became effective on July 13, 2023. The 2023 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards. As of December 31, 2025, 5,964,549 shares of common stock were available for future grants under the 2023 Plan. The number of shares available for grant and issuance under the 2023 Plan is automatically increased on January 1 of each year by a number of shares equal to up to 5% of the outstanding shares of common stock on such date.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options granted, with the following assumptions:

	YEAR ENDED DECEMBER 31, 2025
Risk-free interest rate	3.7% - 4.4%
Expected dividend yield	0.0%
Expected term (in years)	5.5 - 6.25
Expected volatility	72.8% - 75.5%

The following table provides a summary of stock option activity during the year ended December 31, 2025:

	OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2024	5,155,414	$ 35.12	9.37	$ 61,506
Granted	936,151	$ 43.24		
Exercised	(222,104)	$ 23.86		
Forfeited	(259,017)	$ 34.53		
Outstanding as of December 31, 2025	5,610,444	$ 36.95	8.56	$ 216,170
Exercisable as of December 31, 2025	1,879,583	$ 32.11	8.25	$ 81,514

The fair value of options vested during the year ended December 31, 2025 was $38.5 million.

The total intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $7.0 million and $1.3 million, respectively. No options were exercised during the year ended December 31, 2023.

The following table provides a summary of the unvested restricted stock unit activity under the 2023 Plan during the year ended December 31, 2025:

	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested restricted stock units as of December 31, 2024	267,564	$ 38.48
Vested	(72,374)	36.67
Forfeited	(17,575)	37.04
Unvested restricted stock units as of December 31, 2025	177,615	$ 39.36

The fair value of restricted stock units vested during the year ended December 31, 2025 was $2.7 million.

2023 Employee Stock Purchase Plan

In July 2023, the Board adopted and the Company's stockholders approved the 2023 Employee Stock Purchase Plan (the "ESPP"), which became effective on July 13, 2023. The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock, subject to any plan limitations. The purchase period under the ESPP has a duration of six months, and the purchase price with respect to each purchase period is equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month purchase period or (ii) the fair market value of the Company's common stock on the exercise date. As of December 31, 2025, 69,405 shares have been issued under the ESPP and 1,473,613 shares remain available for issuance.

The following table presents the classification of equity-based compensation expense related to equity awards granted to employees, executives, and service providers (in thousands):

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Research and development expense	$ 22,381	$ 9,964	$ 1,574
General and administrative expense	23,896	13,368	4,529
Total	$ 46,277	$ 23,332	$ 6,103

As of December 31, 2025, the total unrecognized compensation expense related to the Company's stock options, unvested restricted stock awards and units and ESPP was $110.1 million, which the Company expects to recognize over a weighted-average period of approximately 2.3 years.

In August 2023, the Board approved two option grants to the new Chairman of the Board, (1) to purchase 50,000 shares of the Company's common stock under the 2023 Plan ("first option"), and (2) to purchase 100,000 shares of the Company's common stock outside of the 2023 Plan ("second option"), in which the shares underlying both options will vest and become exercisable in equal monthly installments over a three-year period from August 2023. The second option was contingent upon approval of the shares underlying the award by the Company's stockholders at the 2024 Annual Meeting of Stockholders, and failure to obtain stockholder approval would have resulted in the forfeiture of the award. Prior to receiving stockholder approval for the second option, neither a grant date nor a service inception date occurred, and no compensation cost was recognized for the award. In June 2024, the Company's stockholders approved the shares underlying the second option at the 2024 Annual Meeting of Stockholders. Therefore, a cumulative catch-up in equity-based compensation was recognized during the second quarter of 2024.

12. Related Parties

We consider Paragon to be a related party because Fairmount Funds Management LLC, which beneficially owns more than 5% of Paragon, beneficially owns more than 5% of our capital stock and has two seats on our Board of Directors (the "Board"). Under the Option Agreements and the License Agreements, Paragon received upfront consideration in the form of common units, is entitled to receive milestone and royalty payments upon specific conditions and receives payments from the Company for providing ongoing services under the agreements (see Note 8). As of December 31, 2025 and 2024, $2.1 million and $0.1 million were due to Paragon, respectively. The Company incurred research and development expenses with Paragon of $2.2 million, $19.2 million and $26.3 million, respectively, for the years ended December 31, 2025, 2024, and 2023.

13. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Numerator:			
Net loss	$ (255,843)	$ (182,146)	$ (83,985)
Net loss attributable to common stockholders, basic and diluted	$ (255,843)	$ (182,146)	$ (83,985)
Denominator:			
Weighted average shares of common stock outstanding, basic and diluted	60,690,820	55,193,971	25,005,774
Net loss per share attributable to common stockholders, basic and diluted	$ (4.22)	$ (3.30)	$ (3.36)

The following potential common shares, presented based on amounts outstanding at period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the period indicated because including them would have been anti-dilutive:

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Stock options	5,610,444	5,155,414	2,506,017
Unvested restricted common stock	637,594	1,415,827	2,316,902
Unvested restricted stock units	177,615	267,564	144,090
Total	6,425,653	6,838,805	4,967,009

14. Operating Leases

In November 2023, the Company entered into a lease agreement for lab space. In June 2024, the agreement was amended to expand the space and extend the lease term through November 2026, with the option to extend for one year. In January 2025, the agreement was amended to further expand the space. As of December 31, 2025, the remaining lease term was 0.9 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 9.1%.

In September 2024, the Company entered into a lease agreement for office space. The lease term is five years with two one-year options to extend. As of December 31, 2025, the remaining lease term was 3.8 years and the incremental borrowing rate used to determine the operating lease liability was 6.0%.

As of December 31, 2025, the current and non-current operating lease liabilities were $3.5 million and $5.3 million, respectively. The Company incurred lease expense of $4.4 million, $2.3 million and $0.1 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2025, the weighted average remaining lease term was 3.2 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 6.7%.

As of December 31, 2025, the future minimum lease payments for the Company's operating lease for each of the years ending December 31 were as follows (in thousands):

	Amount
2026	$ 3,916
2027	2,049
2028	2,110
2029	1,617
Thereafter	—
Total undiscounted lease payments	9,692
Present value adjustment	(843)
Total net lease liabilities	$ 8,849

15. Income Tax

Apogee Therapeutics, Inc. and its U.S. subsidiary, are taxed as a consolidated C corporation for federal tax purposes. The Company's loss before income taxes is comprised solely of domestic losses. The Company generated taxable losses for all periods presented.

The provision for income taxes consists of the following (in thousands):

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Current:			
Federal	$ —	$ —	$ —
State	278	18	—
Total Current	278	18	—
Deferred:			
Federal	—	—	—
State	—	—	—
Total Deferred	—	—	—
Total Provision	$ 278	$ 18	$ —

The income taxes paid by jurisdiction consisted of the following:

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Income Taxes Paid			
Massachusetts	$ —	$ 360	$ —
Total Current	$ —	$ 360	$ —

The difference between the effective tax rate and the U.S. federal tax rate were as follows:

	YEAR ENDED DECEMBER 31,					
	2025		2024		2023	
	Amount	Percent	Amount	Percent	Amount	Percent
U.S. federal statutory tax rate	$ (53,669)	(21.0)%	$ (38,247)	(21.0)%	$ (17,637)	(21.0)%
State and local income taxes, net of federal income tax benefit [1]	(195)	(0.1)%	(542)	(0.3)%	(147)	(0.2)%
Tax credits						
Research and development tax credits	(6,308)	(2.5)%	(7,801)	(4.3)%	(2,151)	(2.6)%
Change in valuation allowance	53,013	20.7%	41,309	22.7%	17,882	21.3%
Nontaxable or nondeductible items	4,775	1.9%	2,738	1.5%	1,222	1.5%
Changes in unrecognized tax benefits	2,049	0.8%	2,551	1.4%	865	1.0%
Other adjustments	613	0.3%	10	—%	(34)	—%
Effective tax rate	$ 278	0.1%	$ 18	0.0%	$ —	0.0%

(1) State taxes in Massachusetts made up the majority (greater than 50%) of the tax effect in this category.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Deferred tax assets:			
Capitalized license and research and development payments	$ 52,758	$ 46,240	$ 21,034
Net operating loss carryforwards	58,580	16,095	5,370
Research and development credits	14,864	9,947	2,415
Intangible assets	1,199	1,342	1,244
Stock compensation	5,599	2,352	186
Lease liability	2,063	2,849	502
Fixed asset basis differences	81	—	—
Other	74	13	1
Total deferred tax assets	135,218	78,838	30,752
Deferred tax liabilities:			
Fixed asset basis differences	—	(18)	—
Right-of-use asset	(2,025)	(2,737)	(574)
Total deferred tax liabilities	(2,025)	(2,755)	(574)
Valuation allowance	(133,193)	(76,083)	(30,178)
Net deferred tax assets	$ —	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's cumulative net losses and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2025.

The change in the valuation allowance for the years ended December 31, 2025 and 2024 was $57.1 million and $45.9 million, respectively. Management reevaluates the positive and negative evidence at each reporting period.

As of December 31, 2025 and 2024, the Company had U.S. federal net operating loss carryforwards of approximately $250.7 million and $68.1 million, respectively, which have no expiration for federal tax purposes.

As of December 31, 2025 and 2024, the Company had state net operating loss carryforwards of approximately $94.3 million and $28.5 million, respectively, which will begin to expire in 2043.

As of December 31, 2025 and 2024, the Company had federal research and development credit carryforwards of approximately $16.7 million and $10.5 million, respectively, which will begin to expire in 2042.

The Company also had California research and development credit carryforwards of approximately $2.9 million and $1.5 million as of December 31, 2025 and 2024, respectively, which will not expire.

Additionally, the Company had Massachusetts research and development credit carryforwards of approximately $1.7 million and $2.1 million as of December 31, 2025 and 2024, respectively, which will begin to expire in 2043.

The Company will conduct a study of its research and development credit carryforwards, which may result in an adjustment to its unrecognized tax benefits. However, a full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the accompanying consolidated balance sheet or statement of operations if an adjustment were required.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows (in thousands):

	2025	2024
Beginning balance	$ 3,603	$ 904
Changes related to tax positions taken in the prior year	42	28
Changes related to tax positions taken in the current year	2,117	2,671
Ending balance	$ 5,762	$ 3,603

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. Net operating losses are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant members over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not yet finalized a study to determine if any such changes have occurred that could limit its ability to use the net operating losses and tax credit carryforwards.

All tax returns will remain open for examination by the federal and state taxing authorities for three and four years, respectively, from the date of utilization of any net operating loss carryforwards or research and development credits.

It is the Company's policy to include penalties and interest expense related to income taxes as a component of income tax expense, as necessary. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

The Tax Cuts and Jobs Act ("TCJA") included a change in the treatment of research and development expenditures for tax purposes under Section 174. Effective for tax years beginning after December 31, 2021, specified R&D expenditures must undergo a 5-year amortization period for domestic spend and a 15-year amortization period for foreign spend. Prior to the effective date (2021 tax year and prior), taxpayers were able to immediately expense R&D costs under Section 174(a) or had the option to capitalize and amortize R&D expenditures over a 5-year recovery period under Section 174(b).

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. OBBBA introduces significant changes to U.S. income-tax legislation. Key provisions affecting the Company include (i) permanent immediate expensing of domestic research and experimental expenditures starting January 1, 2025, and (ii) 100 percent bonus depreciation for qualified property placed in service after January 19, 2025. The Company has evaluated the current legislation at this time and has appropriately adopted the new rules under OBBBA.

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures. Under the ASU, public business entities ("PBEs") must annually "(1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income (loss) by the applicable statutory income tax rate)." FASB released the ASU in response to stakeholder feedback indicating that "the existing income tax disclosures should be enhanced to provide information to better assess how an entity's operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows."

The ASU's amendments are effective for PBEs for annual periods beginning after December 15, 2024. The Company adopted ASU 2023-09 in the current annual period and elected to apply the amendments retrospectively to all periods presented to enhance comparability of income tax disclosures, including the rate reconciliation and disaggregation of income taxes paid.

16. Segment Information

The Company has one operating segment and one reporting unit. The Company's chief operating decision maker ("CODM"), its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of assessing performance and allocating resources. All of the Company's assets are located in the United States.

The following table summarizes the Company's segment information for the periods presented (in thousands):

	YEAR ENDED DECEMBER 31,		
	2025	2024	2023
Operating expenses[1]:			
Research and development personnel-related (excluding equity-based compensation)	$ 68,490	$ 39,013	$ 9,387
External research and development costs - zumilokibart (APG777)	76,441	49,241	21,644
External research and development costs - APG990 / APG279	16,250	20,000	—
External research and development costs - APG333 / APG273	5,257	28,095	—
External research and development costs - APG808	3,136	10,311	20,801
External-discovery related costs and other	22,469	11,064	15,019
General and administrative personnel-related (excluding equity-based compensation)	26,740	16,935	8,047
General and administrative operations[2]	19,117	18,690	12,002
Equity-based compensation	46,277	23,332	6,103
Depreciation expense	1,418	189	—
Interest income	(30,030)	(34,742)	(9,018)
Provision for income taxes	278	18	—
Consolidated net loss	$ 255,843	$ 182,146	$ 83,985

(1) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM

(2) General and administrative operations are comprised of finance, investor relations, business development, human resources, legal, facilities & IT, and certain other overhead expenses

17. Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the financial statements as of December 31, 2025 and events which occurred subsequently and not recognized in the financial statements. No subsequent events have occurred that require disclosure.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and our Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Based on the foregoing evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Principal Executive Officer and our Principal Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Our independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of our internal control over financial reporting as of December 31, 2025, and has issued an attestation report, which is included herein.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Apogee Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Apogee Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Apogee Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2025 consolidated financial statements of the Company and our report dated March 2, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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 risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 2, 2026

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Trading Plans

During the quarter ended December 31, 2025, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to the 2026 Proxy Statement, including under headings “Executive Compensation,” “Election of Directors,” and “Corporate Governance,” “Insider Trading Policy and Anti-Hedging Policy” and, as applicable, “Delinquent Section 16(a) Reports.”

Item 11. Executive Compensation

The information required by this item is incorporated by reference to the 2026 Proxy Statement, including under headings “Executive Compensation” and “Corporate Governance.”

Item 12. Security Ownership of Certain beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference to the 2026 Proxy Statement, including under headings “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation-Securities Authorized for Issuance Under Equity Compensation Plans.”

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference to the 2026 Proxy Statement, including under headings “Corporate Governance” and “Certain Relationships and Related Party Transactions.”

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to the 2026 Proxy Statement, including under the heading “Ratification of Independent Auditor Appointment.”

PART IV

Item 15. Exhibits

1. *Financial Statements*: For a list of the financial statements included herein, see the Index to the Financial Statements on page 107 of this Annual Report, which is incorporated into this Item by reference.

2. *Financial Statement Schedules:* Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

Exhibit Number	Description of Exhibit
2.1	Contribution and Exchange Agreement, effective July 13, 2023, by and among the Company and the Unit Holders named therein (incorporated by reference to Exhibit 2.1 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
4.1	Form of Common Stock Certificate of the Company (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1/A filed on July 3, 2023).
4.2	Registration Rights Agreement, dated July 13, 2023, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 4.2 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 10, 2025).
4.4	Description of the Company's Securities (incorporated by reference to Exhibit 4.3 of the Company's Annual Report on Form 10-K filed on March 3, 2025).
10.1+	Employment Agreement, dated August 25, 2023, by and between the Company and Michael Henderson, M.D. (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
10.2+	Employment Agreement, dated August 25, 2023, by and between the Company and Jane Pritchett Henderson (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
10.3+	Employment Agreement, dated August 25, 2023, by and between the Company and Carl Dambkowski, M.D. (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
10.4+	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1/A filed on July 3, 2023).
10.5+	Equity Incentive Plan (incorporated by reference to Exhibit 10.9 of the Company's Quarterly Report on Form 10-Q filed on August 28, 2023).
10.6+	Equity Incentive Plan Form of Restricted Unit Award Grant Notice (incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K filed on March 5, 2024).

10.7*	Apogee Therapeutics, Inc. Executive Severance Policy, dated August 25, 2023
10.8#	Antibody Discovery and Option agreement, dated February 24, 2022, by and between Paragon Therapeutics, Inc. and Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.9	Amendment No. 1 to Antibody Discovery and Option agreement, dated November 10, 2022, by and between Paragon Therapeutics, Inc. and Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.10#	IL-13 License Agreement, dated November 4, 2022, by and between Paragon Therapeutics, Inc. and Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.11	Amendment No. 1 to IL-13 License Agreement, dated November 10, 2022, by and between Paragon Therapeutics, Inc. and Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.12#	2023 Option Agreement, dated November 9, 2023, by and between the Company and Paragon Therapeutics, Inc. (incorporated by reference to Exhibit 10.7 of the Company's Quarterly Report on Form 10-Q filed on November 13, 2023).
10.13#	IL-4Rα License Agreement, dated April 3, 2023, by and between Paragon Therapeutics, Inc. and Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) (incorporated by reference to Exhibit 10.9 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.14#	OX40L License Agreement, dated April 28, 2023, by and between Paragon Therapeutics, Inc. and Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) (incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.15#	TSLP License Agreement, dated August 9, 2024 by and between Paragon Therapeutics, Inc. and Apogee Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 11, 2025).
10.17	Novation Agreement, dated April 1, 2023, by and between Paragon Therapeutics, Inc., Apogee Biologics, Inc. (f/k/a Apogee Therapeutics, Inc.) and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.18#	Biologics Master Services Agreement, dated June 20, 2022 by and between Paragon Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.19#	Cell Line License Agreement, effective as of June 20, 2022, by and between Paragon Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 filed on June 22, 2023).
10.20#	Master Services Agreement, effective February 28, 2025, by and between the Company and Samsung Biologics Co. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on May 12, 2025).
10.21#	Product Specific Agreement, effective February 28, 2025, by and between the Company and Samsung Biologics Co. (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on May 12, 2025).

10.22+	First Amendment to the Apogee Therapeutics 2023 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.23	License Agreement, dated November 22, 2023, by and between the Company and MIL 6T, LLC (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.24	First Amendment to License Agreement, dated December 4, 2023, by and between the Company and MIL 6T, LLC (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.25	Second Amendment to License Agreement, dated February 26, 2024, by and between the Company and MIL 6T, LLC (incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.26	Third Amendment to License Agreement, dated June 10, 2024, by and between the Company and MIL 6T, LLC (incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024).
10.27	Fourth Amendment to License Agreement, dated January 23, 2025, by and between the Company and MIL 6T, LLC (incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on May 12, 2025).
10.28	Open Market Sale Agreement℠ dated August 12, 2024 between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed on August 12 2024).
10.29*+	Non-Employee Director Compensation Policy.
19.1*	Insider Trading Policy.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Company's Annual Report on Form 10-K filed on March 3, 2025).
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32.1*(1)	Certification of the principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) under the Securities Exchange Act of 1934.
97.1	Incentive Compensation Clawback Policy (incorporated by reference to Exhibit 97.1 of the Company's Annual Report on Form 10-K filed on March 5, 2024).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition

101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

+ Indicates management contract or compensatory plan.

Portions of the exhibit have been omitted for confidentiality purposes.

(1) Furnished herewith and not to be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liability of such section, and not to be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Apogee Therapeutics, Inc.

Date: March 2, 2026

By: /s/ Michael Henderson, M.D.
Michael Henderson, M.D.
Director and Chief Executive Officer
(principal executive officer)

Date: March 2, 2026

By: /s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer
(principal financial and accounting officer)

SIGNATURES

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

Signature	Title	Date
/s/ Michael Henderson, M.D. Michael Henderson, M.D.	Director and Chief Executive Officer (*principal executive officer*)	March 2, 2026
/s/ Jane Pritchett Henderson Jane Pritchett Henderson	Chief Financial Officer (*principal financial and accounting officer*)	March 2, 2026
/s/ Mark C. McKenna Mark C. McKenna	Chair and Director	March 2, 2026
/s/ Peter Harwin Peter Harwin	Director	March 2, 2026
/s/ Jennifer Fox Jennifer Fox	Director	March 2, 2026
/s/ Andrew Gottesdiener, M.D. Andrew Gottesdiener, M.D.	Director	March 2, 2026
/s/ Tomas Kiselak Tomas Kiselak	Director	March 2, 2026
/s/ William Jones, Jr. William Jones, Jr.	Director	March 2, 2026
/s/ Nimish Shah Nimish Shah	Director	March 2, 2026
/s/ Lisa Bollinger, M.D. Lisa Bollinger, M.D.	Director	March 2, 2026

APOGEE THERAPEUTICS, INC.
EXECUTIVE SEVERANCE POLICY

1. INTRODUCTION

This Apogee Therapeutics, Inc. Executive Severance Policy (the "Policy") is effective as of August 25, 2023 (the "Effective Date"). The purpose of the Policy is to provide for the payment of severance benefits to certain executives of Apogee Therapeutics, Inc. or one of its subsidiaries in connection with a termination of employment in certain circumstances.

2. DEFINITIONS

For purposes of the Policy, the terms below are defined as follows:

(a) "Base Salary" means the annual base salary payable to an Eligible Employee at the time of the Termination Date.

(b) "Cause" has the meaning set forth in the written employment, offer, services or severance agreement or letter between such Eligible Employee and the Company or an affiliate, or if there is no such agreement or no such term is defined in such agreement, means such Eligible Employee's termination of employment by the Company or an affiliate by reason of (i) such Eligible Employee's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business that results in or is reasonably anticipated to result in material harm to the Company; (ii) such Eligible Employee's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) such Eligible Employee's failure to perform in all material respects such Eligible Employee's assigned duties and responsibilities to the reasonable satisfaction of the Board of Directors of the Company, which failure continues, in the reasonable judgment of the Board of Directors of the Company, for thirty (30) days after written notice given to such Eligible Employee describing such failure; (iv) such Eligible Employee's gross negligence, willful misconduct that results in or is reasonably anticipated to result in harm to the Company; or (v) such Eligible Employee's violation of any material provision of any agreement(s) between such Eligible Employee and the Company or any Company policies including, without limitation, agreements relating to noncompetition, non-solicitation, nondisclosure and/or assignment of inventions or policies related to ethics or workplace conduct. and such violation, if curable, is not cured within thirty (30) days after the Company provides written notice to Executive of such violation.

(c) "Change in Control" has the meaning set forth in the Company's 2023 Equity Incentive Plan as in effect from time to time (or any successor equity incentive plan).

(d) "Change in Control Period" shall mean the three (3) month period immediately before and the twelve (12) month period that immediately follows the first event constituting a Change in Control.

(e) "Code" means the Internal Revenue Code of 1986, as amended.

(f) "Company" means Apogee Therapeutics, Inc. and its subsidiaries.

(g) "Disability" means a condition entitling the Eligible Employee to receive benefits under a long-term disability plan of the Company in which the Eligible Employee is eligible to

participate, or, in the absence of such a plan, the complete and permanent inability of the Eligible Employee by reason of illness or accident to perform the duties of the Eligible Employee's position to the Company. Any determination of whether Disability exists in the absence of a long-term disability plan shall be made by the Company in its sole and absolute discretion.

(h)"Eligible Employee" means an executive officer or other key employee of the Company who has been designated by the Board of Directors of the Company or a committee thereof as eligible under the Policy.

(i) "Good Reason" has the meaning set forth in a written employment or services agreement between the Eligible Employee and the Company or an affiliate thereof, or if no such meaning applies, means that such Eligible Employee has complied with the Good Reason Process following the occurrence of any of the following events: (A) with respect to a resignation by the Eligible Employee outside of the Change in Control Period: (i) the material breach of such Eligible Employee's written employment or services agreement by the Company or (ii) a requirement by the Company that such Eligible Employee's primary work location shall be in-office when remote work is feasible and does not impair such Eligible Employee's ability to perform such Eligible Employee's duties or (B) with respect to a resignation by the Eligible Employee within the Change in Control Period: (i) a material diminution in such Eligible Employee's base salary or target bonus except for across-the-board salary and target bonus reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; or (ii) a material change in the geographic location at which such Eligible Employee provides services to the Company; or (iii) a material reduction in such Eligible Employee's duties, authority or responsibilities, but excluding any change in title that does not represent a material reduction in such Eligible Employee's duties, authority or responsibilities; or (iv) the failure of the Company to obtain the assumption of such Eligible Employee's written employment or services agreement by a successor; or (v) the material breach of such Eligible Employee's written employment or services agreement by the Company; or (vi) a requirement by the Company that such Eligible Employee's primary work location shall be in-office when remote work is feasible and does not impair such Eligible Employee's ability to perform such Eligible Employee's duties.

(j) "Good Reason Process" means that (i) such Eligible Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) such Eligible Employee notifies the Company in writing of the first occurrence of the Good Reason condition within 90 days of the first occurrence of such condition; (iii) such Eligible Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) such Eligible Employee terminates his or her employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred; provided, however, that repeated incidents of the same or substantially related violation shall not be subject to cure.

(k)"Involuntary Termination" means at any time, (i) any termination of an Eligible Employee's employment with the Company (or its successor) by the Company (or its successor) without Cause and other than by reason of the Eligible Employee's death or Disability, or (ii) a resignation by an Eligible Employee for Good Reason.

(l) "Termination Date" means the date specified in the written notice of termination that the Company delivers to the Eligible Employee, or, in the case of Good Reason, the effective date of the Eligible Employee's resignation.

3. SEVERANCE BENEFITS

In the event of an Involuntary Termination, the Eligible Employee shall be entitled to the following benefits:

(a) Accrued Rights. A payment of the accrued rights due to the Eligible Employee consisting of the sum of (i) Eligible Employee's Base Salary through the Termination Date not theretofore paid; (ii) any expenses owed to the Eligible Employee under the Company's expense reimbursement policy; (iii) any amount arising from the Eligible Employee's participation in, or benefits under, any employee benefit plans, which amounts shall be payable in accordance with the terms and conditions of such employee benefits plans and (iv) any annual bonus for a prior completed year that has not been paid as of the time of Involuntary Termination, without any reduction for individual performance (clauses (i)-(iv) collectively shall be the "Accrued Rights"), which (except for amounts under clause (iii) which shall be paid pursuant to the applicable plan) shall be paid to the Eligible Employee promptly, but in all events within 30 days following the Termination Date or within such other time period as required by applicable law.

(b) Severance. Severance pay as set forth in Exhibit A hereto, which amount shall be payable to the Eligible Employee in equal monthly installments commensurate to the number of months of severance pay as set forth in Exhibit A; provided, however, that if the Involuntary Termination occurs within the Change in Control Period, the Eligible Employee shall be entitled to the additional months of severance pay as set forth in Exhibit A and payment in a single lump sum, in each case, subject to the Eligible Employee's General Separation Agreement and Release (as provided in Section 3(f) hereof) becoming effective and irrevocable. Severance pay shall commence on the date that is thirty (30) days following the Termination Date, subject to the Separation Agreement and Release becoming effective and irrevocable prior to such date.

(c) Annual Bonus. Payment of a pro-rata portion of the annual cash bonus (the "Pro-Rata Annual Bonus") that would have been earned by the Eligible Employee for the year in which the Termination Date occurs based on the number of days between and including the first day of the fiscal year of the Company in which the Termination Date occurs and the Termination Date, payable on the date when such bonuses are otherwise paid to Company executives generally and in all events by March 15th of the calendar year following the year in which such termination occurs. For avoidance of doubt, no reduction shall be made to the Pro-Rata Annual Bonus on account of the Executive not being employed for the entire year or Executive's individual performance. If the Involuntary Termination occurs within the Change in Control Period, the Eligible Employee shall be entitled to payment of the full annual cash bonus that would have been earned by the Eligible Employee for the year in which the Termination Date occurs.

(d) Benefits Continuation. Subject to the Eligible Employee's timely election of continuation coverage under COBRA, the Company shall directly pay, or reimburse the Eligible Employee for the premium for the Eligible Employee and the Eligible Employee's covered dependents to maintain continued health coverage pursuant to the provisions of COBRA for the period set forth in Exhibit A, and at the same premium cost to the Eligible Employee that was

paid by the Eligible Employee as of the Termination Date (subject to the terms and conditions of such benefit plans as in effect from time to time).

(e) Equity Treatment. Acceleration of equity-based awards as set forth in Exhibit A hereto; provided, however, that if the Involuntary Termination occurs within the Change in Control Period, the Eligible Employee shall be entitled to the enhanced acceleration of equity-based awards as set forth in Exhibit A.

(f) Release. Notwithstanding anything herein to the contrary, an Eligible Employee shall be entitled to the payments and benefits provided for in this Section 3 (other than the Accrued Rights) if and only if the Eligible Employee executes and delivers to the Company a general release of claims against the Company in a form substantially in the same form as attached hereto as Exhibit B (the "Separation Agreement and Release") within twenty-one (21) days following the Termination Date (which Separation Agreement and Release shall be provided to the Eligible Employee on or about the Termination Date) and the Separation Agreement and Release has become effective and irrevocable in accordance with its terms. For the avoidance of doubt, no payments shall be made to any Eligible Employee pursuant to Section 3(b) until the date that is thirty (30) days following the Termination Date, at which time any installments that should have been paid prior to that date shall be paid in lump sum.

4. LIMITATIONS ON BENEFITS

(a) Termination of Benefits. In the event an Eligible Employee, at any time, materially violates any proprietary information of confidentiality obligation to the Company, any other obligations of the Eligible Employee under an employment or other agreement with the Company or any of the Company's policies and procedures, (i) the Eligible Employee will be deemed in material breach of this Policy and (ii) the Company will be relieved of any ongoing obligation to comply with any of the terms of this Policy, including without limitation the obligation to make the payments described in Sections 3 (other than the Accrued Rights).

(b) Non-Duplication of Benefits. No Eligible Employee is eligible to receive benefits under the Policy more than one time.

(c) Indebtedness of Eligible Employees. If the Eligible Employee is indebted to the Company or an affiliate of the Company at his or her Termination Date, the Company reserves the right to offset any payments due under the Policy by the amount of such indebtedness. For avoidance of doubt, indebtedness means an undisputed obligation to pay an amount to the Company or its Affiliates.

5. MISCELLANEOUS

(a) Exclusive Discretion. The Board of Directors of the Company or a committee thereof will have the exclusive discretion and authority to establish rules, forms and procedures for the administration of the Policy and to construe and interpret the Policy and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Policy, including, but not limited to, the eligibility to participate in the Policy and amount of benefits paid under the Policy.

(b) Amendment or Termination. The Company may amend or terminate the Policy at any time and from time to time prior to the three (3) month period before the occurrence of a

Change in Control or at any time and from time to time more than one (1) year following a Change in Control. For the avoidance of doubt, this Policy may not be amended in any manner during the one-year period following a Change in Control. Termination or amendment of the Policy shall not affect any obligation of the Company under the Policy which has accrued and is unpaid as of the effective date of the termination or amendment (including, but not limited to, the obligation to make payments in respect of an Involuntary Termination that occurs prior to the effective date of the termination or amendment).

(c) No Right to Continued Employment or Service. Nothing herein shall confer upon an Eligible Employee any right to continue in the employ or service of the Company or any of its affiliates and this Policy shall not be deemed a contract of employment. If an Eligible Employee's employment terminates for any reason other than an Involuntary Termination, the Eligible Employee shall not be entitled to any benefits, damages, awards or compensation under this Policy, but may be entitled to payments or benefits in accordance with the Company's other established employee plans and practices or pursuant to other agreements with the Company.

(d) Successors. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) or to all or substantially all of the Company's business and/or assets will assume the obligations under the Policy and agree expressly to perform the obligations under the Policy in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of the Policy and all rights of the Eligible Employee hereunder will inure to the benefit of, and be enforceable by, the Eligible Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

(e) Notice. Any and all notices, requests, demands and other communications provided for by this Policy shall be in writing and shall be effective when delivered in person, consigned to a reputable national courier service or deposited in the United States mail, postage prepaid, registered or certified, and addressed to the Eligible Employee at his or her last known address on the books of the Company or, in the case of the Company, at its principal place of business, attention of the Head of People or to such other address as any party may specify by notice to the other actually received.

(f) No Waiver. The failure of a party to insist upon strict adherence to any term of the Policy on any occasion shall not be considered a waiver of such party's rights or to deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of the Policy.

(g) Severability. In the event that any one or more of the provisions of the Policy shall be or become invalid, illegal or unenforceable in any respect or to any degree, the validity, legality and enforceability of the remaining provisions of the Policy shall not be affected thereby. The parties intend to give the terms of the Policy the fullest force and effect so that is any provision shall be found to be invalid or unenforceable, the court reaching such conclusion may modify or interpret such provision in a manner that shall carry out the parties' intent and shall be valid and enforceable.

(h) Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof or to affect the meaning thereof.

(i) Creditor Status of Eligible Employees. In the event that any Eligible Employee acquires a right to receive payments from the Company under the Policy such right shall be no greater than the right of any unsecured general creditor of the Company.

(j) Withholding Taxes. The Company may withhold from any amounts payable under the Policy such federal, state and local taxes as may be required to be withheld pursuant to any applicable law or regulation.

(k) Section 409A Compliance. This Policy is intended to be interpreted and operated to the fullest extent possible so that the payments and benefits hereunder either shall be exempt from the requirements of Section 409A of the Code ("Section 409A") or shall comply with the requirements of Section 409A; provided, however, that notwithstanding anything to the contrary in this Policy, in no event shall the Company be liable to the Eligible Employee for or with respect to any taxes, penalties or interest which may be imposed upon the Eligible Employee pursuant to Section 409A. To the extent that any payment or benefit pursuant to this Policy constitutes a "deferral of compensation" subject to Section 409A (after taking into account to the maximum extent possible any applicable exemptions as noted below) (a "409A Payment") treated as payable upon a separation from service, then, if on the date of the Eligible Employee's separation from service, the Eligible Employee is a Specified Employee (as defined in Section 409A), then to the extent required for Eligible Employee not to incur additional taxes pursuant to Section 409A, no such 409A Payment shall be made to the Eligible Employee sooner than the earlier of (i) six (6) months after the Eligible Employee's separation from service; or (ii) the date of the Eligible Employee's death. Should this paragraph result in payments or benefits to the Eligible Employee at a later time than otherwise would have been made under this Policy, on the first day any such payments or benefits may be made without incurring additional tax pursuant to Section 409A (the "409A Payment Date"), the Company shall make such payments and provide such benefits as provided for in this Policy, provided that any amounts that would have been payable earlier but for the application of this paragraph shall be paid in lump-sum on the 409A Payment Date. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), the Eligible Employee's right to receive installment payments under this Policy shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. For the avoidance of doubt, the portion of any payment under this Policy that is paid within the short-term deferral period (within the meaning of Code Section 409A and Treas. Reg. § 1.409A-1(b)(4)) will be treated as a short-term deferral and shall not aggregated with other plans or payments. Any other portion of the payment that does not meet the short-term deferral requirement will, to the maximum extent possible, be deemed to satisfy the exception from Section 409A of the Code under Treas. Reg. § 1.409A-1(b)(9)(iii)(A) for involuntary separation pay and shall not be aggregated with any other payment.

(l) 280G Provisions**.** Notwithstanding anything in this Policy to the contrary, if any payment or distribution the Eligible Employee would receive pursuant to this Policy or otherwise ("Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by the Eligible

Employee on an after-tax basis, of the largest payment, notwithstanding that all or some portion the Payment may be taxable under Section 4999 of the Code. All determinations required to be made under this Section 5(l) will be made by an independent accounting firm or law firm selected by the Company in writing prior to a Change in Control and its selection shall be irrevocable. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The selected firm shall provide its calculations to the Company and the Eligible Employee within fifteen (15) calendar days after the date on which the Eligible Employee's right to a Payment is triggered (if requested at that time by the Company or the Eligible Employee) or such other time as requested by the Company or the Eligible Employee. Any good faith determinations of the selected firm made hereunder shall be final, binding and conclusive upon the Company and the Eligible Employee. Any reduction in payments and/or benefits pursuant to this Section 5(l) shall be made in a manner that maximizes the net after-tax amount payable to an Eligible Employee, which typically will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to the Eligible Employee.

EXHIBIT A

EXECUTIVE SEVERANCE TERMS

Outside of a CIC	***Benefits***
Benefit Elements	• Base salary • Prorated bonus • Benefits continuation
Severance Amount (of base salary)	• CEO: 12 months • C-Suite: 12 months • SVPs: 6 months • VPs: 5 months
Equity Treatment	• Grandfather equity acceleration for current CEO (partial vesting acceleration of 30%). • No equity acceleration outside CIC for other executives
During Change in Control Period	***Benefits***
Benefit Elements	• Base salary • Full Target bonus • Benefits continuation
Severance Amount (of base salary)	• CEO: 18 months • C-Suite: 12 months • SVPs: 9 months • VPs: 6 months
Equity Treatment	• Receive full acceleration as part of CIC severance upon double trigger

EXHIBIT B

FORM OF SEPARATION AGREEMENT AND RELEASE

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Non-Employee Director Compensation Policy (this "Policy") of Apogee Therapeutics, Inc. (the "Company"), is to provide a compensation package that enables the Company to attract and retain high-caliber directors and aligns their interests with the interests of the Company's stockholders.

1. Eligibility

The Policy applies to all members of the Company's Board of Directors (the "Board") who are not employees or officers of the Company or its subsidiaries. Directors who are employees or officers of the Company or its subsidiaries do not receive compensation for their service on the Board.

2. Cash Retainers

The Company shall pay annual cash retainers as set forth below:

Annual retainer for Board membership (other than the Chair)	$	40,000
Annual retainer for Non-Executive Chair of the Board (if applicable)	$	70,000
Additional annual retainers		
Chair of the Audit Committee	$	20,000
Chair of the Compensation Committee	$	15,000
Chair of the Nominating and Corporate Governance Committee	$	10,000
Member of the Audit Committee (other than Chair)	$	10,000
Member of the Compensation Committee (other than Chair)	$	7,500
Member of the Nominating and Corporate Governance Committee (other than Chair)	$	5,000

3. Equity Awards

The Compensation Committee of the Board shall also grant: (i) to each new non-employee director (and any current director who has not yet received an initial equity grant) an initial, one-time award upon his or her election to the Board of stock options with a grant date fair value of $800,000 (valued based on the grant date fair value and subject to a limit of 35,000 stock options) under the Company's equity incentive plan that vests over a three-year period subject to such director's continued service; and (ii) to each non-employee director on an annual basis, an award of stock options with a grant date fair value of $400,000 (valued based on the grant date fair value and subject to a limit of 17,500 stock options) under the Company's equity incentive plan that vest on the one-year anniversary of the date of grant.

4. Director Pay Limit

The total amount of cash retainers paid and equity awards (valued based on the grant date fair value) granted by the Company to any director for his or her service on the Board shall not exceed $1,000,000 during the year the director is appointed and $750,000 annually thereafter.

5. Administration

The Board, with the assistance of the Compensation Committee, administers the Policy and may amend the Policy at any time in its sole discretion.

Policy last updated on March 26, 2025 (Effective as of the 2025 Annual Meeting of Shareholders)

INSIDER TRADING POLICY

I. INTRODUCTION

Federal and state laws prohibit buying, selling or making other transfers of securities by persons who have material information that is not generally known or available to the public. These laws also prohibit persons with such material nonpublic information ("***MNPI***") from disclosing this information to others who trade. Trading while aware of MNPI is often referred to as "insider trading".

Who Is Subject to this Policy. Apogee Therapeutics, Inc. (the "***Company***") has adopted the following policy (this "***Policy***") regarding trading in securities by all of its directors, officers, employees, certain contractors and consultants (together, "***Company Personnel***") as well as their family members who reside with them, anyone else who lives in their household and any family members who do not live in their household but whose transactions in Company securities (as defined below) are directed by them or are subject to their influence or control (collectively, "***Family Members***"), and corporations or other business entities over which you or your Family Members have the ability to influence or direct investment decisions concerning Company securities, (other than any entity that invests in securities in the ordinary course of its business, such as a venture or other investment fund, if such entity has established and represented to the Company that it has its own insider trading controls and procedures in compliance with applicable securities laws with respect to trading in the Company's securities), and trusts for which such persons are a trustee or in which they have a beneficial or pecuniary interest (collectively, "***Controlled Entities***," and together with "Company Personnel" and "Family Members," "***Insiders***"). Unless otherwise indicated, all references to "you" in this Policy should be read to include all of your Family Members and Controlled Entities.

Which Securities Are Subject to this Policy. This Policy applies to transactions, whether direct or indirect, in the Company's securities, including its common stock, options to purchase common stock, restricted stock awards or restricted stock units or any other type of securities that the Company may issue from time to time, including but not limited to preferred stock and convertible debentures, as well as derivative securities relating to the Company but that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities (collectively, "***Company securities***"). Similarly, this Policy applies to all securities, including common stock, options to purchase common stock or any other type of securities, that are issued by a Company Counterparty (as defined below), as well as any derivative securities that are relating to the Company Counterparty but that are not issued by such Company Counterparty, such as puts, calls or swaps.

Application of this Policy to Company Counterparties. The principles discussed in this Policy also apply to nonpublic information that you obtain in the course of your employment or other involvement with the Company about another public company (or its securities) with which the Company has a preexisting or prospective relationship, such as the Company's customers, suppliers, contract research, manufacturing, licensing or other collaboration partners, companies in which the Company has an investment, or a firm with which the Company is negotiating a major transaction, such as a joint venture, licensing transaction, collaboration arrangement, or material acquisition or disposition (a "***Company Counterparty***" or "***Company Counterparties***").

No Exceptions. The prohibition against trading while aware of MNPI is absolute and unconditional. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to high standards of conduct. There is no exception for small transactions or transactions that may seem necessary or justifiable for independent reasons, such as the need to raise money for an emergency expenditure.

Individual Responsibility. You are responsible for ensuring that you (as well as your Family Members and Controlled Entities) do not violate federal or state securities laws or this Policy. The Company has designed this Policy to promote compliance with the federal securities laws and to protect the Company and you from the serious liabilities and penalties that can result from violations of these laws.

Consequences for Violating Insider Trading Laws. If you violate insider trading laws, you may have to pay civil fines for up to three times the profit gained or loss avoided by such trading, as well as criminal fines of up to $5 million. You also may be subject to criminal charges and may have to serve a jail sentence of up to 20 years. In addition, the Company may face civil penalties up to the greater of $1 million, or three times the profit gained or loss avoided as a result of your insider trading violations, as well as criminal fines of up to $25 million. Both the Securities and Exchange Commission ("***SEC***") and The Nasdaq Stock Market ("***Nasdaq***") are very effective at detecting and pursuing insider trading cases. The SEC has successfully prosecuted cases against employees trading through foreign accounts, trading by family members and friends and trading involving only a small number of shares. Therefore, it is important that you understand the breadth of activities that constitute illegal insider trading. This Policy sets out the Company's policy in the area of insider trading and should be read carefully and complied with fully.

Administrative Provisions. All Company Personnel will be required to certify their understanding of and intent to comply with this Policy by signing the Receipt and Acknowledgment attached hereto periodically. This Policy will be reviewed, evaluated and revised by the Company from time to time in light of regulatory changes, developments in the Company's business and other factors.

II. POLICIES AND PROCEDURES

A. Trading Policy

1. *No Trading on the Basis of MNPI.* You may not buy, sell, gift or otherwise transact in securities of the Company or a Company Counterparty while you are aware of MNPI about that company or its securities that you learned in the course of your employment or service with the Company.

2. *No Tipping.* You may not convey to anyone else, including family members, MNPI about the Company or a Company Counterparty or its securities that you learned in the course of your employment or service with the Company. You also may not suggest that anyone purchase or sell the Company's or a Company's Counterparty's securities while you are aware of MNPI about that company or its securities. These practices, known as "tipping," also violate U.S. securities laws and can result in the same civil and criminal penalties that apply if you engage in insider trading directly, even if you do not receive any money or derive any benefit from trades made by persons to whom you passed MNPI. Persons with whom you have a history, pattern or practice of sharing confidences—such as family members, close friends and financial and personal counselors—may be presumed to act on the basis of information known to you; therefore, special care should be taken so that MNPI is not disclosed to such persons. This policy does not restrict legitimate business communications on a "need to know" basis. MNPI, however, should not be disclosed to persons outside the Company unless you are specifically authorized to disclose such information and such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company.

3. *No Short-Term or Speculative Trading.* It is against Company policy for you to engage in short-term or speculative transactions in Company securities. As such, you may not engage in: (a) short-term trading (generally defined as selling Company securities within six months following a purchase); (b) short sales (selling Company securities you do not own); (c) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (d) other hedging transactions (such as "cashless" collars, forward sales, equity swaps and other similar arrangements). Additionally, because securities held in a margin account or pledged as collateral may be sold without your consent, if you fail to meet a margin call or if you default on a loan, a margin or foreclosure sale may result in unlawful insider trading. Because of this danger, you should exercise caution when purchasing Company securities on margin, borrowing against any account in which Company securities are held or pledging Company securities as collateral for a loan, and the Company's directors and Section 16 Officers (as defined below) are prohibited from doing so.

4. *Applying the Trading Policy.* As stated above, these restrictions also apply to your Family Members and Controlled Entities. For purposes of this Policy, references to "trading," "transact" and "transactions" include, among other things:

- purchases and/or sales of securities in public markets;
- sales of securities obtained through the exercise of stock options or vesting of other equity awards granted by the Company;
- making gifts of securities; and
- using securities to secure a loan.

Transactions in mutual funds that are invested in Company or Company Counterparty securities are not transactions subject to this Policy as long as (a) the Insider does not control the investment decisions on individual stocks within the fund and (b) Company or Company Counterparty securities do not represent a substantial portion of the assets of the fund.

In addition, transactions pursuant to a Rule 10b5-1 Trading Plan (as defined below) are subject to certain exceptions and requirements set forth below.

Insiders should consult the Chief Legal Officer ("***CLO***") or other attorneys designated by the CLO if they have any questions.

5. *Company Transactions.* From time to time, the Company may engage in transactions in its own securities. When engaging in transactions in Company securities, it is the Company's policy to comply with all applicable securities laws and regulations and state corporate laws. This includes consultation, as appropriate, with the CEO, CFO, CLO and outside counsel, and, if required or advisable, approval by the Board of Directors or appropriate board committee. Transactions pursuant to equity-based compensation arrangements are conducted in accordance with the terms of the plans and agreements.

B. What is "Material Nonpublic Information"? When is Information "Public"?

1. *Material Information*

Information is generally considered "material" if there is a likelihood a reasonable investor would consider such information important in making an investment decision to buy, hold or sell securities. Either positive or negative information may be material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances. The CLO or other attorneys designated by the CLO should be consulted and shall determine whether information is material, but in general, any information that could reasonably be expected to affect the Company's or a Company Counterparty's stock price should be considered material. Depending on the circumstances, common examples of information that may be material include:

- significant new product or product candidate developments, innovations or discoveries (including new targets or indications) or changes to research or business strategies;

- significant interactions with or pending action (such as an approval) by the U.S. Food and Drug Administration, European Medicines Agency or other regulatory agency;
- pre-clinical or clinical trial details, including enrollment, site information, participant characteristics, status, results, and data relating to the Company or a Company product candidate;
- changes in intellectual property status, including patent filings, issuances or potential interference and infringement proceedings;
- financial and operating results, estimates, forecasts, earnings, earnings projections, cash runway, sales, revenue, or similar financial information;
- financial results, including unexpected financial results;
- unpublished financial reports or projections, including knowledge of changes of research analyst views/ratings;
- changes in control or sale of all or part of the Company's business, including potential partnerships;
- changes in directors, senior management or auditors;
- information about current, proposed or contemplated transactions, business plans, financial restructurings, acquisition targets or significant expansions or contractions of operations;
- changes in dividend policies, the declaration of a stock split or the proposed or contemplated issuance, redemption or repurchase of securities;
- public or private debt or equity offerings;
- negotiations or changes regarding an important contract, license, distribution agreement, joint venture or collaboration agreement;
- material defaults under agreements or actions by creditors, clients or suppliers relating to the company's credit rating;
- extraordinary borrowing, liquidity or financial problems, and material defaults under agreements or actions by creditors related to the Company's credit rating;
- gain or loss of a significant customer or supplier;
- significant cybersecurity incidents, events or risks that affect the Company or third-party providers that support the Company's business operations;
- product candidate safety issues or product recalls;
- the interruption of production or other aspects of a company's business as a result of an accident, fire, natural disaster, public health emergency or breakdown of labor negotiations;
- developments related to the manufacturing of the Company's products, including as a result of inspections, regulatory actions and disruptions;

- major environmental incidents;
- developments regarding significant litigation, investigations, or regulatory actions or proceedings;
- information specified above relating to the Company's affiliates and Company Counterparties; and
- the imposition of a trading "blackout" by the Company on transactions in Company securities or the securities of a Company Counterparty.

This list is not exhaustive. Federal and Nasdaq investigators will scrutinize a questionable trade after the fact with the benefit of hindsight, so you should always err on the side of caution. The mere fact that a person is aware of MNPI is a bar to trading. It is no excuse that such person's reasons for trading were not based on the MNPI. If you have questions regarding specific transactions, please contact the CLO.

2. *Nonpublic Information*

Nonpublic information is information that is not generally known by or available to the public. We consider information to be available to the public only when:

- it has been released to the public by the Company through appropriate channels (e.g., by means of a press release or a filing with the SEC); and
- enough time has elapsed to permit the investment market to absorb and evaluate the information. As a general rule, you should consider information to be nonpublic until two full trading days have lapsed following the time of public disclosure.

The fact that rumors, speculation or statements attributed to unidentified sources are public is insufficient to be considered "generally available to the public" even when the information is accurate.

C. Unauthorized Disclosure; Prohibition on Certain Public Speaking

All Company Personnel must maintain the confidentiality of Company information for competitive, security and other business reasons, as well as to comply with securities laws. All information you learn about the Company or its business plans is potentially nonpublic information until it is publicly disclosed. You should treat this information as confidential and proprietary to the Company. You may not disclose it to others, such as Family Members, other relatives or business or social acquaintances.

In addition, you are prohibited from participating as an "expert," consultant, advisor and/or in any capacity for an "expert network" and/or any other outside firm which compensates individuals for speaking with investors and other investment professionals. This prohibition is designed to protect the Company, its stockholders and you. Indeed, United States criminal authorities and the SEC have prosecuted numerous public company employees who received monetary compensation by expert networks to speak with investors and disclose confidential company information which investors then used for trading purposes.

Legal rules govern the timing and nature of our disclosure of material information to outsiders or the public. Violation of these rules could result in substantial liability for you, the Company and its management. For this reason, we permit only specifically designated representatives of the Company to discuss the Company with the news media, securities analysts and investors and only in accordance with the Company's Guidelines For Public Disclosures And Communications With The Investment Community. If you receive inquiries of this nature, refer them to the CFO.

D. When and How to Trade Company Stock

1. *Overview*

Directors, officers, as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") (such officers, "***Section 16 Officers***", and together with directors, "***Section 16 Persons***"), all other employees, and certain contractors and consultants who are so designated by the CLO from time to time (such designated contractors and consultants, together with Section 16 Persons and all other employees, and each of their respective Family Members and Controlled Entities, "***Restricted Persons***"), are for purposes of this Policy required to comply with the restrictions covered below. Even if you are not a Restricted Person, however, following the procedures listed below may assist you in complying with this Policy.

2. *Quarterly Blackout Periods and Trading Windows*

The Company imposes a blackout period in connection with its quarterly release of financial information, during which time Insiders are not permitted to transact with respect to the Company's securities (subject to the exceptions set forth in Section II.D.4 or pursuant to an approved Rule 10b5-1 Trading Plan pursuant to Section II.E). Unless otherwise determined and communicated by the Company for a particular quarter, the quarterly blackout period will typically begin upon completion of the trading day on the final day of each calendar quarter and end two full business days after the public release of the Company's quarterly or annual earnings results. For example, if the Company publicly releases earnings results at the open of market on a Friday, then trading in the Company's securities may commence at the open of market on the following Tuesday.

As a result, Insiders may trade in Company securities only from the date that is two full trading days after an earnings release to the completion of the trading day on the final day of each calendar quarter (such period, the "***Trading Window***"). However, even if a Trading Window is open, you may not trade in Company securities if you are aware of MNPI about the Company. In addition, if you are subject to the Company's pre-clearance policy (described below), you must pre-clear transactions even if you initiate them when the Trading Window is open. Generally, all pending purchase and sale orders regarding Company securities must be executed or cancelled before the Trading Window closes.

3. *Special Blackout Periods*

From time to time, due to certain developments (such as a significant event or transaction) during which there may exist MNPI about the Company or a Company Counterparty, the Company may implement special blackout periods during which the Company may notify particular individuals that they should not transact in Company securities or the securities of a Company Counterparty, as applicable (subject to the exceptions set forth in Section II.D.4 or pursuant to an approved Rule 10b5-1 Trading Plan pursuant to Section II.E). If you are subject to a special blackout period, you should not trade in the applicable company's securities during such time and you should not disclose to others the fact that you are prohibited from trading, as the existence of a special blackout period may, itself, be deemed MNPI. These special blackout periods, which may vary in length, will be determined by the CLO and be communicated to the appropriate personnel via e-mail. Termination of a blackout period will also be communicated to the appropriate personnel via e-mail.

However, it is not the Company's policy to impose special blackout periods every time that MNPI exists or every time that an Insider may be aware of MNPI. Thus, the absence of a special blackout period should not be interpreted as permission to trade. In addition, if you are subject to the Company's pre-clearance policy (described below), you must pre-clear transactions even if you initiate them while a blackout period is not in place. Generally, all pending purchase and sale orders regarding Company securities must be executed or cancelled before a special blackout period is implemented so as to avoid any transactions during such period.

In light of these restrictions, if you expect a need to sell Company stock at a specific time in the future, including executing sales to satisfy tax withholding obligations in connection with the exercise of stock options, vesting of restricted stock or settlement of restricted stock units in the future, you may wish to consider entering into a prearranged Rule 10b5-1 Trading Plan (as discussed below).

4. *Pre-clearance*

The Company requires all Restricted Persons to contact the CLO or other attorneys designated by the CLO in advance of effecting any purchase, sale, gift or other trading of Company securities and to obtain prior approval of the transaction, other than transactions made under an approved Rule 10b5-1 Trading Plan pursuant to Section II.E below. Pre-clearance requests must be approved by the CLO or other attorneys designated by the CLO for employees that are not Section 16 Officers, by the CLO for Section 16 Persons, or, by the CEO or CFO in the case of the CLO (in each case including the person's Family Members and Controlled Entities). All requests must be submitted to the CLO or other attorneys designated by the CLO at least two business days in advance of the proposed transaction. **This pre-clearance policy applies to Restricted Persons even if they are initiating a transaction while a blackout period is not in place.**

If a transaction is approved under the pre-clearance policy, the transaction must be executed by the end of the second full trading day after the approval is obtained, but regardless may not be executed if you acquire MNPI concerning the Company during that time. If a transaction is not completed within the period described above, the transaction must be approved again before it may be executed.

If a proposed transaction is not approved under the pre-clearance policy, you may not transact in Company securities, and you should not inform anyone within or outside of the Company of the restriction. For the avoidance of doubt, there should be no presumption that the CLO or his or her designee will grant any or all pre-clearance requests and there shall be no obligation to inform a Restricted Person of the reasons for any request approval or denial. Any transaction under a Rule 10b5-1 Trading Plan will not require pre-clearance at the time of the transaction, but the adoption, amendment, modification or termination of any such Rule 10b5-1 Trading Plan is subject to the pre-clearance and other restrictions set forth in Section II.E and Appendix A, "Guidelines for Rule 10b5-1 Trading Plans" below.

5. *Exceptions*

The restrictions contained in this Policy shall not apply to:

- the exercise of Company stock options if (a) no shares are to be sold to third parties or (b) there is only a "net exercise" (defined as the Company withholding shares to satisfy your tax obligations or to cover the exercise price or equivalent);
- "sell to cover" transactions involving a sale of shares of common stock directed by the Company in its sole discretion in order to cover the Company's or such individual's or entity's withholding tax obligations in connection with the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;
- the vesting of Company stock options, restricted stock, restricted stock units or other equity incentive awards according to their terms;
- the withholding of shares to satisfy the exercise price or a tax withholding obligation upon the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;
- purchases of shares through the Company's Employee Stock Purchase Plan in accordance with your pre-established participation elections;
- transferring shares to an entity that does not involve a change in the beneficial ownership of the shares (for example, transferring shares from one brokerage account to another brokerage account that you control);
- sales of Company securities as a selling stockholder in a registered public offering, including a "synthetic secondary" offering, in accordance with applicable securities laws; or
- any other purchase of Company securities from the Company or sale of Company

securities to the Company in accordance with applicable securities and state laws.

To the extent applicable and such elections are permitted, your elections regarding (1) participation in "net exercise" or "sell to cover" transactions or (2) participation in or an increase in contributions to the Company's Employee Stock Purchase Plan, in each case including changes from any defaults established by the Company, may only be made when you are not subject to a blackout period and are not aware of MNPI.

E. Rule 10b5-1 Trading Plans

Rule 10b5-1 under the Exchange Act provides an affirmative defense from insider trading liability if trades occur pursuant to a pre-arranged trading plan that meets specified conditions (a "***Rule 10b5-1 Trading Plan***"). A Rule 10b5-1 Trading Plan is a written trading plan between you and your broker and must either specify the number of securities to be bought or sold, along with the price and the date, or provide a written formula for determining this information. Alternatively, such Rule 10b5-1 Trading Plan can delegate investment discretion to a third party, such as a broker, who then makes trading decisions without further input from the person implementing the plan. A Rule 10b5-1 Trading Plan must be established at a time when you are not aware of any MNPI and must not permit you to exercise any subsequent control or influence over how, when or whether the purchases or sales are made. Under this Policy, the adoption, amendment, modification or termination of a Rule 10b5-1 Trading Plan must meet the requirements set forth in Appendix A, "Guidelines for Rule 10b5-1 Trading Plans," including applicable pre-clearance procedures.

Because the SEC rules on trading plans are complex, you should consult with your broker and be sure you fully understand the limitations and conditions of the rules before you establish a Rule 10b5-1 Trading Plan (or a transaction that is intended to constitute a "non-Rule 10b5-1 trading arrangement" within the meaning of SEC rules).

F. Noncompliance

Anyone subject to this Policy who fails to comply with this Policy will be subject to appropriate disciplinary action, up to and including termination of employment.

G. Post-Termination Transactions

This Policy, other than the pre-clearance provisions, will continue to apply to your transactions in Company securities after your employment or service with the Company has terminated until such time as you are no longer aware of MNPI or until that information has been publicly disclosed or is no longer material.

Questions about this Policy should be directed to the CLO or his or her designee.

RECEIPT AND ACKNOWLEDGMENT

I, ___, hereby acknowledge that I have received and read a copy of the Apogee Therapeutics, Inc. Insider Trading Policy (this "***Policy***"). I agree to comply with this Policy and certify that I will communicate with all members of my household to inform them of the obligations in this Policy that apply to them. I understand that violation of SEC regulations may subject me to severe civil and/or criminal penalties, and that violation of this Policy may subject me to discipline by Apogee Therapeutics, Inc. up to and including termination for cause.

Signature	Date

APPENDIX A

Apogee Therapeutics, Inc. Guidelines for Rule 10b5-1 Trading Plans

As discussed in the Policy, Rule 10b5-1 under the Exchange Act provides an affirmative defense from insider trading liability. In order to be eligible to rely on this affirmative defense, you must enter into a Rule 10b5-1 Trading Plan for transactions in Company securities that meets certain conditions specified in Rule 10b5-1, including the guidelines set forth below. These guidelines generally do not apply to any transactions that are intended to constitute "non-Rule 10b5-1 trading arrangements" within the meaning of SEC rules. Capitalized terms used in these guidelines without definition have the meaning set forth in the Policy.

These guidelines are in addition to, and not in lieu of, the requirements and conditions of Rule 10b5-1. The CLO or other attorneys designated by the CLO will interpret and administer these guidelines for compliance with Rule 10b5-1 and the Policy. No personal legal or financial advice is being provided by the CLO, other attorneys designated by the CLO or other members of the Company regarding any Rule 10b5-1 Trading Plan or proposed trades. You remain ultimately responsible for ensuring that your Rule 10b5-1 Trading Plans and contemplated transactions fully comply with applicable securities laws. It is recommended that you consult with your own attorney or other advisor about any contemplated Rule 10b5-1 Trading Plan. Note that for any Section 16 Persons, the Company is required to disclose the material terms of his or her (and any Family Members' and Controlled Entities') Rule 10b5-1 Trading Plan, other than with respect to price, in its periodic report for the quarter in which the Rule 10b5-1 Trading Plan is adopted or terminated or modified (as described below).

1. **Pre-Clearance Requirement.** The Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the CLO or other attorneys designated by the CLO for employees that are not Section 16 Officers, by the CLO for Section 16 Persons (or, in the case of the CLO, by the CEO or CFO) at least five trading days prior to the entry into the plan in accordance with the procedures set forth in the Policy and these guidelines. The Company may require that you use a standardized form of Rule 10b5-1 Trading Plan.

2. **Time of Adoption.** Subject to pre-clearance requirements described above, the Rule 10b5-1 Trading Plan must be adopted at a time:
    - when you are not aware of any MNPI; and
    - when you are not subject to a blackout period.

3. **Plan Instructions.** Any Rule 10b5-1 Trading Plan must be in writing, signed and either:
    - specify the amount, price and date of the sales (or purchases) of Company securities to be effected;
    - provide a formula, algorithm or computer program for determining when to sell (or purchase) the Company's securities, the quantity to sell (or purchase) and the price; or

- delegate decision-making authority with regard to these transactions to a broker or other agent without any MNPI about the Company or its securities.

For the avoidance of doubt, you may not subsequently influence how, when or whether to effect purchases or sales with respect to the securities subject to an approved and adopted Rule 10b5-1 Trading Plan.

4. **No Hedging.** You may not have entered into or alter a corresponding or hedging transaction or position with respect to the securities subject to the Rule 10b5-1 Trading Plan and must agree not to enter into any such transaction while the Rule 10b5-1 Trading Plan is in effect.

5. **Good Faith Requirements.** You must enter into the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Exchange Act. You must act in good faith with respect to the Rule 10b5-1 Trading Plan for the entirety of its duration.

6. **Certifications for Section 16 Persons.** Section 16 Persons and their Family Members and Controlled Entities that enter into Rule 10b5-1 Trading Plans must certify that they are: (1) not aware of any MNPI about the Company or the Company securities; and (2) adopting the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Exchange Act.

7. **Cooling Off Periods.** The first trade under the Rule 10b5-1 Trading Plan may not occur until the expiration of a cooling-off period as follows:
    - For Section 16 Persons (as well as their Family Members and Controlled Entities), the later of (1) two business days following the filing of the Company's Form 10-Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Trading Plan was adopted and (2) 90 calendar days after adoption of the Rule 10b5-1 Trading Plan; provided, however, that the required cooling-off period shall in no event exceed 120 days.
    - For other Insiders, 30 days after adoption of the Rule 10b5-1 Trading Plan.

8. **No Overlapping Rule 10b5-1 Trading Plans.** You may not enter into overlapping Rule 10b5-1 Trading Plans (subject to certain exceptions). Please consult with the CLO or other attorneys designated by the CLO for any questions regarding overlapping Rule 10b5-1 Trading Plans.

9. **Single Transaction Plans.** You may not enter into more than one Rule 10b5-1 Trading Plan designed to effect the open-market purchase or sale of the total amount of securities as a single transaction during any rolling 12-month period (subject to certain exceptions). A single-transaction plan is "designed to effect" the purchase or sale of securities as a single transaction when the terms of the plan would, for practical purposes, directly or indirectly require execution in a single transaction.

10. **Modifications and Terminations.** Modifications/amendments and terminations of an existing Rule 10b5-1 Trading Plan are strongly discouraged due to legal risks, and can affect the validity of trades that have taken place under the plan prior to such modification/amendment or termination. Under Rule 10b5-1 and these guidelines, any modification/amendment to the amount, price or timing of the purchase or sale of the securities underlying the Rule 10b5-1 Trading Plan (a "***Material Modification***") will be deemed to be a termination of the current Rule 10b5-1 Trading Plan and creation of a new Rule 10b5-1 Trading Plan. As such, the modification/amendment of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the CLO or other attorneys designated by the CLO in accordance with the pre-clearance procedures set forth in the Policy and these guidelines, and any Material Modification will be subject to all the other requirements set forth in these guidelines regarding the adoption of a new Rule 10b5-1 Trading Plan.

    The termination (other than through an amendment or modification) of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the CLO or other attorneys designated by the CLO in accordance with the pre-clearance procedures set forth in the Policy and these guidelines. Except in limited circumstances, the CLO will not approve the termination of a Rule 10b5-1 Trading Plan unless:

    - you are not aware of any MNPI; and
    - when you are not subject to a blackout period.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1) Registration Statement (Form S-3 No. 333-281503) of Apogee Therapeutics, Inc.,
2) Registration Statement (Form S-8 No. 333-274234) pertaining to the Apogee Therapeutics, Inc. 2023 Equity Incentive Plan and Apogee Therapeutics, Inc. 2023 Employee Stock Purchase Plan,
3) Registration Statement (Form S-8 No. 333-279354) pertaining to the Apogee Therapeutics, Inc. 2023 Equity Incentive Plan and Apogee Therapeutics, Inc. 2023 Employee Stock Purchase Plan,
4) Registration Statement (Form S-8 No. 333-281477) pertaining to the Non-Plan Stock Option Grant of Apogee Therapeutics, Inc.,
5) Registration Statement (Form S-8 No. 333-285478) pertaining to the Apogee Therapeutics, Inc. 2023 Equity Incentive Plan and Apogee Therapeutics, Inc. 2023 Employee Stock Purchase Plan;

of our reports dated March 2, 2026, with respect to the consolidated financial statements of Apogee Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Apogee Therapeutics, Inc. included in this Annual Report (Form 10-K) of Apogee Therapeutics, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 2, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Henderson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apogee Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2026

By: /s/ Michael Henderson, M.D.
Michael Henderson, M.D.
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jane Pritchett Henderson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apogee Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2026

By: /s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Apogee Therapeutics, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his or her knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 2, 2026

By: /s/ Michael Henderson, M.D.
Michael Henderson, M.D.
Chief Executive Officer
(principal executive officer)

Date: March 2, 2026

By: /s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.