

**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, 2024

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  
(State or other jurisdiction of  
incorporation or organization)

88-0588063  
(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, 2024 was approximately \$1,433.6 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 24, 2025, the registrant had 59,503,184 shares of common stock, \$0.00001 par value per share, outstanding, comprised of 46,016,542 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 2025 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 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;
- our plans regarding, and our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our programs;
- 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 and clinical utility 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;

- 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 ®, <sup>SM</sup>, or <sup>TM</sup> 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 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 four antibody programs being developed initially for the treatment of I&I indications as monotherapies and combinations. Our most advanced programs are APG777, APG990, APG333, and APG808. 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. Our programs incorporate advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. We believe each of our programs has potential for broad application across multiple I&I indications, including in combination.

In March 2024, we announced positive interim safety, pharmacokinetic (“PK”) and pharmacodynamic (“PD”) data from our Phase 1 trial of APG777 in healthy volunteers and in May 2024, we initiated a Phase 2 trial of APG777 in patients with moderate-to-severe AD. In February 2025, we announced that the last patient in Part A of the Phase 2 trial had been dosed and that we had commenced dosing of Part B.

In August 2024, we initiated a Phase 1 trial of APG990 in healthy volunteers and in March 2025, we announced positive interim safety and PK data from that trial.

In December 2024, we initiated a Phase 1 trial of APG333 in healthy volunteers.

In March 2024, we initiated a Phase 1 trial of APG808 in healthy volunteers and in December 2024, we announced positive interim safety, PK and PD data from that trial.

**Our Pipeline**

Our pipeline comprises four programs being developed initially for the treatment of I&I indications, as shown below. Our programs incorporate advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. We believe each of our programs has potential for broad application across multiple I&I indications.



**APG777 – anti-IL13 antibody, same mechanism of action as EBGLYSS (lebrikizumab)**

APG777 is a subcutaneous (“SQ”) extended half-life monoclonal antibody (“mAb”) targeting IL-13. In August 2023, we announced the dosing of our first participant in our first clinical trial for APG777. In 2024, we announced positive interim safety and PK data from this trial with APG777 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 APG777 demonstrated a deep and sustained effect on PD markers out to approximately 12 months. APG777 was well-tolerated across all dose groups. In May 2024, we commenced dosing in the Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD. In February 2025, we announced that the last patient in the Part A portion of the trial had been dosed with 16-week topline data from Part A expected in mid-2025. In February 2025, we also announced that we had commenced dosing of Part B of the Phase 2 trial. All patients benefiting from treatment will have the opportunity to continue to APG777 maintenance treatment, which will evaluate three- to six-month dosing intervals. We anticipate maintenance data from Part A in the first half of 2026 and 16-week topline data from Part B in the second half of 2026.

Based on our initial clinical data, we plan to advance the development of APG777 in asthma and EoE by initiating a Phase 1b trial in asthma in the first half of 2025, followed by a Phase 2b trial in asthma in the second half of 2025, and a Phase 2 trial in EoE in 2026. Based on our clinical data, we expect to further evaluate additional opportunities to develop APG777 for other I&I indications, including alopecia areata (“AA”), chronic rhinosinusitis with nasal polyps (“CRSwNP”), chronic spontaneous urticaria (“CSU”), and prurigo nodularis (“PN”).

In addition, we plan to evaluate APG777 in combination with other investigational therapies within our pipeline to potentially enable greater efficacy for I&I conditions. We plan to initiate our first combination study, a Phase 1b trial of APG777 and APG990, a novel, SQ, half-life extended mAb targeting OX40L, in 2025. This combination study is designed to evaluate the coformulation of APG777 and APG990 (“APG279”) against DUPIXENT in patients with moderate-to-severe AD, with readout expected in the second half of 2026.

***APG990 – anti-OX40L antibody, same mechanism of action as amltelimab; potential combination therapy with APG777***

APG990 is an SQ extended half-life mAb that utilizes advanced antibody engineering to target OX40L.

We plan to develop APG777 and APG990 together as a potential first-in-class coformulation for the treatment of AD by combining deep and sustained inhibition of Type 2 inflammation via APG777's inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990's inhibition of OX40L. APG279 has been shown to retain stability, injectability, and convenience of individual components in preclinical studies. In preclinical studies, APG279 has also demonstrated broad inhibition of Type 1, Type 2 and Type 3 inflammation, similar to what was seen with Janus kinase ("JAK") inhibition, but with potential for better tolerability than JAK inhibitors. We believe these combined mechanisms offer the potential for improved clinical responses over monotherapy while our planned approach of coformulating two extended half-life mAbs holds the potential for best-in-class dosing.

In August 2024, we initiated a Phase 1 clinical trial of APG990 in healthy volunteers to establish safety, tolerability and PK profile, which could enable the combination with APG777.

In March 2025, we announced positive interim safety and PK data from the APG990 Phase 1 clinical 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. In addition, preclinical toxicology studies of the combination of APG777 and APG990 showed no findings at any dose level, including the highest dose tested of 150 mg/kg per agent. Based on these results, we plan to submit an Investigational New Drug application or foreign equivalent for APG279. Following clearance, we plan to initiate in 2025 a Phase 1b trial of APG279 against DUPIXENT in approximately 50 to 75 patients with moderate-to-severe AD with a data readout expected in the second half of 2026.

***APG333 – anti-TSLP antibody, same mechanism of action as TEZPIRE (tezepelumab); potential combination therapy with APG777***

APG333 is a fully-human mAb against thymic stromal lymphopoietin ("TSLP"), an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of people living with asthma and COPD. In preclinical studies, the combination of APG777 and APG333 has been shown to impact both central inflammation and local airway responses. This has the potential to improve clinical outcomes compared to approved or in-development biologics which only target peripheral or central inflammation, not both, and retains the potential for a significantly less frequent dosing schedule. In December 2024, we initiated a Phase 1 trial of APG333 in healthy volunteers and we expect interim data from the trial in the second half of 2025.

We plan to evaluate APG777 and APG333 monotherapies in respective Phase 1b trials in patients with asthma in 2025 to support advancement into future combination trials in asthma and COPD. Subject to positive data, we plan to study APG777 in combination with APG333 to drive potential best-in-class efficacy in respiratory conditions.

***APG808 – anti-IL4R $\alpha$  antibody, same mechanism of action as DUPIXENT***

APG808 is an SQ extended half-life mAb targeting IL-4R $\alpha$ , 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. We are also now evaluating APG808 in a Phase 1b trial in patients with asthma, with data expected in the first half of 2025.

## **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. For instance, each of our programs, APG777, APG990, APG333 and APG808, bind to the same epitopes, or binding sites, on IL-13, OX40L, TSLP and IL-4R $\alpha$  as EBGLYSS (lebrikizumab), amltelimab, 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 programs, 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 programs 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 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 APG777 targeting IL-13 through clinical development and regulatory filings for AD;
- Advancing APG990 targeting OX40L and APG279 for the dual inhibition of OX40L and IL-13;
- Advancing APG333 targeting TSLP and the combination of APG777 and APG333 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 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: Eczema Area and Severity Index (“EASI”) and Investigator’s Global Assessment (“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 1 below.

**Figure 1 — Eczema Area and Severity Index**

Score	Erythema (Redness)	Induration (Thickness)	Excoriation (Scratching)	Lichenification (Lined Skin)
NONE <b>0</b>				
MILD <b>1</b>	 Faintly detectable, pink	 Barely perceptible elevation	 Scant, superficial excoriations	 Slight thickening of the skin, skin markings minimally exaggerated
MODERATE <b>2</b>	 Clearly distinguishable dull red	 Clearly perceptible elevation but not prominent	 Many superficial and/or some deeper excoriations	 Clearly thickened skin with exaggerated skin markings and/or some prurigo nodules
SEVERE <b>3</b>	 Deep dark or fiery bright red	 Prominent elevation	 Diffuse extensive superficial and/or deep excoriations	 Prominent thickening with exaggerated skin markings creating deep furrows and/or many prurigo nodules

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

As shown in Figure 2 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 2 — Investigator’s Global Assessment**

Score	Morphological Description
CLEAR 0	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Postinflammatory hyperpigmentation and/or hypopigmentation may be present.
ALMOST CLEAR 1	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
MILD 2	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
MODERATE 3	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
SEVERE 4	Marked erythema (deep or bright red), clearly perceptible induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.

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 U.S. Food and Drug Administration (“FDA”)-approved mAbs, DUPIXENT, ADBRY, EBGLYSS, and NEMLUVIO, labeled to treat moderate-to-severe AD that is inadequately controlled by topical corticosteroids.

DUPIXENT is indicated for the treatment of adult and pediatric patients aged six months and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can be used with or without topical corticosteroids. DUPIXENT is a fully human mAb that inhibits the signaling of the IL-4 and IL-13 pathways. For adults with AD, DUPIXENT is dosed via SQ injection with an initial loading dose requiring two injections, followed by one injection every two weeks for adults with AD. For pediatric patients, it is dosed as one or two injections every two to four weeks depending on age and weight. DUPIXENT was studied in over 2,800 patients across multiple pivotal trials and demonstrated clinically meaningful improvements at Week 16 in adult, adolescent and pediatric patients.

ADBRY is indicated for the treatment of moderate-to-severe AD in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can be used with or without topical corticosteroids. ADBRY is a fully human, high-affinity mAb that targets IL13. It selectively inhibits IL13, preventing IL13 induced immune responses in the skin. It is dosed via SQ injection with an initial loading dose requiring either (i) in the case of prefilled syringes, four injections, followed by two injections every two weeks for 16 weeks then, for select patients, maintenance injections every month may be considered; or (ii) in the case of

autoinjectors, two injections, followed by one injection every two weeks for 16 weeks then, for select patients, maintenance injections every month may be considered. ADBRY was evaluated in nearly 2,000 patients with AD in three pivotal trials. Across the three trials, ADBRY demonstrated improvements in both skin clearance and lesion extent and severity at Week 16.

EBGLYSS is indicated for the treatment of moderate-to-severe AD in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can also be used with or without topical corticosteroids. EBGLYSS is designed to inhibit the IL-13 pathway. In three Phase 3 clinical trials, SQ administration of EBGLYSS was dosed every two weeks in the induction phase (first 16 weeks of treatment) and every two or four weeks in the maintenance phase (from 16 weeks to 52 weeks). EBGLYSS met all primary and key secondary endpoints at Week 16 in Phase 3 trials. The most commonly reported adverse events (“AEs”) were conjunctivitis, common cold and headache. In Phase 3 studies, ~30% higher exposure was seen in the low body weight group (less than 60kg), which also had numerically higher efficacy than the overall study population across all key endpoints, including EASI-75 and more stringent endpoints such as EASI-90 and IGA 0/1.

NEMLUVIO is indicated for the treatment of moderate-to-severe AD patients aged 12 and over in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies. NEMLUVIO is a humanized IgG2 mAb that inhibits IL-31 signaling by binding selectively to IL-31R $\alpha$ . It is dosed via SQ injection with an initial loading dose requiring two injections, followed by one injection every four or eight weeks in maintenance. NEMLUVIO was evaluated in combination with topical corticosteroids and/or calcineurin inhibitors in over 1,700 patients with AD in two pivotal trials. Across the two trials, NEMLUVIO in combination with topical corticosteroids and/or calcineurin inhibitors demonstrated improvements in both skin clearance and lesion extent and severity at Week 16.

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. Systemic JAK inhibitors represented just 7% of the AD market in 2022.

An emerging mechanism in treatments for AD is targeting OX40L, which occurs higher up in the inflammatory pathway than IL-13 or IL-4R $\alpha$  and potentially broadens the impact on the inflammatory cascade. OX40L is the ligand for OX40. Amltelimab, which targets OX40L, has demonstrated activity in Phase 2 trials in AD.

#### *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.

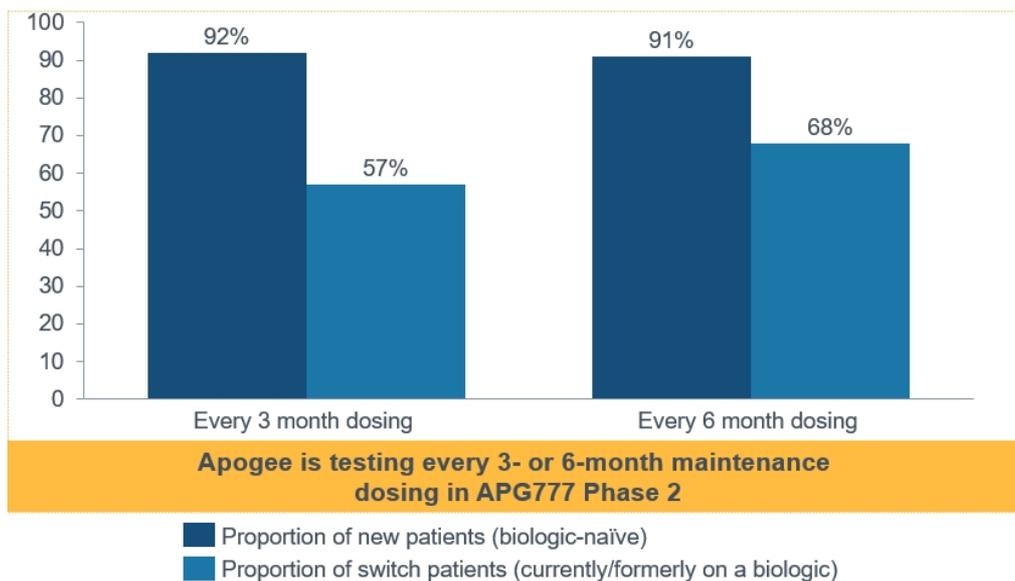
In 2023, we conducted a single-blinded market research survey of 25 practicing dermatologists in 14 states in the United States, with the assistance of an expert search network.

Dermatologists were selected based on years of experience in the field (four or more years of practice post residency or fellowship training), number of AD patients treated (30 or more AD patients seen per month), experience prescribing biologic therapies in AD (10% or more of AD patients on biologics) and no previous contact with us. We conducted approximately 30-minute interviews using standardized questions to solicit sentiments towards a potential new product offering with every three-month dosing in maintenance and the same efficacy and safety as DUPIXENT, which was presented as a blinded Target Product Profile (“TPP”). The dermatologists selected for the survey have an average of 20 years in practice, treat an average of 88 AD patients per month and see a mix of both adult and pediatric patients.

In the interviews, dermatologists described how they would incorporate the TPP in treatment algorithms for biologic naïve patients (i.e., patients who have never taken a biologic treatment, but qualify based on failure to topical therapies) and biologic-experienced patients (i.e., patients who are either currently or have previously used a biologic therapy for AD). On average, dermatologists indicated they expect that approximately 92% of their biologic patients would start a product with the TPP as frontline treatment. For patients currently or previously on biologic therapy, dermatologists estimated approximately 57% would switch to a product with the TPP. Likewise, patients were given APG777 TPP and two other available treatments. When asked their preference, 94% of patients preferred a Q3M dosing regimen. Finally, payers were asked how they might cover a product with the TPP, at a similar net price, and most see this product as a first line biologic product.

Dermatologists were then asked how their intent to use a product with the TPP would change if (i) it was dosed every two months in the maintenance setting, or (ii) it was dosed every six months in the maintenance setting. As shown in Figure 3 below, results for the every two-month dosing were consistent with the every three month dosing. With every two-month dosing, dermatologists on average indicated they would prescribe a product with the TPP to 91% of their biologic naïve patients and they estimated 56% of their patients currently or previously on biologic therapy would switch to a product with the TPP. As shown in Figure 3 below, results for the every six-month dosing showed a greater proportion of patients would switch from a current biologic than for the every three-month dosing. With every six-month dosing, dermatologists on average indicated they would prescribe a product with the TPP to 91% of their biologic naïve patients and they estimated 68% of patients currently or previously on biologic therapy would switch to a product with the TPP.

**Figure 3 — Intent to use a product with the APG777 Target Product Profile with every three- or six-month maintenance dosing and equivalent efficacy and safety to DUPIXENT**



We are not aware of any programs in development in AD that have the potential to reduce dosing frequency past four weeks and the related burden of administration on patients. A more convenient dosing schedule is especially important for pediatric patients, which has the potential to expand the market significantly.

## **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. Currently, the asthma market is greater than \$10 billion in these seven major markets. 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.

### *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 and TEZSPIRE). All have shown reductions in annualized exacerbation rates of approximately 50% to 60% and are dosed every two to eight weeks.

## **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. DUPIXENT's approval in EoE further supports the scientific rationale for IL-13/IL-4R $\alpha$  targeting agents in treating EoE. DUPIXENT was studied in approximately 300 EoE patients across two pivotal trials and demonstrated clinically meaningful improvements in histological remission defined as peak esophageal intraepithelial eosinophil count in adult, adolescent, and pediatric patients. In adults and adolescents, DUPIXENT demonstrated clinically meaningful reduction in dysphagia symptoms as measured by reduction in Dysphagia Symptom Questionnaire score. In pediatric patients (1-11 years of age), DUPIXENT demonstrated clinically meaningful reduction in symptoms as measured by reduction in Pediatric EoE Sign/Symptom Questionnaire-Caregiver score.

## **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 in 2019 (prior to the COVID-19 pandemic), COPD was the third leading cause of death globally. 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). A pooled analysis from two Phase 3 trials of DALIRESP in COPD patients 40 years of age and older with severe airflow limitation, bronchitis symptoms and a history of exacerbations showed a 17% reduction in moderate or severe exacerbations.

In 2024, the FDA approved DUPIXENT as the first biologic treatment for add-on maintenance for inadequately controlled COPD and an eosinophilic phenotype. Two Phase 3 studies demonstrated that DUPIXENT dosed every 2 weeks reduced exacerbations by an average of 31% compared to placebo in patients with elevated peripheral eosinophils ( $\geq 300$  cell/ $\mu$ L). TEZSPIRE (tezepelumab) is a biologic being developed in COPD. Tezspire dosed as 420 mg monthly, showed a 37% reduction in annualized exacerbations in a subset (n=92) of moderate to very severe COPD patients with eosinophils  $\geq 150$  cell/ $\mu$ L in an initial Phase 2 trial. OHTUVAYRE (ensifentrine), a twice daily nebulized treatment for moderate to severe COPD, was approved in 2024. However, the trials did not require a recent history of exacerbations. Despite these recent advancements in COPD treatment, a significant number of patients continue to suffer and die from the disease.

Given the complexity of COPD, we believe biologics targeting Th2 immune response in patients with high peripheral eosinophils show the greatest promise, as supported by DUPIXENT's approval in COPD and TEZSPIRE's encouraging Phase 2 data in COPD.

## **Our Solution: Building Differentiated Biologics**

We are engineering therapies for AD, asthma, EoE, COPD, and other related I&I indications. Our programs, APG777, APG990, APG333 and APG808, target IL-13, OX40L, TSLP, and IL4R $\alpha$ , respectively, and are designed to overcome limitations of frequent dosing associated with currently available treatments. We believe that each of our programs has potential for broad application across multiple I&I indications, including the potential for higher efficacy either through an improved monotherapy or via rationale combinations. Despite advances in care, there is still high unmet medical need for patients suffering from the I&I indications that we are targeting, both in terms of reduced injection burden as well as improved efficacy.

Our programs incorporate advanced antibody engineering approaches, and are designed to optimize for 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), potentially improving on each of those qualities over existing, non-optimized antibodies.

We utilize and test a number of half-life extension technologies, including YTE and LS, 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).

APG777, leverages YTE amino acid modification half-life extension technology and is an SQ mAb targeting IL-13. APG777 demonstrated a 77-day half-life in a Phase 1 clinical trial in healthy volunteers. We initiated a Phase 2 clinical trial in patients with moderate-to-severe AD in May 2024. The Phase 2 trial is designed to combine the

typical Phase 2a and 2b portions of a clinical trial into a single protocol. In February 2025, we announced that the last patient in the Part A portion had been dosed and that we had commenced dosing of the Part B portion. We anticipate maintenance data from Part A in the first half of 2026 and 16-week topline data from Part B in the second half of 2026.

APG990, leverages half-life extension technology and is an SQ mAb targeting OX40L. We initiated a Phase 1 clinical trial of APG990 in healthy volunteers in August 2024 and announced positive interim safety and PK data in March 2025. In 2025, we plan to initiate a Phase 1b trial designed to evaluate APG279 against DUPIXENT in approximately 50 to 75 patients with moderate-to-severe AD with a data readout expected in the second half of 2026.

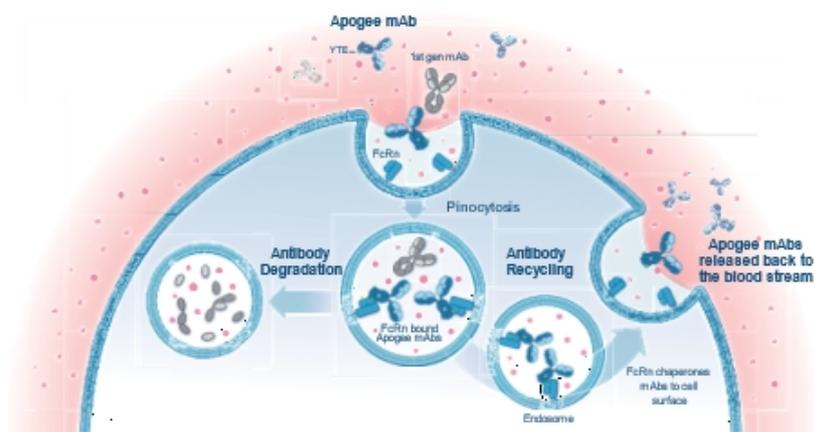
APG333, leverages half-life extension technology and is an SQ mAb targeting TSLP. We initiated a Phase 1 clinical trial of APG333 in healthy volunteers in December 2024 and expect a data readout in the second half of 2025. Subject to positive data and required regulatory approvals, we plan to evaluate the combination of APG777 and APG333.

APG808, leverages half-life extension technology and is an SQ mAb targeting IL-4R $\alpha$ . We initiated a Phase 1 clinical trial of APG808 in March 2024 and announced positive interim safety, PK and PD data in December 2024. We are also now evaluating APG808 in a Phase 1b trial in patients with asthma, with data expected in the first half of 2025.

### **Half-Life Extension and Antibody Engineering Technologies**

Our antibody engineering programs 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 programs 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 4 below.

**Figure 4 — 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 three-to four-fold compared to non-YTE mAbs, with half-lives observed to often exceed 100 days in third-party trials. 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.** For example, 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.

YTE amino acid modifications have been introduced in numerous mAbs in late-stage ongoing clinical trials (e.g., depemokimab) and completed trials (e.g., motavizumab-YTE and ziltvekimab), as well as one approved product, BEYFORTUS. The targets of these antibodies include cytokines (IL-5 for depemokimab and IL-6 for ziltvekimab) and viruses (RSV for motavizumab-YTE and BEYFORTUS).

Similarly, LS amino acid modifications have been introduced into numerous mAbs in early- and late-stage clinical trials (e.g., VIR-7831, VIR-2482 and VRC01LS) as well as approved products (e.g., ULTOMIRIS and XEVUDY). The targets of these antibodies include complement (C5 for ULTOMIRIS) and viruses (SARS-CoV-2 for XEVUDY, HbsAg for VIR-2482 and HIV for VRC01LS).

*The safety and immunogenicity profile of YTE-or LS-modified mAbs compares favorably to non-YTE or non-LS modified mAbs with identical targets*

For example, in third-party clinical trials, the safety profile of motavizumab-YTE was comparable to that of the parent antibody, motavizumab, with no significant difference in the occurrence of self-limited AEs. Similarly, a Phase 1 trial of depemokimab, an anti-IL-5 with a YTE amino acid modification for half-life extension, was notable for its overall benign safety profile and similar AE rate compared to mepolizumab (NUCALA), an anti-IL-5 without half-life extension. Finally, among infants with prematurity or other RSV risk factors, serious adverse event (SAE) frequency and type were comparable between nirsevimab (YTE) and palivizumab (non-YTE)-dosed infants.

In human subjects, we are not aware of administration of mAbs bearing YTE amino acid modifications being associated with greater immunogenicity than unmodified mAbs. For example, similar levels of anti-drug antibodies (ADAs) have been measured in motavizumab as compared to motavizumab-YTE. As another example, nirsevimab, a mAb with YTE amino acid modifications targeting RSV, exhibited lower levels of ADAs than an antibody for the same target without YTE amino acid modifications (palivizumab).

Similarly, administration of mAbs bearing LS amino acid modifications does not appear to confer any additional safety risk or immunogenicity risk. For example, ULTOMIRIS (ravulizumab) is an LS modified version of SOLIRIS (eculizumab). In third-party clinical trials, the AE profile of ULTOMIRIS and SOLIRIS were shown to be similar in a head-to-head study and one ADA-positive sample was found in each treatment arm.

## **APG777**

APG777 leverages YTE amino acid modifications half-life extension technology and is an SQ mAb targeting IL-13. We are evaluating APG777 in AD, and plan to evaluate APG777 in a number of expansion indications, including asthma and EoE and in combination with certain of our other programs.

In our head-to-head preclinical studies of APG777 and lebrikizumab in non-human primates (“NHPs”). APG777 showed a significantly longer half-life than lebrikizumab. In these studies, APG777’s half-life was 27.6 days, as compared to 18.0 days for lebrikizumab based on cumulative fit models across SQ and IV groups for each compound.

In 2024, we announced interim safety, PK and PD data from our Phase 1 trial of APG777 in healthy volunteers. PK data showed a half-life of 77 days across doses tested. Generally, the half-life of mAbs is consistent between healthy volunteers and patients since mAbs are degraded by endogenous catabolic processes and are not subject to the same drug-drug interaction potential of many traditional small molecules. Consequently, this gives us confidence that the PK parameters derived from the Phase 1 trial in healthy volunteers can be used to effectively model dosing regimens in the subsequent Phase 2 and Phase 3 safety and efficacy trials in patients with AD and other I&I indications.

We are testing three- and six-month dosing in our Phase 2 clinical trial of APG777. Compared to more frequent dosing schedules associated with existing AD therapies, every three- or six-month dosing, should our clinical trials be successful in demonstrating the requisite efficacy and safety profile, has the potential to be significantly more convenient for patients, enabling them to better adhere to their dosing schedule. Additionally, every three- or six-month dosing improves quality of life given that many patients experience “needle fatigue” and pediatric patients in particular often suffer from fear of needles.

*APG777's target, IL-13, has no known non-disease function*

APG777'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<sup>-/-</sup> 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-13R $\alpha$ 1, forming an inactive complex that then binds to IL-4R $\alpha$  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.

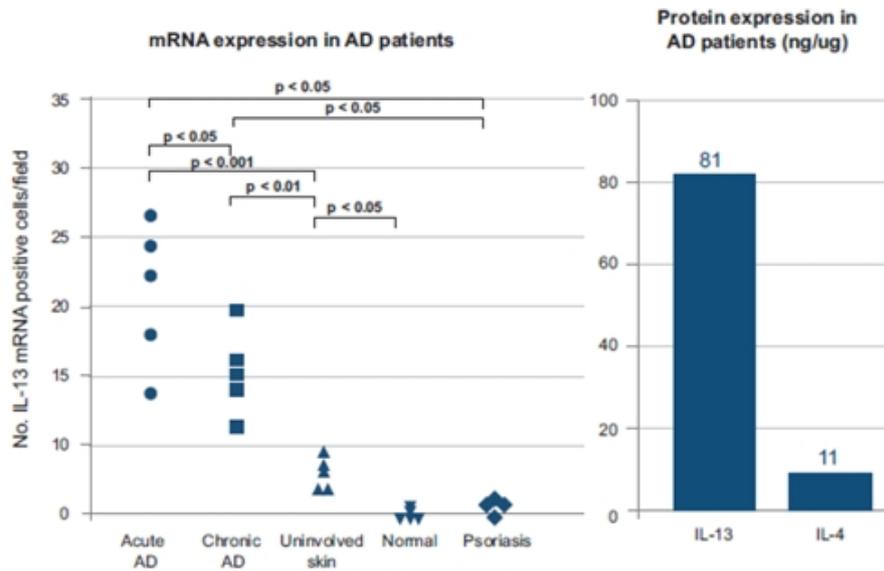
*IL-13 is a known driver of AD pathogenesis and broader I&I indications*

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 cytokines, 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 5 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 5 below).

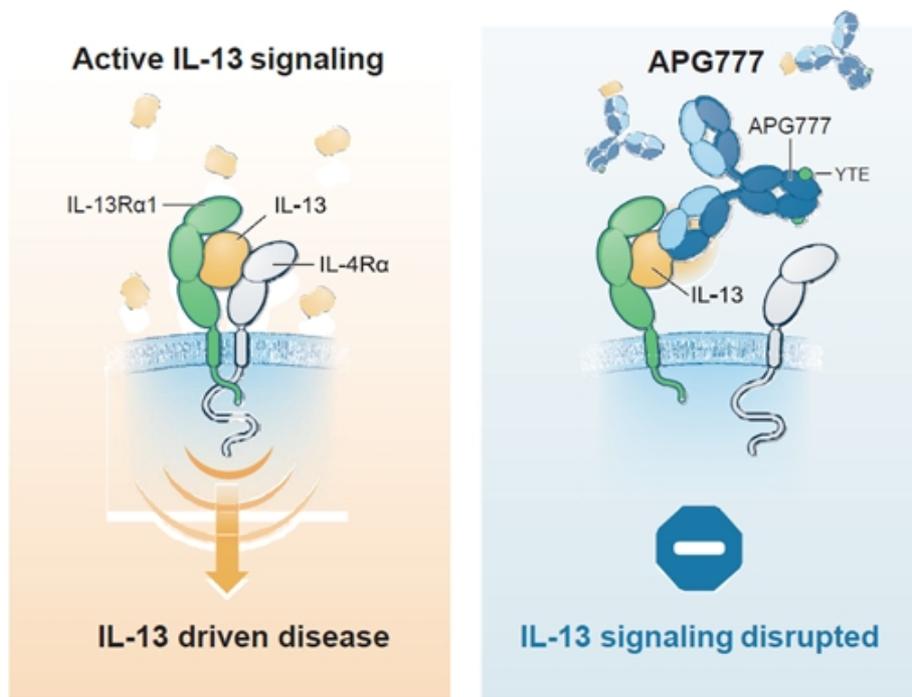
Figure 5 — Cytokine expression in AD and Non-AD skin samples in third-party studies



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-13R $\alpha$ 1-IL4R $\alpha$  heterodimer. In turn, the active IL-13R $\alpha$ 1-IL4R $\alpha$  heterodimer, through a signaling cascade, leads to skin barrier defects, immune cell recruitment, tissue inflammation, lichenification (skin thickening) and pruritis (skin itching). APG777 is designed to interrupt the heterodimer formation and thus disrupt IL-13 signaling as shown in Figure 6 below.

**Figure 6 — APG777 is designed to disrupt IL-13 signaling by preventing the formation of the IL-13R $\alpha$ 1-IL4R $\alpha$  heterodimer**



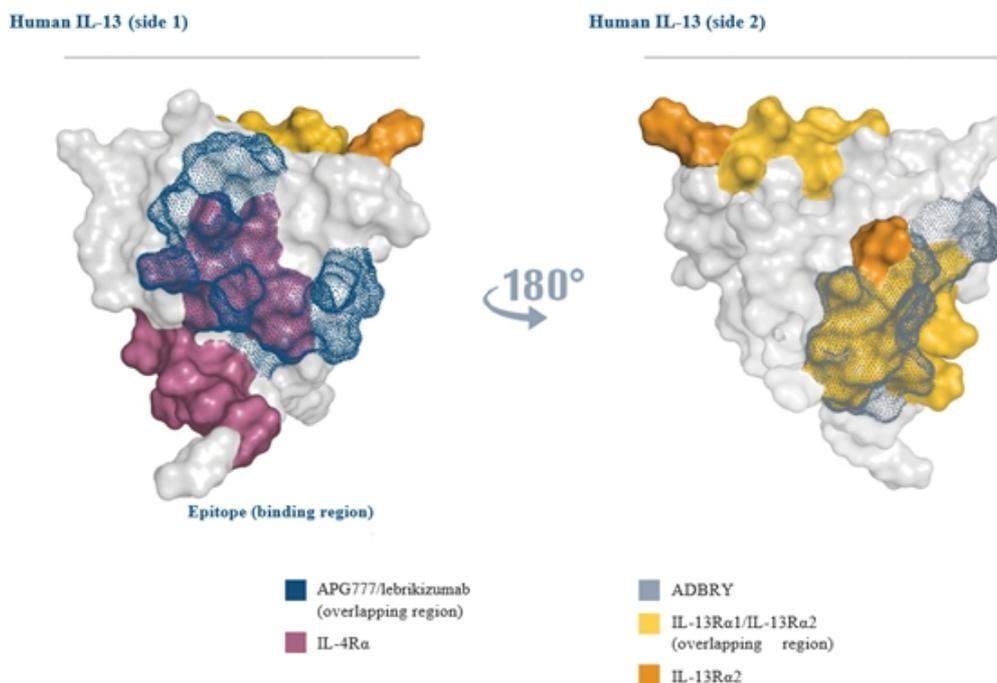
In addition to AD, elevated IL-13 has been observed in other inflammatory conditions such as asthma, CRSwNP and EoE.

*Epitope, or binding site, is key in preventing the IL-13R $\alpha$ 1-IL-4R $\alpha$  active heterodimer formation*

As previously described, IL-13 signaling begins with the binding of IL-13 to IL-13R $\alpha$ 1, forming an inactive complex that then binds to IL-4R $\alpha$  to form the complete, active receptor heterodimer. This active receptor heterodimer is key to the pathogenesis of AD. Therefore, we believe a therapeutic approach for AD needs to prevent the formation of this heterodimer.

As shown in Figure 7 below, a 3D rendering of human IL-13 generated from our head-to-head preclinical studies described below, the dark blue highlights the epitope, or binding site, of lebrikizumab, which overlaps with APG777's epitope, also highlighted in blue. Importantly, these epitopes also overlap with the IL-4R $\alpha$  epitope on IL-13. Thus, we believe mAb binding to this location is likely to prevent the formation of the IL-13R $\alpha$ 1-IL-4R $\alpha$  active heterodimer, limiting the inflammatory signaling that is key to AD pathogenesis as well as the pathogenesis of other I&I conditions. This contrasts with the epitope of ADBRY, highlighted in gray, which does not overlap with the IL-4R $\alpha$  epitope on IL-13 and therefore we believe may have a more limited ability to prevent heterodimerization.

Figure 7 — 3D rendering of human IL-13 and epitopes for antibodies and receptors that bind to IL-13



Furthermore, IL-13 also binds a second receptor, IL-13R $\alpha$ 2. Often described as a “decoy” receptor, IL-13R $\alpha$ 2 has a limited cytoplasmic domain and does not appear to mediate signal. IL-13R $\alpha$ 2 does, however, bind to IL-13 with very high affinity, effectively removing IL-13 from circulation. Third-party studies involving IL-13R $\alpha$ 2 knockout mice demonstrated worsened atopic features, including fibrosis and itch.

ADBRY, but not lebrikizumab or APG777, has an epitope that inhibits the binding of IL-13 to IL-13R $\alpha$ 2, which could lead to increased circulating IL-13 levels and, in a counterproductive fashion, worsen AD. However, there can be no assurance that our programs targeting IL-13 will not have similar or comparable results to other third-party agents based on epitope.

*IL-13 is a soluble cytokine which exists at low concentrations in circulation, making it highly amenable to half-life extension*

Half-life for antibodies is a product of degradation or elimination through three pathways: pinocytosis, target-mediated drug disposition (TMDD) and receptor-mediated endocytosis.

- Pinocytosis is a non-specific process in which extracellular fluid and substances are brought into the cell, resulting in an internalized vesicle. This internal vesicle then fuses with lysosomes. All antibodies are subject to this elimination pathway.
- TMDD is a receptor-mediated endocytosis process, meaning that the interactions of the antibody with the receptor on the cell surface results in the internalization of the antibody and subsequent degradation via lysosomes, specialized organelles, or areas within the cell that degrade molecules and other biomaterial. Only mAbs with receptor targets, such as APG808, which targets IL-4R $\alpha$ , are subject to this elimination pathway. mAbs with soluble targets, such as APG777, which target the soluble cytokine IL-13, are not eliminated via TMDD.

- Receptor-mediated endocytosis is the binding of antibodies to Fc-gamma-receptors, which are present on many immune cells, can also trigger an elimination process similar to TMDD. However, third-party preclinical studies have demonstrated that this degradation pathway plays only a minor role in the elimination of antibodies, if at all.

Importantly, antibody recycling through FcRn only impacts degradation via pinocytosis and has no impact on elimination via TMDD. Half-life extension throughYTE amino acid modifications, which increases affinity for FcRn, therefore increasing recycling and antibody half-life, is more limited for receptor targets than soluble targets. This is because mAbs with receptor targets are subject to TMDD in addition to pinocytosis. Therefore, we believe soluble targets, like IL-13, which APG777 has been engineered to target, have potential for the longest half-life extension withYTE amino acid modifications. However, there can be no assurance that soluble targets will have such results.

*APG777 and lebrikizumab have the same epitope on IL-13 in our head-to-head preclinical studies*

Epitope binning describes a technique that characterizes whether two antibodies specific to the same target (in this case, IL-13) can each bind the target at the same time. mAb pairs are binned together if they block each other's ability to bind to the target antigen. mAb pairs that are found to bin together typically bind to the same or similar epitopes on the antigen.

To characterize the binning of APG777 and lebrikizumab, we studied APG777 and lebrikizumab in head-to-head preclinical studies. Lebrikizumab was immobilized to a sensor chip surface capable of measuring mAb-antigen interactions. IL-13 was first injected into the flow channel, where binding of IL-13 to lebrikizumab generated a response. APG777 was then subsequently injected into the flow channel and the interaction response was recorded. In these studies, no response was observed after APG777 injection. This indicated that APG777 and lebrikizumab binned together and provided evidence to support that the two mAbs likely bind to a similar or the same epitope, or binding site, on IL-13.

In our similar head-to-head preclinical study, ADBRY was found to have a binding response, suggesting that it has a different epitope on IL-13 than lebrikizumab.

*APG777 matched the in vitro potency of lebrikizumab and dupilumab across all relevant assays in our head-to-head preclinical studies*

APG777 was engineered to demonstrate similar preclinical activity to available therapies in our head-to-head studies. Specifically, several assays were used to assess not only affinity for binding to IL-13, but downstream functional inhibition of the IL-13/IL-4 pathway, meaning after IL-13R $\alpha$ 1-IL-4R $\alpha$  heterodimerization. Measuring downstream functional inhibition of the pathway is critical as this measures the mAb's impact not only on IL-13, but also the impacts of the resulting inflammatory cascade that causes the features, signs and symptoms associated with AD. To measure these parameters, APG777 was tested *in vitro* across four assays: Human Affinity by SPR, Inhibition of pSTAT6 Induction, Inhibition of TF-1 Proliferation and Inhibition of TARC Secretion. These assays are described in detail below and outputs are measured in IC90, the concentration or amount of drug it takes to cause a 90% inhibition in the assay.

Results from our head-to-head preclinical studies demonstrated that each of ADBRY, lebrikizumab and APG777 had similar affinity for IL-13. Notably, since DUPIXENT does not target IL-13, it cannot be compared in this assay, but can be tested in assays on pSTAT6, TF-1 proliferations and TARC release as these assays measure inhibition in the IL-13/IL-4 pathway downstream. On these assays, DUPIXENT, lebrikizumab and APG777 all showed similar inhibition, whereas ADBRY showed inferior downstream inhibition, as demonstrated by the higher IC90, which suggests greater drug concentrations are needed to obtain the same *in vitro* potency. This provides preclinical evidence of similar *in vitro* potency among DUPIXENT, lebrikizumab and APG777 across a variety of *in vitro* assays.

## **APG777 Preclinical Dosing**

*APG777 has demonstrated significantly extended half-life in NHPs*

In our head-to-head studies of APG777 and lebrizumab in NHPs, APG777 showed a significantly longer half-life than lebrizumab. In these studies, APG777's half-life was 27.6 days, as compared to 18.0 days for lebrizumab, based on cumulative fit models across SQ and IV groups for each compound.

*An Extensive Nonclinical Program Has Been Completed to Characterize the Toxicology, Toxicokinetics and ADA Profile of APG777 in NHPs*

After evaluating APG777 across a broad range of species, NHPs represented the only pharmacologically relevant species for evaluation. Studies were conducted using an SQ route of administration, as this is the intended route of human administration. Three general toxicology studies with APG777 were designed to assess the toxicology, toxicokinetics and presence of ADAs in NHPs. These included a single-dose non-GLP dose-range finding study, as well as 29-day and six-month GLP toxicology studies.

Our single-dose non-GLP study in NHPs was conducted to select doses for the subsequent one-month and six-month studies in NHPs. No adverse findings were observed at doses up to the maximum feasible dose and the highest dose tested.

We have conducted a 29-day repeat-dose, GLP-compliant toxicology study in NHPs, in support of our Phase 1 clinical trial in healthy volunteers. NHPs (three to five animals per sex per group) were administered APG777 weekly (five doses in total) at 0, 30, 75 or 150mg/kg/dose via SC administration. No adverse findings were observed up to the highest dose tested (150mg/kg), which was the maximum feasible dose and was considered the no observed adverse effect level (NOAEL) in this study.

In support of dosing in clinical trials longer than one month in duration, we completed a six-month GLP-compliant toxicology study in NHPs. NHPs (three to five animals per sex per group) were administered APG777 weekly (27 doses in total) at 0, 30, 75 or 150mg/kg/dose via SC administration. No adverse findings were observed up to the highest dose tested (150mg/kg), which was the maximum feasible dose and was considered the NOAEL in this study. We believe the results of this study will support progression from Phase 1 to Phase 2 trials of extended duration.

## **APG777 Development**

*Phase 1 Trial in Healthy Volunteers*

In August 2023, we initiated a Phase 1 trial of APG777 in healthy volunteers. The APG777 Phase 1 trial was a double-blind, placebo-controlled study in healthy volunteers and consisted of a single-ascending dose ("SAD") component and a MAD component. Eight healthy volunteers, six treated with APG777 and two treated with placebo, were enrolled in each cohort, and we enrolled a total of 40 healthy adult subjects in the trial.

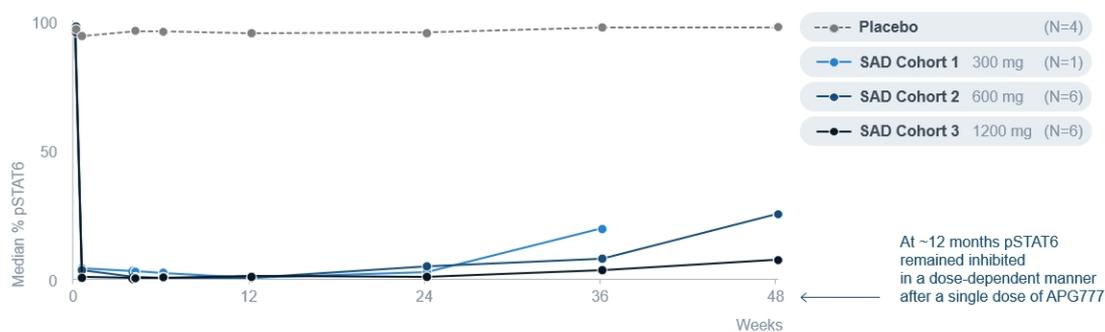
In March 2024, we announced positive interim safety and PK data and, in October and December 2024, we announced positive updated data from this trial. Interim PK data for APG777 showed a half-life of 77 days across doses tested and PD data showed near complete inhibition of key AD biomarker pSTAT6 for approximately twelve months after a single administration and sustained TARC inhibition. Results from the trial exceeded our trial objectives and support the potential for APG777, a novel anti-IL-13 antibody, to optimize exposure levels in 16-week induction and be dosed once every three or six months in maintenance. These findings represent the potential for improved clinical responses from greater exposures in induction and significantly less frequent dosing in maintenance compared to currently approved monotherapy biologic therapies, which are dosed at every two to four weeks, a potential major advancement for patients with AD and other inflammatory diseases.

APG777's PK differentiation supports further development of APG777 as a treatment for moderate-to-severe AD and other inflammatory diseases. APG777's PK profile supports testing higher exposures of drug in induction to potentially achieve improved clinical responses; and testing of maintenance dosing of every three or six months,

representing two to four injections per year compared to the current treatment paradigm of 13 to 26 injections per year. Dose-proportional increases in serum concentrations and key parameters (e.g.,  $C_{max}$ , AUC) were observed in the Phase 1 trial. PK was generally consistent across subjects with low variability.

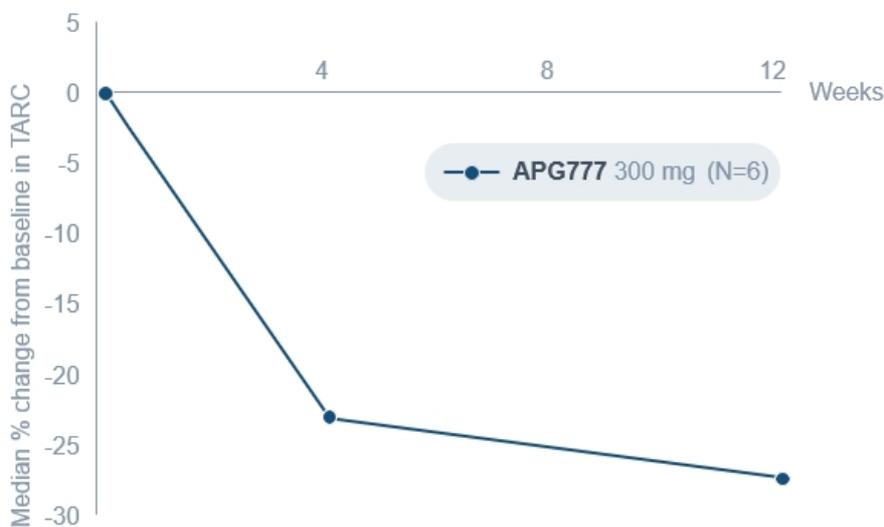
Single doses of APG777 demonstrated a deep and sustained effect on PD markers for approximately twelve months. As shown in Figure 8 below, single doses of APG777 suppressed pSTAT6, one of the first downstream markers of IL-13 pathway inhibition, with near-complete inhibition (both in terms of median and mean percent change from baseline) for approximately twelve months.

**Figure 8 — Mean percent pSTAT6 inhibition data for APG777 from our Phase 1 trial**



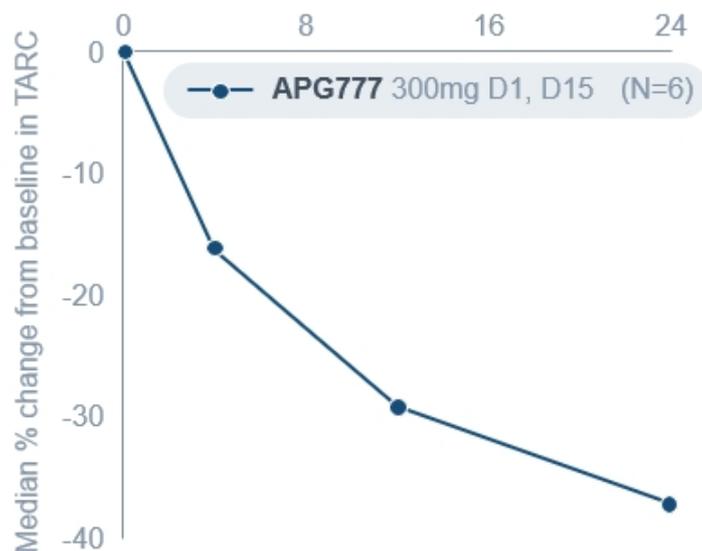
As shown in Figure 9 below, single doses of APG777 suppressed TARC, an inflammatory mediator and the most strongly correlated biomarker to AD severity, with deep and sustained inhibition for approximately three months.

**Figure 9 — TARC inhibition data for APG777 from our Phase 1 trial in 6 healthy volunteers receiving a single SC injection of 300mg of APG777; median percent change from baseline in TARC**



In addition, as shown in Figure 10 below, multiple doses of APG777 suppressed TARC with deep and sustained inhibition for approximately six months.

**Figure 10 — TARC inhibition data for APG777 from our Phase 1 trial in receiving a multi-dose injection of 300mg D1, D15 of APG777**



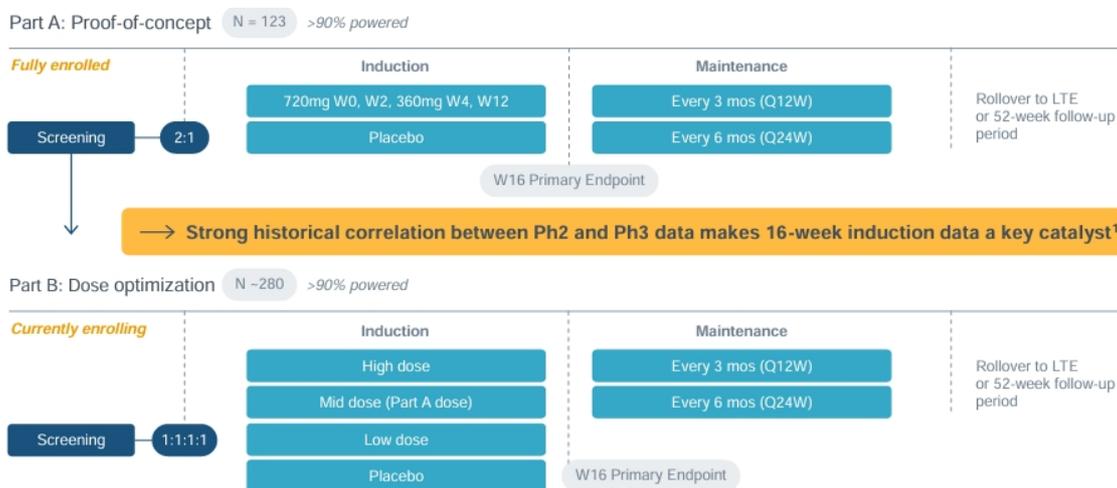
In March 2024, we reported that single doses of APG777 up to 1,200 mg and multiple doses of 300 mg were well-tolerated with a favorable safety profile consistent with the existing third-party data supporting the safety of the anti-IL-13 class. In December 2024, we confirmed that safety data were consistent with the data reported in March 2024. The most common treatment-emergent adverse events (“TEAEs”) were vascular access site pain, vessel puncture site bruise, headache, and vascular access bruising. 83.3% of participants observed at least one TEAE; 16.7% of participants observed at least one drug-related AE. There were no Grade 3 TEAEs or severe adverse events related to study drug. No AEs led to discontinuation of the study. The last participant visit in the Phase 1 trial occurred in January 2025.

In the first quarter of 2024, we filed an IND for APG777. In the first quarter of 2024, we also initiated a Phase 1 trial in healthy volunteers in the United States for subjects of Japanese descent and have completed dosing in that trial.

*Phase 2 Trial in AD*

In May 2024, we initiated APEX, a randomized, placebo-controlled, 16-week Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD. The trial is designed to combine the typical Phase 2a and 2b portions of a clinical trial into a single protocol. A schematic of the trial design is shown in Figure 11 below.

**Figure 11 — Phase 2 trial design evaluating APG777 in patients with AD**

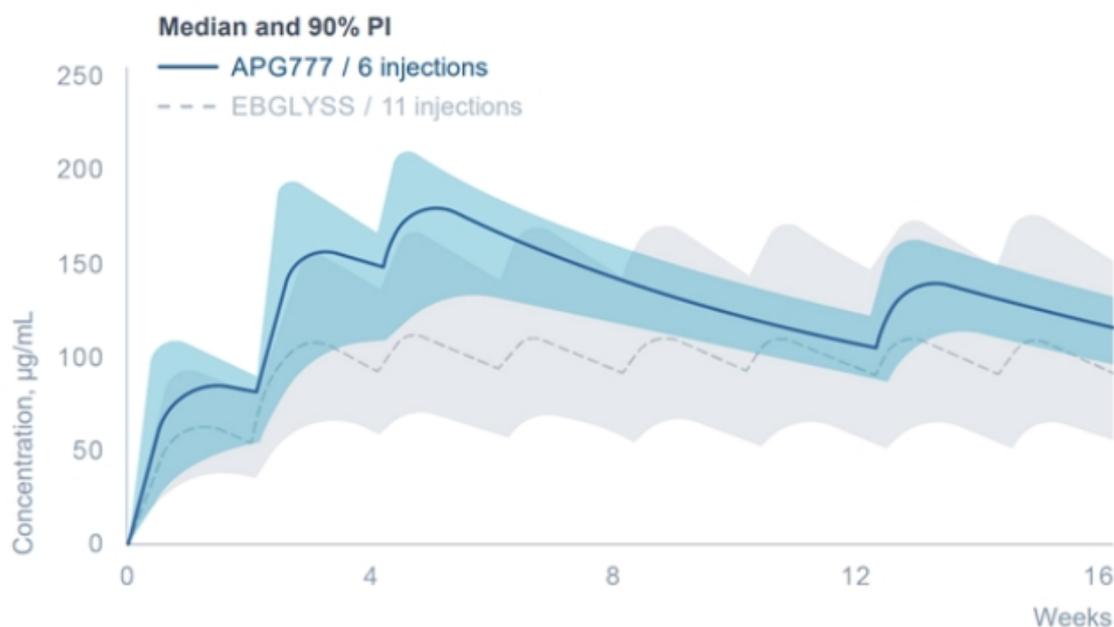


16-week topline data from Part A of the integrated Phase 2 AD trial are expected in mid-2025. We enrolled 123 patients randomized 2:1 to APG777 and placebo with a primary endpoint of mean percentage changes in EASI score from baseline to Week 16 and secondary endpoints include EASI75 and IGA0/1 at week 16. In February 2025, we announced that the last patient in the Part A portion of the APEX trial had been dosed and we expect 16-week topline data from Part A portion in mid-2025. Also in February 2025, we announced that we had commenced dosing of the Part B portion of the APEX Phase 2 trial, which is a randomized, placebo-controlled dose optimization with approximately 280 patients randomized 1:1:1:1 to high, medium, or low dose APG777 and placebo with primary endpoint of mean percentage changes in EASI score from baseline to Week 16. All patients benefiting from treatment will have the opportunity to continue to APG777 maintenance, which will evaluate three- to six-month dosing.

The integrated design is expected to provide for significant timeline acceleration by combining Phase 2a and Phase 2b elements into a single study protocol and we were able to transition from completing enrollment in Part A to enrolling Part B within one week. We expect that Part A sites will participate in Part B, which we anticipate will avoid delays for site startup between the two parts. Doses in the Phase 2 trial are enabled by APG777’s potentially best-in-class PK profile, extended half-life, and high-concentration formulation. Our 180mg/mL formulation enables a 44% higher dose of APG777 compared to EBGLYSS in the same volume.

Generally, the half-life of mAbs is consistent between healthy volunteers and patients. Consequently, we believe that the PK parameters derived from the Phase 1 trial in healthy volunteers can be used to model dosing regimens in the subsequent Phase 2 and Phase 3 trials in patients with AD and other I&I indications.

The APG777 Phase 2 induction regimen is designed to exceed EBGLYSS (lebrizumab) exposures by approximately 30 to 40% with potential for improved clinical outcomes and maintenance regimen is designed to equal lebrizumab’s exposures. In third-party Phase 3 trials of lebrizumab, approximately 30% higher exposure was seen in the low bodyweight group (less than 60 kg), which also had numerically higher efficacy than the overall study population across all key endpoints, including EASI-75 and more stringent endpoints such as EASI-90 and IGA 0/1. APG777’s higher induction exposures are based on a planned six injection induction regimen given in the first sixteen weeks of APG777 treatment. This is approximately half as many of the 11 injections of lebrizumab given during the same period. Modeling of the targeted induction exposures are shown in Figure 12 below.

**Figure 12 — Modeled target induction exposures in APG777 Phase 2 trial**

At 52 weeks, exposures of APG777 dosed every three or six months are designed to approximately equal those of EBGLYSS.

#### *Expansion opportunities for APG777*

IL-13 has been found to be elevated in other inflammatory conditions. Based on our initial clinical data, we plan to advance the development of APG777 in asthma and EoE, by initiating a Phase 1b trial in asthma in the first half of 2025, followed by a Phase 2b trial in asthma in the second half of 2025, and launching a Phase 2 trial in EoE in 2026.

#### *Asthma*

We believe asthma to be an important expansion opportunity for APG777 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.

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. Currently, the asthma market is greater than \$10 billion in the seven major markets. We plan to advance the development of APG777 in asthma by initiating a Phase 1b trial in asthma in the first half of 2025, followed by a Phase 2b trial in asthma in the second half of 2025. We expect data from the Phase 1b trial in 2026.

### *Eosinophilic Esophagitis*

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. The only available biologic for the treatment of EoE is DUPIXENT, which was approved for this indication in 2022, and requires weekly dosing. DUPIXENT's approval in EoE further supports the scientific rationale for IL-13/IL-4R $\alpha$  targeting agents in treating EoE. We plan to initiate a Phase 2 trial in EoE in 2026.

### *Other Indications*

We expect to further evaluate opportunities to develop APG777 for other I&I indications, including AA, CRSwNP, CSU, and PN.

### **APG990**

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.

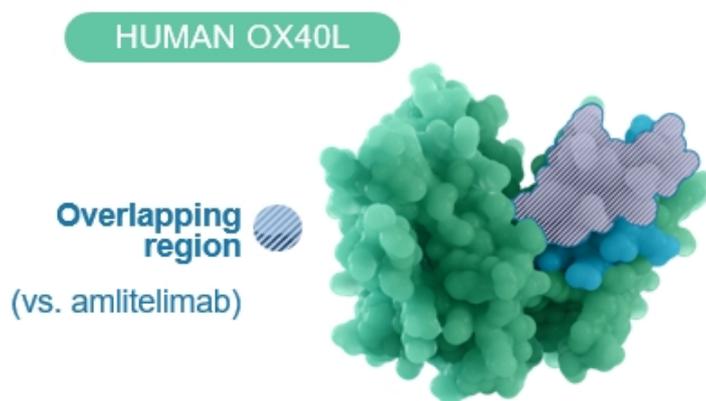
Currently, there are only two mechanisms of action targeted by approved biologic agents in atopic dermatitis, IL-13 and IL-4R $\alpha$ . Targeting OX40L could represent a third mechanism of action. OX40L, which is positioned further upstream in the inflammatory pathway than IL-13, allowing for a potentially broader impact on the inflammatory cascade by inhibiting Type 1, Type 2, and Type 3 pathways.

### **APG990 Development**

In May 2024, we finalized the nomination of a development candidate for APG990 and in August 2024, we commenced dosing of the first participants in the Phase 1 clinical trial in healthy volunteers. In our head-to-head preclinical assays, APG990 has demonstrated similar or improved potency to amlitelimab, an OX40L antibody candidate in late-stage clinical development.

Figure 13 below depicts a 3D rendering of human OX40L generated from our head-to-head preclinical studies. The blue highlights the epitope, or binding site, of amlitelimab, which overlaps with APG990's epitope, also highlighted with hatch marks.

**Figure 13 — Binding site of APG990 against amlitelimab**

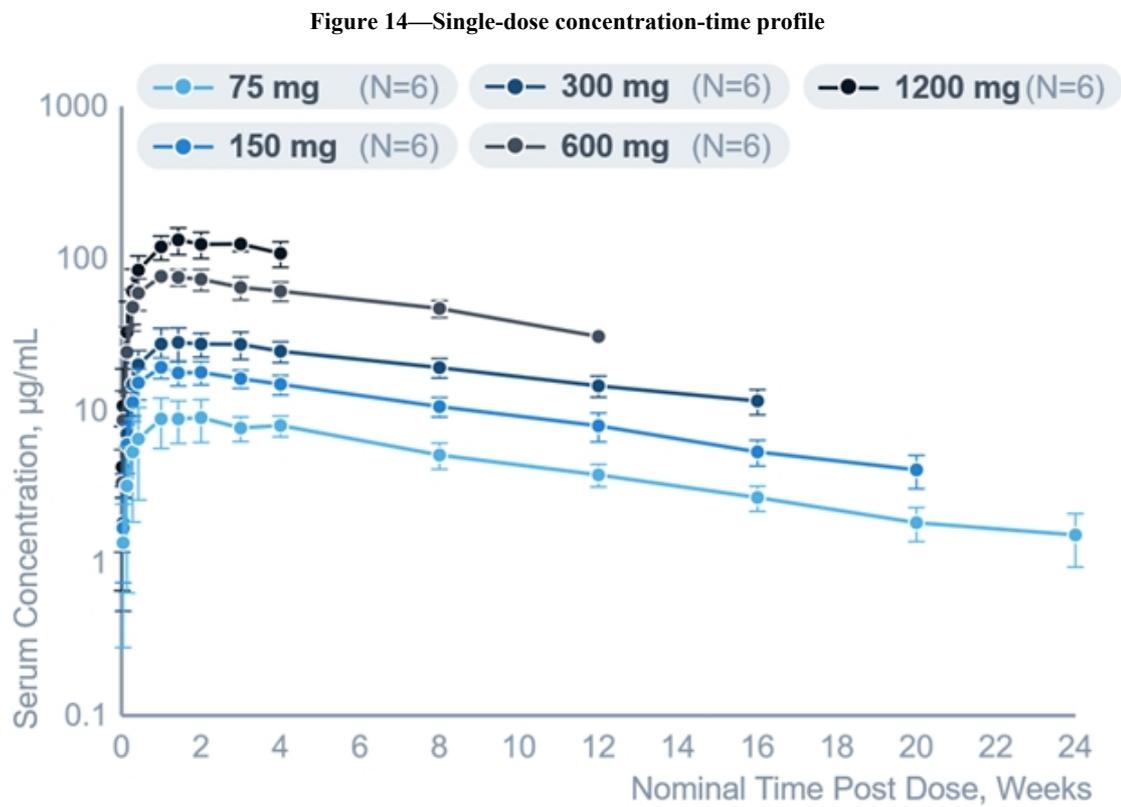


In our head-to-head studies of APG990 and amlitelimab in NHPs, APG990 demonstrated half-life of 26 days versus 21 days for amlitelimab. In addition, based on our preclinical studies, we believe APG990 can be dosed every three to six months in maintenance, which, if our clinical trials are successful, would represent a significant improvement compared to first generation OX40L antibodies that are expected to be dosed every four to twelve weeks.

Our APG990 Phase 1 clinical trial is 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 data from our APG990 Phase 1 clinical trial. APG990 interim Phase 1 pharmacokinetic (PK) data showed a half-life of approximately 60 days across doses tested, supporting the potential for testing every three- and six-month maintenance dosing with as little as 50 mg. APG990 generally demonstrated dose proportionality and low variability.

Figure 14 below depicts the single-dose concentration-time profile from the ongoing APG990 Phase 1 trial.



APG990 was well tolerated across all cohorts, with doses up to 1,200mg. The most common ( $\geq 10\%$ ) treatment-emergent adverse events (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 have been no cases of pyrexia or chills.

#### *Potential clinical benefit of targeting both IL-13 and OX40L*

Multiple studies have demonstrated that the upregulation of type 2 cytokines in the skin, particularly IL-13, is a key driver of inflammation in AD. However, other pathways that are activated in AD include Type 1 (e.g., interferon-gamma [IFN $\gamma$ ]) and Type 3 (e.g., IL-22, IL-17) responses. Therefore, due to the heterogeneity of inflammatory involvement in AD, we believe that blocking multiple targets, such as simultaneous inhibition of IL-13 and OX40L, could allow us to provide benefit to patients with AD and other I&I indications. More specifically, we believe that inhibition of IL-13 with APG777 could provide depth of inhibition for the core driver of inflammation in AD, namely Type 2 inhibition, while inhibition of OX40L with APG990 could provide breadth of inhibition across a broader range of inflammatory subtypes (Types 1-3) and cytokines, but with less depth, addressing AD heterogeneity. This dual mechanism could, therefore, improve the breadth or depth (or both) of clinical outcomes.

We have generated preclinical data to support our approach to targeting both IL-13 and OX40L. In our preclinical ex vivo human allogeneic lymphocyte reaction assay, we demonstrated that APG279 targets all inflammatory types, including near-complete Type 2 inhibition, with the potential for every 3-month (or less frequent) dosing.

We plan to develop APG279 as a potential first-in-class coformulation for the treatment of AD combining deep and sustained inhibition of Type 2 inflammation via APG777's inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990's inhibition of OX40L. APG279 has been shown to retain stability, injectability, and convenience of individual components. In preclinical studies it has demonstrated broad inhibition of Type 1, Type 2 and Type 3 inflammation, similar to what was seen with JAK inhibition, but with potential for better tolerability than JAK inhibitors. We believe these combined mechanisms offer the potential for improved clinical responses over monotherapy while our planned approach of coformulating two extended half-life mAbs holds the potential for best-in-class dosing.

Following our positive interim results from the APG990 Phase 1 clinical trial, we believe that APG990's PK profile supports the potential for a single 2 mL co-formulated injection of APG279 (APG777 + APG990) administered every three- and six- months in maintenance.

In addition, preclinical toxicology studies of the combination of APG777 and APG990 showed no findings at any dose level, including the highest dose tested of 150 mg/kg per agent.

Based on these results, we plan to submit an IND application or foreign equivalent for APG279. Following clearance, we plan to initiate a Phase 1b clinical trial designed to evaluate APG279 against DUPIXENT in approximately 50 to 75 patients with moderate-to-severe AD with a readout expected in the second half of 2026. APG279 will be co-administered in the proof-of-concept Phase 1b trial with coformulation planned for future clinical studies.

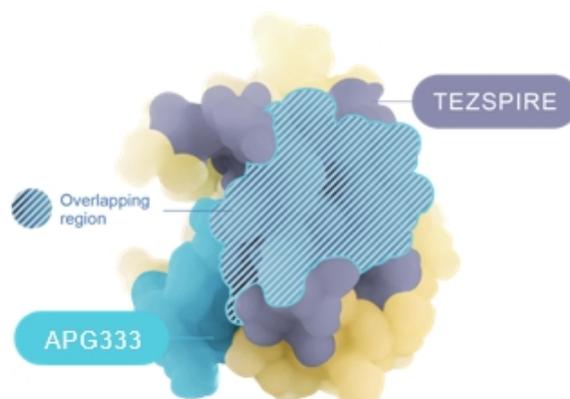
### **APG333**

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, with the potential for extended half-life and to be used in combination with other mAbs for potentially greater efficacy in broader populations.

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.

APG333 has similar binding as a first generation mAb, TEZSPIRE, for TSLP across our head-to-head preclinical assays. Figure 15 below depicts a 3D rendering of human TSLP generated from our head-to-head preclinical studies. The gray highlights the epitope, or binding site, of TEZSPIRE, which overlaps with APG333's epitope, also highlighted with blue hatch marks. Additionally, in our head-to-head studies of APG333 and TEZSPIRE in NHPs, APG333 showed a significantly longer half-life than TEZSPIRE. In these preclinical studies, APG333's half-life was 24 days, as compared to 11 days for TEZSPIRE. Based on these preclinical studies, we believe that the longer half-life could support dosing every three to six months in the clinic.

**Figure 15 — Binding site of APG333 against tezepelumab (TEZSPIRE)**



### **APG333 Development**

In October 2024, we finalized the nomination of a development candidate for APG333 and in December 2024 we initiated a Phase 1 clinical trial of APG333 in healthy volunteers. The APG333 Phase 1 clinical trial is designed as a double-blind, placebo controlled, first-in-human, SAD trial in healthy volunteers. The study will evaluate the safety, tolerability and pharmacokinetics of APG333 and is expected to enroll approximately 32 healthy adults into four cohorts. We expect interim data from the APG333 Phase 1 trial in the second half of 2025.

#### *Potential clinical benefit of targeting both IL-13 and TSLP*

In preclinical studies, the combination of APG777 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. In our preclinical studies, we showed that APG777 activates bronchial smooth muscle cells that promote local airway responses to inflammation while APG333 targeted inflammation centrally and more broadly, showing inhibition of both Type 2 and non-Type 2 cytokines. We believe targeting both central and local inflammation for respiratory diseases has the potential to improve clinical outcomes for patients.

We plan to evaluate APG777 and APG333 monotherapies in respective Phase 1b trials in patients with asthma in 2025 to support advancement into future combination trials in asthma and COPD. Subject to positive data, we plan to study APG777 in combination with APG333 to drive potential best-in-class efficacy in respiratory conditions.

### **APG808**

APG808 is an SQ extended half-life mAb targeting IL-4R $\alpha$ , a target with clinical validation across eight different Type 2 allergic diseases.

Based on our head-to-head preclinical studies of APG808, we have demonstrated the potential to increase the half-life of IL-4R $\alpha$ -targeting mAbs using half-life extension modifications. In our head-to-head studies of APG808 and DUPIXENT in NHPs, APG808 demonstrated half-life of 27 days versus 11 days for DUPIXENT. Moreover, in our head-to-head preclinical assay, APG808 demonstrated equivalent potency of IL-4R $\alpha$  inhibition compared to DUPIXENT in a head-to-head in vitro assay.

In March 2024, we initiated a Phase 1 clinical trial of APG808 in healthy volunteers and announced positive interim safety, PK and PD data from the Phase 1 trial in December 2024 demonstrating a potential best-in-class PK

profile, including a half-life of approximately 55 days, supporting the potential for every two- to three-month maintenance dosing.

*IL-4R $\alpha$  is a known driver of disease pathology in I&I indications*

APG808's target, IL-4R $\alpha$ , is a known driver of pathogenesis for a number of diseases. By blocking IL-4R $\alpha$ , we believe APG808 will prevent formation of the IL-13R $\alpha$ 1-IL-4R $\alpha$  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-13R $\alpha$ 1-IL-4R $\alpha$  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.

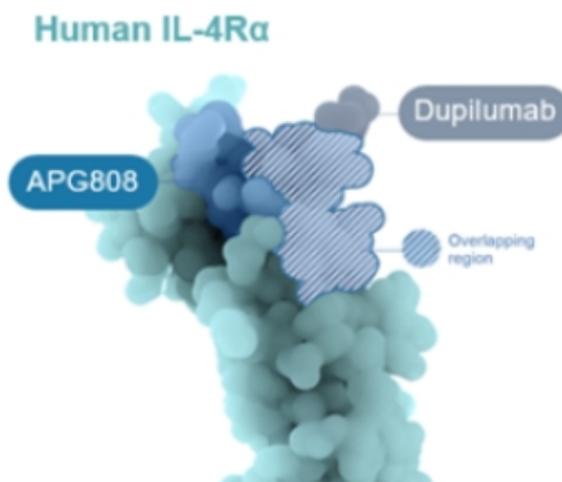
*APG808 has demonstrated equivalent potency to DUPIXENT in head-to-head in vitro assays*

APG808 was engineered to demonstrate similar preclinical activity to available therapies in our head-to-head studies. Specifically, an assay was performed to measure downstream functional inhibition of the IL-13/IL-4 pathway, meaning after IL-13R $\alpha$ 1 and IL-4R $\alpha$  heterodimerization. Measuring downstream functional inhibition of the pathway is critical, as this measures the mAb's impact on the inflammatory cascade that causes the features, signs, and symptoms associated with I&I indications.

In our head-to-head preclinical study, DUPIXENT and APG808 showed similar binding, with femtomolar affinity for IL-4R $\alpha$ , and similar inhibition across the three in vitro assays which measure downstream functional inhibition of the IL-13/IL-4 pathway (pSTAT6 induction, inhibition of TF-1 proliferation, and inhibition of TARC secretion).

Figure 16 below depicts a 3D rendering of human IL-4R $\alpha$  generated from our head-to-head preclinical studies. The gray highlights the epitope, or binding site, of dupilumab (DUPIXENT), which overlaps with APG808's epitope, also highlighted with hatch marks.

**Figure 16 — APG808's epitope on IL-4R $\alpha$  overlaps with dupilumab and leverages proven mechanism of action and biology**



## **APG808 Dosing**

In our head-to-head preclinical studies of APG808 and DUPIXENT in NHPs, APG808 showed a significantly longer half-life than DUPIXENT. In these preclinical studies, APG808's half-life was up to 27 days, as compared to 11 days for DUPIXENT.

## **APG808 Development**

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. The APG808 Phase 1 trial was designed as a double-blind, placebo-controlled study in healthy volunteers with single ascending doses. The APG808 Phase 1 trial enrolled 32 healthy adult participants into four SAD cohorts. In December 2024, we shared 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, 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. We are also now evaluating APG808 in a Phase 1b trial in patients with asthma, with data expected in the first half of 2025.

### *Expansion opportunities for APG808*

IL-4R $\alpha$  biology has been implicated in a number of different indications, including AD, asthma, COPD, CRSwNP, EoE, PN and CSU. We intend to evaluate additional expansion opportunities in one or more of such indications.

### *Asthma*

We believe that APG808 could potentially benefit patients with eosinophilic asthma. DUPIXENT, which also targets IL-4R $\alpha$  but is dosed every other week, is approved in asthma in patients six years of age or older with moderate-to-severe-asthma with eosinophilic phenotype or oral corticosteroids dependent regardless of phenotype and has shown a 46% reduction in the rate of annualized exacerbations in pivotal studies, which we believe validates targeting IL-4R $\alpha$  as an approach to treating asthma.

## **Additional Expansion Opportunities**

We believe that each of our programs has the potential to impact multiple additional I&I indications beyond AD and COPD, including asthma and EoE as well as AA, CRSwNP, CSU, and PN. 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. Based on third-party claims data, 31% of AD patients also carry an asthma diagnosis. Based on feedback from dermatologists, we believe that there is significant value in having both indications on a label because of this overlap. 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. We do not yet have clinical data showing the ability of our programs to treat other indications and there can be no assurance that our programs will have similar or comparable results to any products or later-stage product candidates for these indications.

### *Alopecia Areata*

Patients with AA represent a population with high unmet need, given there are no approved targeted biologic therapies. Recent third-party Phase 2a data for DUPIXENT demonstrated clinical benefit in patients with AA, which we believe provides support for the IL-4/IL-13 pathway blockade as a potential treatment for AA.

### *Chronic Rhinosinusitis with Nasal Polyps*

CRSwNP is commonly comorbid with asthma and the two diseases have overlapping biology. IL-4 and IL-13 have been shown to play important roles in the pathophysiology of CRSwNP. Further, DUPIXENT is approved for this indication, which we believe demonstrates the potential for IL-13 and/or IL-4R $\alpha$  targeting.

### *Chronic Spontaneous Urticaria*

CSU is a disease where mast cells are believed to be the key effector cells, although data has also demonstrated that IL-4 and IL-13 may be key in the development and maintenance of CSU. Further, we believe the positive Phase 3 data for DUPIXENT in patients with CSU that is not adequately controlled with the current standard of care suggests the role of the IL-4/IL-13 heterodimer signaling complex's involvement in CSU.

### *Prurigo Nodularis*

PN is a chronic inflammatory condition of the skin where lesions have shown Th2-associated cytokines such as IL-4, IL-13 and IL-31. DUPIXENT is approved for this indication, which we believe demonstrates the potential for IL-13 and/or IL-4R $\alpha$  targeting.

### *Additional I&I Indications*

We may expand into additional I&I indications, such as Crohn disease, lupus, rheumatoid arthritis, psoriasis and ulcerative colitis, that are implicated in the disease pathways targeted by our current or future programs.

## **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-4R $\alpha$ , 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-4R $\alpha$ . 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 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 outlines the services that will 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-4R $\alpha$  Research Program and the OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the “IL-4R $\alpha$  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-4R $\alpha$  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-4R $\alpha$  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 participants in the Phase 1 trial of 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-4R $\alpha$  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 participants 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 participants 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.

***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 our APG777, APG990, APG333 and APG808 programs, as well as potential future programs, 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 a component of the APG777, APG990, APG333 and APG808 programs.

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.

#### **Competition**

The biotechnology and biopharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our programs, 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 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, 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 programs. We do not yet have clinical data for any of our programs and there can be no assurance that our programs 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-4R $\alpha$  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-31R $\alpha$  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.

Change in EASI score at 16 weeks is a common endpoint in AD. For example, the percentage of patients achieving EASI 75 on a placebo-adjusted basis in Phase 2 and average of Phase 3 monotherapy trials in AD were 59% and 62%, respectively, for upadacitinib at 30mg dosed daily, 42% and 51%, respectively, for upadacitinib at 15mg dosed daily, 36% and 38%, respectively, for lebrikizumab at 250mg dosed every two weeks, 40% and 34%, respectively, for DUPIXENT at 300mg dosed every two weeks, 49% and 51%, respectively, for abrocitinib at 200mg dosed daily, and 25% and 21%, respectively, for abrocitinib at 100mg dosed daily.

With respect to biologics with global Phase 3 data in AD, DUPIXENT, EBGLYSS, ADBRY, and NEMLUVIO have all demonstrated statistically significant results.

In two Phase 3 trials of DUPIXENT dosed every two weeks in patients with AD, at 16 weeks, DUPIXENT showed 38.0% and 36.1% of treated patients achieved IGA 0/1 compared to 10.3% and 8.5% on placebo, respectively. Further, 51.3% and 44.2% of patients treated with DUPIXENT achieved EASI-75, compared to 14.7% and 11.9% on placebo, respectively. All differences were statistically significant. Of the 16-week responders who received DUPIXENT every two weeks during the induction period, 44% of patients dosed every four weeks and 54% of patients dosed every two weeks in the maintenance period achieved IGA 0/1 and 58% of patients dosed every four weeks and 72% of patients dosed every two weeks in the maintenance period achieved EASI-75 at 52 weeks.

In two Phase 3 trials of EBGLYSS dosed every two weeks in patients with AD, at 16 weeks, EBGLYSS showed 43.1% and 33.2% of treated patients achieved IGA 0/1 compared to 12.7% and 10.8% on placebo, respectively. Further, 58.8% and 52.1% of patients treated with EBGLYSS achieved EASI-75, compared to 16.2% and 18.1% of patients on placebo, respectively. All differences were statistically significant. Of the 16-week responders who received EBGLYSS every two weeks during the induction period, 78% of patients dosed every four weeks and 71% of patients dosed every two weeks in the maintenance period achieved IGA 0/1 and 82% of patients dosed every four weeks and 78% of patients dosed every two weeks in the maintenance period achieved EASI-75 at 52 weeks.

In two Phase 3 trials of ADBRY dosed every two weeks in patients with AD, at 16 weeks, ADBRY showed 15.8% and 22.2% of treated patients achieved IGA 0/1 compared to 7.1% and 10.9% on placebo, respectively. Further, 25.0% and 33.2% of patients treated with ADBRY achieved EASI-75, compared to 12.7% and 11.4% of patients on placebo, respectively. All differences were statistically significant.

In two Phase 3 trials with topical corticosteroids and topical calcineurin inhibitors, NEMLUVIO dosed every four weeks in patients with AD, showed 35.6% and 37.7% IGA 0/1 compared to 24.6% and 26.0% in the placebo group. For EASI-75, 43.5% and 42.1% of treated patients achieved the endpoint compared to 29.0% and 30.2% in the placebo group. All differences were statistically significant.

We do not yet have clinical data in patients with AD for our programs and there can be no assurance that our programs will have similar or comparable results.

We are also aware of several product candidates in clinical development for AD. Amlitelimab is an OX40L mAb, which is currently being evaluated in a Phase 3 trial by Sanofi and has demonstrated EASI-75 of 61.5% compared to 29.4% in the placebo group at week 16 when dosed every four weeks at 250mg with a 500mg loading dose (LD) in a Phase 2b trial.

22.1% of patients treated with amlitelimab 250mg with LD achieved IGA0/1 at Week 16 compared to 5.1% of placebo patients. Rocatinlimab is an OX40 mAb, which is currently being evaluated in a Phase 3 trial by Amgen and Kyowa Kirin Co., Ltd. and has demonstrated EASI-75 of 54% compared to 11% for placebo in a Phase 2 trial. The first Phase 3 trial showed EASI-75 of 32.8% compared to 13.7% placebo at week 24. For IGA 0/1, 19.3% of treated patients achieved the endpoint versus 6.6% in the placebo group. Other agents include rezpegaldesleukin, a rIL-2 in Phase 2 trials by NEKTAR, temptokibart, an IL-22R in Phase 2 trials by LEO Pharma, GSK1070806, an IL-18 in Phase 2 trials by GSK, and KT-621, an oral STAT6 degrader in Phase 1 trials, by Kymera.

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 COPD, including DUPIXENT and OHTUVAYRE (ensifentrine), a PDE3/PDE4 inhibitor marketed as OHTUVAYRE by Verona Pharma. We are aware of several other biologics in development, including mepolizumab, an IL-5 mAb from GSK which met its primary endpoint in a Phase 3 trial, itepekimab, an IL-33 mAb from Sanofi/Regeneron, which is currently being evaluated in a Phase 3 trial; tozorakimab, an IL-33 mAb from AstraZeneca, which is currently being evaluated in Phase 3 trials; benralizumab, an IL-5R mAb, from AstraZeneca, which is currently being evaluated in a Phase 3 trial; tezepelumab, a TSLP mAb from AstraZeneca/Amgen, which is expected to begin a Phase 3 trial; astegolimab, an ST2 mAb from Roche, which is currently being evaluated in Phase 2/3 trials; and depemokimab, an IL-5 mAb from GSK, which is expected to begin Phase 3 trials.

## **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 programs rather than diverting resources to internally develop and maintain manufacturing facilities. As our programs 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 expect to use industry standard sterile liquid drug product manufacturing processes and to develop formulations and presentations that enable SQ delivery of all of our planned clinical development candidates. APG777 drug substance and drug product have been successfully manufactured at clinical scale with acceptable yields for near-term, planned clinical trials. Our formulation for APG777 is suitable for SQ injection. By the time of commercialization, we expect APG777 to be administered via a pre-filled syringe and/or autoinjector. We use a similar approach to development and supply for our APG990, APG333 and APG808 programs. APG990, APG333 and APG808 drug substance and drug product have been successfully manufactured at clinical scale with acceptable yields for use in our initial 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 APG777, we believe the manufacturing processes for mAbs such as APG777 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. However, 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. 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 programs. While any reduction or halt in the supply of raw materials, drug substance or drug product could limit our ability to develop our programs 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 APG777, APG990, APG333 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 recently introduced BIOSECURE Act, which would prohibit 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 or one of our other manufacturers or other supply chain vendors is impacted. Although the BIOSECURE Act did not become law in 2024, it may be proposed again in 2025 and we have secured second source drug product manufacturing in the U.S. and have entered into an agreement with Samsung Biologics for drug substance supply. We intend to continue 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 mitigations 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 programs 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 programs, their methods of use, related technologies, diagnostics, and other inventions.

#### ***Patent Rights Relating to Our IL-13 Program***

As of January 31, 2025, we own eight patent families directed to antibodies that target IL-13, including 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. If issued, 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 APG777 and includes an international (PCT) patent application and applications 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 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 APG777 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 2044, absent any applicable patent term extensions. The fourth patent family is directed to other APG777 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 remaining four patent families are directed to other APG777 compositions and methods of using APG777 and each family, as of January 31, 2025, includes between one and 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 2045 and 2046, absent any applicable patent term extensions.

#### ***Patent Rights Relating to Our IL-4Ra Program***

As of January 31, 2025, 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 a PCT application and patent applications 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 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 remaining two patent families are directed to APG808 compositions and methods of using APG808 and as of January 31, 2025, each family includes one provisional patent application. If these provisional applications are pursued non-provisionally and mature 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 OX40L Program***

As of January 31, 2025, 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 includes a PCT application and applications in Argentina and Taiwan. If the PCT application is pursued in the U.S. or any foreign jurisdictions and matures into an issued patent or the Argentina or Taiwan applications are pursued and mature into issued patents, we would expect those patents to expire in 2044, absent any applicable patent term extensions. The second, third and fourth patent families are directed to pharmaceutical formulations and compositions including APG990 and methods of using APG990 and as of January 31, 2025, each family includes one or 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 2045, absent any applicable patent term extensions.

***Patent Rights Relating to Our TSLP Program***

As of January 31, 2025, we have licensed one patent family from Paragon directed to antibodies that target TSLP, including APG333, and methods of using those antibodies. As of January 31, 2025, this family 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 2045, absent any applicable patent term extensions. We also own two patent families directed to compositions of TSLP antibodies, including APG333, and methods of using APG333. As of January 31, 2025, each of these families includes one provisional application. If these provisional applications are pursued non-provisionally and mature 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 Combination Programs***

As of January 31, 2025, we own six patent families directed to combinations of APG777, APG990, APG333 and/or APG808 and pharmaceutical formulations and compositions thereof. As of January 31, 2025, each of these families includes between one and 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 2045, absent any applicable patent term extensions. We have also licensed three patent families from Paragon directed to combinations of APG777, APG990, APG333 and/or APG808 and methods of using those combinations. As of January 31, 2025, each of these families includes between one and 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 2045, 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, 2024, we had 196 full-time employees, 47 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 144 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. 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.

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 I 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.

### ***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 ACA includes a subtitle called the 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. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. On December 20, 2020, Congress amended the PHS Act 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 (IRA) is a significant new 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 activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an 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. Instead, 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.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, 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 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 (“HITECH”), and their respective implementing regulations imposes 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 the HITECH Act on covered entities and business associates include entering into agreements that require business associates 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 and Washington’s My Health My Data Act, 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 — unless it is subject to HIPAA — and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, also exempt some data processed in the context of clinical trials; but 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 and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence 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 products 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 rebates from list prices. 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 legislative 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 response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators 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 its drugs or put pressure on its 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 collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (“GDPR”), which came into force in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes 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 the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to 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 European Economic Area (“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 SCCs, data exporters 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 SCCs 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 EU to the United Kingdom (“UK”), personal data may freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions

include a ‘sunset clause’ which entails that the decisions will automatically expire four years after their entry into force, unless renewed.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties 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 EU Member States 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 EU.

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), 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.

Additionally, following the UK’s withdrawal from the EU and the EEA, companies also have to comply with the UK’s data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (“DPA 2018”)), the DPA 2018, and related data protection laws in the UK). Separate from the fines that can be imposed by the GDPR, the UK regime has the ability to fine up to the greater of £17.5 million or 4% of global turnover.

Companies are subject to specific transfer rules under the UK regime which broadly mirror the 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 (“Addendum”) and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime.

Regarding transfer from the UK to the EEA, personal data may flow freely since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. 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 United States, 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 transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension.

#### *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 new 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.

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. By January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS. On July 19, 2023, the EC published guidance concerning the steps to be taken in this transition. This guidance provides, among other things, that (i) documentation which was previously assessed will not be reassessed, (ii) templates that were developed and endorsed by the EU Clinical Trials Expert Group to provide compliance with the CTR do not need to be updated and (iii) there is no need to retrospectively create a site suitability form, which are only necessary for new trial sites.

Under both the former regime and the new CTR, national laws, regulations, and the applicable GCP and Good Laboratory Practice 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.

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 obtained by a centralized application through EMA or a national application. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the Medicines and Healthcare products Regulatory Agency (“MHRA”) Submissions Portal. The process from application to authorizations generally takes up to 210 days, excluding time taken to provide any additional information or data required by the MHRA.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Reliance Procedure (“IRP”) for MAAs. The IRP applies 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 European Medicines Agency (“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 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 Committee for Medicinal Products for Human Use (“CHMP”) established at the EMA, 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*

MAAs 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. Conversion refers to the procedure by which, as of January 1, 2021, MAs granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland but not in Great Britain, whereas, prior EU authorizations have all been automatically converted into UK MAs effective in Great Britain only.

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. The current draft envisages e.g., a shortening of the periods of data exclusivity, however, there is currently neither a final version of this draft nor a date for its entry into force. While the European Parliament adopted its approving position on the reform on April 10, 2024, no further required legislative steps have been taken since.

### *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, but a UK-wide orphan MA can only be considered in the absence of an active 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.

#### *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 Paediatric Investigation Plans (“PIPs”) which, where possible, mirror the submission format and requirements of the EU system. EU PIPs remain applicable for Northern Ireland and EU PIPs agreed by the EMA prior to January 1, 2021 have been adopted as UK PIPs.

#### *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 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.

#### *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 HMRs. 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](http://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](http://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, APG777, APG990, APG333 and APG808, including in combination, 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 will need to transition at some point 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, APG777, APG990, APG333 and APG808 and advance our other programs, including combination programs, and any future programs and product candidates. Even if one or more of the programs 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 scope, progress, results and costs of discovery, preclinical and clinical development for our programs;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims, including claims of infringement, misappropriation or other violation of third-party intellectual property;
- the costs, timing and outcome of regulatory review of our programs;
- the costs of future commercialization activities, either by ourselves or in collaboration with others, including product sales, marketing, manufacturing, and distribution for any program for which we receive marketing approval;
- the revenue, if any, received from commercial sales of programs for which we receive marketing approval;
- the success of our current or future collaborations;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license products, intellectual property and technologies;
- the costs of operational, financial and management information systems and associated personnel; and
- the costs of operating as a public company.

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 first quarter 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 upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to our programs, or grant licenses on terms that are not 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 public health crises, the conflict between Russia and Ukraine or the conflicts in the Middle East. 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 have to delay, reduce the scope of, suspend or eliminate one or more of our programs, clinical trials 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.***

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 programs. 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 \$182.1 million and \$84.0 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of \$305.9 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 programs 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 programs, we expect to incur substantial additional research and development and other expenditures to develop and market additional programs 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 programs.***

The development and commercialization of drugs is highly competitive. Our programs, 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. 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 will 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 our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance. See the section titled “Business—Competition” 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 programs that are under development for the same indications as our programs. 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 programs, 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 program, if ever. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our programs, either alone or with

third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our programs. 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 programs, 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 programs or any future programs, 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 protocol 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, 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;
- our inability to manufacture sufficient quantities of our programs for use in clinical trials, or delays in manufacturing or distribution;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our programs;
- our failure 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 such as additional toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND, biologics license application (“BLA”) or similar application and finalizing the trial design based on discussions with the FDA and other regulatory authorities. 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 countries in the 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 programs. We or our current or future collaborators' inability to complete development of, or commercialize our programs, 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 programs, APG777, APG990, APG333 and APG808, including in combination, 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 programs, APG777, APG990, APG333 and APG808, including potential combinations of certain of our programs. We are investing a majority of our efforts and financial resources into the research and development of these programs. We commenced dosing in the Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD in May 2024, commenced dosing of the first participants in the Phase 1 clinical trial of APG990 in August 2024, and initiated a Phase 1 clinical trial of APG333 in healthy volunteers in December 2024. In March 2024, we commenced dosing of the first healthy volunteers in the APG808 Phase 1 trial of APG808 in Australia and, in September 2024, we commenced dosing of the first asthma patients as a cohort in that Phase 1 trial. The success of our programs is dependent on observing a longer half-life of our programs 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 programs, 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 NHPs will translate into an extended half-life of our programs in humans. To the extent we do not observe this extended half-life when we dose humans with our programs 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 programs.

Our programs 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 programs, or any other programs, 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 programs 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 programs, even if approved. If we are not successful in commercializing APG777, APG990, APG333 or APG808, including potential combinations of certain of our programs, 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 programs 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 or completion of scientific studies and clinical trials, such as the expected timing for the topline data from our Phase 2 clinical trial of APG777 in AD; initial proof-of-concept data of APG777 in asthma; additional expected data from our Phase 1 clinical trial of APG808; and Phase 1 clinical trials of APG990 and APG333, 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. If we do not meet these milestones as publicly announced, or at all, the commercialization of our programs may be delayed or never 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 programs 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 programs. 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 programs 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 program, 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their programs performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their programs. 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 APG777 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 APG777 or any of our other programs, our development timelines may be

delayed. We cannot be sure that submission of an IND, 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; 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 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 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. 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 programs 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 programs.***

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 have previously 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. Treatment-emergent adverse events 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. 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 programs. 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, APG777, 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 programs. 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 can be sold at a competitive cost and whether it 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 and ADBRY; 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 healthcare providers, 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 APG777 and APG279 for the same indication: atopic dermatitis, and may in the future develop our programs for other I&I indications. Each such program targets a different mechanism of action. Based on the differing mechanisms of action, we are developing APG777 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 either frontline patients or patients who have failed or have inadequate responses to other treatment options. However, developing multiple programs for a single indication may negatively impact our business 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 market share, which could 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 our Phase 1 clinical trials for APG990, APG333 and APG808 in Australia, and our Phase 2 clinical trial for APG777 includes 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 Paragon beneficially owns more than 5% of our capital stock and Fairmount, 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 programs. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our programs and products 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 programs 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 programs.***

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 control only 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 programs. 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 programs.

In addition, we currently rely on foreign CROs and CMOs, including WuXi Biologics, and will likely continue to rely on foreign CROs and CMOs in the future. Foreign CMOs may be subject to U.S. legislation, including the act proposed in 2024 as 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.

For example, 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 manufacturing suites in third-party facilities or on third parties to manufacture our programs, 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.***

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 and manufacturing our programs and product candidates. We have not yet caused our programs or product candidates to be manufactured on a commercial scale and may not be able to do so for any of our programs or product candidates, if approved. We currently have a sole source relationship for our preclinical and clinical supply of APG777, APG990, APG333 and APG808 drug substance, are working to establish a relationship for clinical and commercial scale supply of APG777 and have a sole source relationship for our clinical supply of APG990, APG333, and APG808 drug product. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole suppliers, it could have a negative effect on the clinical development of our programs 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 programs. 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 programs 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 programs, 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 programs or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our programs or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our programs 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 or refusal to permit the import or export of products. 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 programs by the FDA, resulting in higher costs or adversely impacting commercialization of our programs. See the section titled “Business-Manufacturing and Supply” for a more detailed description of our manufacturing and supply plans and assumptions and the factors that may affect the success of our programs.

### **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 sales and marketing. 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 programs in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our programs before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any of our programs. 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 programs, 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 programs will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our programs and ultimately commercialize our programs 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, 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 programs 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” for a more detailed description of the laws that may affect our ability to operate.

***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 dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and 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. The U.S. Congress could restore the current deductibility of research and development expenditures; however, we have no assurance that the provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business 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 do not currently own or in-license any issued patents. Our pending and future patent applications may not result in 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 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 are ultimately granted regulatory approval, 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 products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue 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 programs, we will not be able to commercialize, or will be delayed in commercializing, our programs, 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 programs in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize programs outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our programs, including our most advanced programs, APG777, APG990, APG333 and APG808, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our programs 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 programs 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 programs 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 program 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 programs; we may be unable to demonstrate that a program'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 programs 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 programs; 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.

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 programs, which would significantly harm our business, results of operations and prospects.

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

***Disruptions at the FDA and other government agencies could negatively affect the review 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 disruptions caused by government shutdowns and public health crises, or layoffs of federal workers by the federal government. 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.

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

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 Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, 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 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 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 programs, 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 programs.***

Any regulatory approvals that we may receive for our programs will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the program, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our programs, 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 programs, our programs 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 programs 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 programs. 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” for a more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize our programs.

***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 programs, if approved. See the section titled “Business—Government Regulation— Other Healthcare Laws and Compliance Requirements” 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 programs, 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 programs in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our programs, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any programs that we may develop will depend in part on the extent to which reimbursement for these programs 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 and health maintenance organizations, 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 programs are approved and we are found to have improperly promoted off-label uses of those programs, 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" for a more detailed description of the government regulations and third-party payor practices that may affect our ability to commercialize our programs.

***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 programs 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 program 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. See the section titled “Business—Government Regulation—Expedited Development and Review Programs” 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 may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock has fluctuated, 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 may negatively affect the market price of our common stock, regardless of our actual operating performance. 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. In the past, securities class action litigation has often been instituted 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 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 “Description of Capital Stock—Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law” in the final prospectus for our March 2024 Offering filed with the SEC pursuant to Rule 424(b) on March 11, 2024 (the “March 2024 Prospectus”).

***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 but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the 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 "Description of Capital Stock—Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law—Exclusive Forum Selection Clause" in the March 2024 Prospectus.

***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 programs 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, healthcare providers, 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 programs, 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, causing 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 programs, 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. For example, the COVID 19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve raised interest rates multiple times in response to concerns about inflation and, although it recently 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 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 twenty 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 2025. 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 24, 2025, 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.

##### 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 were 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, including a potential Phase 2 trial, and manufacturing of our 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 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 four antibody programs being developed initially for the treatment of I&I indications as monotherapies and combinations. Our most advanced programs are APG777, APG990, APG333, and APG808. 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. Our programs incorporate advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. We believe each of our programs has potential for broad application across multiple I&I indications, including in combination.

#### ***APG777 – anti-IL13 antibody, same mechanism of action as EBGLYSS (lebrikizumab)***

APG777 is a subcutaneous (“SQ”) extended half-life monoclonal antibody (“mAb”) targeting IL-13. In August 2023, we announced the dosing of our first participant in our first clinical trial for APG777. In 2024, we announced positive interim safety and PK data from this trial with APG777 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 APG777 demonstrated a deep and sustained effect on PD markers out to approximately 12 months. APG777 was well-tolerated across all dose groups. In May 2024, we commenced dosing in the Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD. In February 2025, we announced that the last patient in the Part A portion of the trial had been dosed with 16-week topline data from Part A expected in mid-2025. In February 2025, we also announced that we had commenced dosing of Part B of the Phase 2 trial. All patients benefiting from treatment will have the opportunity to continue to APG777 maintenance treatment, which will evaluate three- to six-month dosing intervals. We anticipate maintenance data from Part A in the first half of 2026 and 16-week topline data from Part B in the second half of 2026.

Based on our initial clinical data, we plan to advance the development of APG777 in asthma and EoE by initiating a Phase 1b trial in asthma in the first half of 2025, followed by a Phase 2b trial in asthma in the second half of 2025, and a Phase 2 trial in EoE in 2026. Based on our clinical data, we expect to further evaluate additional

opportunities to develop APG777 for other I&I indications, including alopecia areata (“AA”), chronic rhinosinusitis with nasal polyps (“CRSwNP”), chronic spontaneous urticaria (“CSU”), and prurigo nodularis (“PN”).

In addition, we plan to evaluate APG777 in combination with other investigational therapies within our pipeline to potentially enable greater efficacy for I&I conditions. We plan to initiate our first combination study, a Phase 1b trial of APG777 and APG990, a novel, SQ, half-life extended mAb targeting OX40L, in 2025. This combination study is designed to evaluate the coformulation of APG777 and APG990 (“APG279”) against DUPIXENT in patients with moderate-to-severe AD, with readout expected in the second half of 2026.

***APG990 – anti-OX40L antibody, same mechanism of action as amltelimab; potential combination therapy with APG777***

APG990 is an SQ extended half-life mAb that utilizes advanced antibody engineering to target OX40L.

We plan to develop APG777 and APG990 together as a potential first-in-class coformulation for the treatment of AD by combining deep and sustained inhibition of Type 2 inflammation via APG777’s inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990’s inhibition of OX40L. APG279 has been shown to retain stability, injectability, and convenience of individual components in preclinical studies. In preclinical studies, APG279 has also demonstrated broad inhibition of Type 1, Type 2 and Type 3 inflammation, similar to what was seen with Janus kinase (“JAK”) inhibition, but with potential for better tolerability than JAK inhibitors. We believe these combined mechanisms offer the potential for improved clinical responses over monotherapy while our planned approach of coformulating two extended half-life mAbs holds the potential for best-in-class dosing.

In August 2024, we initiated a Phase 1 clinical trial of APG990 in healthy volunteers to establish safety, tolerability and PK profile, which could enable the combination with APG777.

In March 2025, we announced positive interim safety and PK data from the APG990 Phase 1 clinical 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. In addition, preclinical toxicology studies of the combination of APG777 and APG990 showed no findings at any dose level, including the highest dose tested of 150 mg/kg per agent. Based on these results, we plan to submit an Investigational New Drug application or foreign equivalent for APG279. Following clearance, we plan to initiate in 2025 a Phase 1b trial of APG279 against DUPIXENT in approximately 50 to 75 patients with moderate-to-severe AD with a data readout expected in the second half of 2026.

***APG333 – anti-TSLP antibody, same mechanism of action as TEZPIRE (tezepelumab); potential combination therapy with APG777***

APG333 is a fully-human mAb against thymic stromal lymphopoietin (“TSLP”), an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of people living with asthma and COPD. In preclinical studies, the combination of APG777 and APG333 has been shown to impact both central inflammation and local airway responses. This has the potential to improve clinical outcomes compared to approved or in-development biologics which only target peripheral or central inflammation, not both, and retains the potential for a significantly less frequent dosing schedule. In December 2024, we initiated a Phase 1 trial of APG333 in healthy volunteers and we expect interim data from the trial in the second half of 2025.

We plan to evaluate APG777 and APG333 monotherapies in respective Phase 1b trials in patients with asthma in 2025 to support advancement into future combination trials in asthma and COPD. Subject to positive data, we plan to study APG777 in combination with APG333 to drive potential best-in-class efficacy in respiratory conditions.

***APG808 – anti-IL4Ra antibody, same mechanism of action as DUPIXENT***

APG808 is an SQ extended half-life mAb targeting IL-4R $\alpha$ , 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. We are also now evaluating APG808 in a Phase 1b trial in patients with asthma, with data expected in the first half of 2025.

### ***Funding and Capital Resources***

Since our inception in February 2022, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business and scientific planning, conducting discovery and research activities, acquiring product programs, establishing and protecting our intellectual property portfolio, developing and progressing our pipeline, establishing arrangements with third parties for the manufacture of our programs and component materials, and providing general and administrative support for these operations. We do not have any programs approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from the issuance of preferred units and sale of common stock. Prior to our IPO, we received gross proceeds of \$169.0 million from sales of our preferred units. On July 13, 2023, our Registration Statement on Form S-1, as amended (File Nos. 333-272831 and 333-273236) (the “IPO Registration Statement”), relating to our IPO was declared effective by the SEC. Pursuant to the IPO Registration Statement, we issued and sold an aggregate of 20,297,500 shares of common stock (inclusive of 2,647,500 shares pursuant to the exercise in full of the underwriters’ option to purchase additional shares) at a public offering price of \$17.00 per share, for aggregate net proceeds of \$315.4 million after deducting underwriting discounts and commissions and other offering expenses.

On March 7, 2024, our Registration Statement on Form S-1, as amended (File Nos. 333-277664 and 333-277763) (the “2024 Registration Statement”), relating to our public offering (the “March 2024 Offering”) was declared effective by the SEC. Pursuant to the 2024 Registration Statement 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 aggregate net proceeds of \$450.0 million after deducting underwriting discounts and commissions and other offering expenses.

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 \$182.1 million for the year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of \$305.9 million. We expect to continue to incur significantly increased expenses for the foreseeable future if and as we:

- advance our programs, APG777, APG990, APG333 and APG808, into and through clinical trials and regulatory approval prior to commercialization;
- continue our research and development and preclinical development of our other programs;
- seek and identify additional research programs and product candidates and initiate preclinical studies for those programs;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- hire additional research and development and clinical personnel;
- experience any delays, challenges, or other issues associated with the clinical development of our programs, including with respect to our regulatory strategies;
- seek marketing approvals for any programs for which we successfully complete clinical trials;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for our programs;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any programs for which we may obtain marketing approval;

- add operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-license product candidates or programs, intellectual property and technologies;
- establish and maintain our current and any future collaborations, including making royalty, milestone or other payments thereunder; and
- operate as a public company.

We will not generate revenue from product sales unless and until we successfully initiate and complete clinical development and obtain regulatory approval for any product candidates. If we obtain regulatory approval for any of our programs and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, and distribution. Further, we expect to incur additional costs associated with operating as a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs.

As a result, we will need substantial additional funding to support our continued operations and growth strategy. Until such a time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We expect that our existing cash and cash equivalents of \$141.8 million, marketable securities of \$378.9 million and long-term marketable securities of \$210.4 million as of December 31, 2024, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. See “Liquidity and Capital Resources” for further information.

### **Reorganization**

Apogee Therapeutics, LLC was formed as a limited liability company under the laws of the State of Delaware in February 2022. Apogee Therapeutics, Inc. was incorporated in June 2023 in connection with our IPO to serve as a holding company that would wholly own the assets of Apogee Therapeutics, LLC. Prior to July 13, 2023, our business was conducted by Apogee Therapeutics, LLC and its subsidiary at the time, Apogee Biologics, Inc. In July 2023, in connection with our IPO, we completed a series of transactions which are referred to, collectively, as the “Reorganization,” and pursuant to which Apogee Therapeutics, Inc., became the parent and holding company that wholly owns the assets of Apogee Therapeutics, LLC, including stock of its subsidiary at the time, Apogee Biologics, Inc. In connection with our Reorganization:

- 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.

Effective December 31, 2024, Apogee Biologics, Inc. merged with and into Apogee Therapeutics, Inc. with Apogee Therapeutics, Inc. surviving the merger.

## **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-4R $\alpha$ , 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-4R $\alpha$ . 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 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 outlines the services that will 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-4R $\alpha$  Research Program and the OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the "IL-4R $\alpha$  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-4R $\alpha$  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-4R $\alpha$  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 participants in the Phase 1 trial of

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-4R $\alpha$  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 participants 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 participants 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.

#### ***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 our APG777, APG990, APG333 and APG808 programs, as well as potential future programs, 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 a component of the APG777, APG990, APG333 and APG808 programs.

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.

#### ***Letter of Intent — Samsung Biologics Limited***

In the fourth quarter of 2024, we executed a Letter of Intent for the manufacturing of drug product with Samsung Biologics, under which we recognized \$9.9 million of research and development expenses.

### **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:

- 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 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;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and current and future clinical trials; 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, such as 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 Agreement 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 related to the continued development of our programs, developing any future programs, including investments in manufacturing, as we advance any programs we may identify and continue to conduct clinical trials. 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 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 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, 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 programs, 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, 2024, we had U.S. federal NOL carryforwards of approximately \$68.1 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 \$28.5 million, which will begin to expire in 2043 for state tax purposes. As of December 31, 2024, we also had U.S. federal and research and development tax credit carryforwards of approximately \$10.5 million, which may be available to reduce future tax liabilities. We also had California research and development credit carryforwards of approximately \$1.5 million. Additionally, we had Massachusetts research and development credit carryforwards of approximately \$2.1 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, 2024 compared to the year ended December 31, 2023 is presented below. A discussion regarding our financial condition and results of operations for the year ended December 31, 2023 compared to the period from February 4, 2022 (inception) to December 31, 2022 can be found in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K filed with the SEC on March 5, 2024.

### **Comparison of the Year Ended December 31, 2024 and Year Ended December 31, 2023**

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

	YEAR ENDED DECEMBER 31,		
	2024	2023	\$ CHANGE
Operating expenses:			
Research and development	\$ 167,865	\$ 68,424	\$ 99,441
General and administrative	49,005	24,579	24,426
Total operating expenses	216,870	93,003	123,867
Loss from operations	(216,870)	(93,003)	(123,867)
Other income, net:			
Interest income	34,742	9,018	25,724
Total other income, net	34,742	9,018	25,724
Net loss before taxes	(182,128)	(83,985)	(98,143)
Provision for income taxes	(18)	—	(18)
Net loss after taxes	\$ (182,146)	\$ (83,985)	\$ (98,161)

**Research and Development Expense**

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

	YEAR ENDED DECEMBER 31,	
	2024	2023
External research and development costs by program:		
APG777	\$ 49,241	\$ 21,644
APG990/APG279 <sup>(1)</sup>	20,000	—
APG333/APG777 + APG333 <sup>(2)</sup>	28,095	—
APG808	10,311	20,801
Unallocated research and development costs:		
External-discovery related costs and other	11,064	15,019
Personnel-related (excluding equity-based compensation)	39,013	9,386
Equity-based compensation	9,964	1,574
Depreciation expense	177	—
Total research and development expenses	<u>\$ 167,865</u>	<u>\$ 68,424</u>

- (1) External research and development costs for APG990/APG279 for the year ended December 31, 2023 were recorded as unallocated external discovery related costs as the development candidate for APG990 was nominated in May 2024.
- (2) External research and development costs for APG333/APG777+APG333 for the year ended December 31, 2023 were recorded as unallocated external discovery related costs as the development candidate for APG333 was nominated in October 2024.

Research and development expenses for the years ended December 31, 2024 and 2023 were \$167.9 million and \$68.4 million, respectively. The increase of \$99.5 million was primarily driven by further development of our APG777, APG990/APG279 and APG333/APG777+APG333 programs and advancement of our pipeline into clinical trials, as well as increases in personnel costs and equity-based compensation expense, associated with the growth in our research and development team.

Research and development expense related to the APG777 program for the years ended December 31, 2024 and 2023 were \$49.2 million and \$21.6 million, respectively. The increase of \$27.6 million was primarily driven by an increase in clinical trial-related expenses and clinical manufacturing activities to support our Phase 1 and Phase 2 clinical trials. For the year ended December 31, 2024, we recorded \$20.0 million of research and development expense related to the APG990/APG279 program, 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 a human patient in a Phase 1 clinical trial in August 2024, respectively. No such expenses were recorded for the year ended December 31, 2023, as APG990/APG279 expenses were recorded as unallocated external-discovery related costs until the program candidate was nominated in 2024. For the year ended December 31, 2024, we recorded \$28.1 million of research and development expenses related to the APG333/APG333+APG777 program, 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. No such expenses were recorded for the year ended December 31, 2023, as expenses related to the APG333/APG333+APG777 program were recorded as unallocated external-discovery related costs until the program candidate was nominated in 2024. For the years ended December 31, 2024 and 2023, we recorded \$10.3 million and \$20.8 million of research and development expense related to the APG808 program, respectively. The decrease of \$10.5 million was primarily driven by decreased clinical manufacturing activities in 2024.

Personnel-related expenses and equity-based compensation increased by \$29.6 million and \$8.4 million in the year ended December 31, 2024, respectively, compared to the year ended December 31, 2023, primarily driven by increased headcount and an increase in the fair value of equity awards granted. External-discovery related costs and other expenses decreased by \$3.9 million, primarily driven by the nomination of development candidates under APG333/APG777+APG333 and APG990/APG279 in 2024, as expenses related to the programs were recorded as unallocated external-discovery related costs until the program candidates were nominated in 2024.

### **General and Administrative Expense**

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

	YEAR ENDED DECEMBER 31,	
	2024	2023
Personnel-related (excluding equity-based compensation)	\$ 16,935	\$ 8,048
Equity-based compensation	13,368	4,529
Legal and professional fees	6,451	4,322
Other	12,251	7,680
Total general and administrative expenses	<u>\$ 49,005</u>	<u>\$ 24,579</u>

General and administrative expenses for the year ended December 31, 2024 were \$49.0 million, compared to \$24.6 million for the year ended December 31, 2023. The increase of \$24.4 million was primarily due to increases of \$8.9 million and \$8.9 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. Additionally, other general and administrative expenses increased \$4.6 million, primarily due to increases in IT related costs, D&O insurance and other employee related expenses. The increase in total general and administrative expenses were the result of the expansion of our operations to support the growth in our business and the cost of operating as a public company.

### **Other Income, Net**

Interest income increased \$25.7 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, 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 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 and our ATM Facility (as defined below). As of December 31, 2024, we had cash and cash equivalents of \$141.8 million, marketable securities of \$378.9 million and long-term marketable securities of \$210.4 million.

Prior to our IPO, we received gross proceeds of \$169.0 million from 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 pursuant to the exercise in full of the underwriters' option to purchase additional shares) at a price of \$17.00 per share for aggregate net proceeds of \$315.4 million, after deducting underwriting discounts and commissions and other offering expenses. In connection with our March 2024 Offering, 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 aggregate net proceeds of \$450.0 million after deducting underwriting discounts and commissions and other offering expenses.

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 at the market offering program (the "ATM Facility"). During the three months ended December 31, 2024, we sold 926,049 shares of common stock under the ATM at a price per share of \$48.50 resulting in net proceeds of \$43.6 million. As of December 31, 2024, \$255.1 million remained available for sale under the Sale Agreement.

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

	YEAR ENDED DECEMBER 31,	
	2024	2023
Net cash, cash equivalents, and restricted cash provided by (used in):		
Operating activities	\$ (171,174)	\$ (74,761)
Investing activities	(300,462)	(273,910)
Financing activities	495,109	315,391
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 23,473	\$ (33,280)

#### *Net Cash used in Operating Activities*

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, 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 for lease expense.

For the year ended December 31, 2023, operating activities used \$74.8 million of cash, primarily due to a net loss of \$84.0 million, partially offset by non-cash charges of \$6.1 million for equity-based compensation and net changes in our operating assets and liabilities of \$6.1 million.

#### *Net Cash used in Investing Activities*

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 used in investing activities for the year ended December 31, 2023 was \$273.9 million, which was primarily related to the \$303.7 million purchase of marketable securities, partially offset by the maturities of \$30.0 million in marketable securities.

#### *Net Cash provided by Financing Activities*

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.

For the year ended December 31, 2023, financing activities provided \$315.4 million of cash related to the issuance and sale of common stock from our IPO, net of paid issuance costs.

#### *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 program and we do not know when, or if at all, that will occur. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and studies and initiate clinical trials. In addition, if we obtain regulatory approval for any programs, 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 APG777, APG990, APG333 and APG808 programs;
- 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 programs 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;
- 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 adding operational, financial and management information systems and personnel;
- 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 programs 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 programs, 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 or licensing arrangements 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. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit 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, 2024, we had \$141.8 million of cash and cash equivalents, \$378.9 million of marketable securities and \$210.4 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 first quarter 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.

### ***Contractual Obligations and Other Commitments***

We enter into contracts in the normal course of business with contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”) and other third parties for preclinical research studies and testing, clinical trials, manufacturing and other services. These contracts do not contain any minimum purchase commitments and provide for termination by us upon prior written notice. 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, 2024, 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.

### **JOBS Act Transition Period and Smaller Reporting Company Status**

As of June 30, 2024, the market value of our common stock held by non-affiliates exceeded \$700 million, and as a result, as of January 1, 2025, we no longer qualified as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) or as a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act of 1934, as amended (the “Exchange Act”). We have transitioned to a large accelerated filer, as defined in Rule 12b-2 of the Exchange Act. As a large accelerated filer, and subject to applicable transition periods, we are subject to certain disclosure requirements that are applicable to other public companies that were not applicable to us as an emerging growth company and smaller reporting company, including compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting imposed by the Sarbanes-Oxley Act of 2002 and full disclosure obligations regarding executive compensation. Additionally, we are no longer able to take advantage of transition periods for complying with new or revised accounting standards that are available to emerging growth companies.

### **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**

We are no longer a smaller reporting company and have transitioned to a large accelerated filer, each as defined in Rule 12b-2 of the Exchange Act. In accordance with SEC rules for this transition, we are not required to provide information under this item.

**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, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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, 2024, 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 3, 2025 expressed an unqualified opinion thereon.

### Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

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

*Description of  
the Matter*

The Company's accrued manufacturing expenses balance totaled \$15.5 million as of December 31, 2024. As discussed in Note 2 to the consolidated financial statements, the Company estimates the value of goods and services received in the reporting period 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. 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 manufacturing expenses was complex in the context of our audit due to the volume of the Company's manufacturing activities. Furthermore, due to the duration of the Company's manufacturing 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*

To evaluate accrued manufacturing expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used by management to determine the accruals. We evaluated the progress of manufacturing 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 3, 2025

**PART I – FINANCIAL INFORMATION****APOGEE THERAPEUTICS, INC.****CONSOLIDATED BALANCE SHEETS**

(In thousands, except unit/share data)

	DECEMBER 31, 2024	DECEMBER 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 141,789	\$ 118,316
Marketable securities	378,864	277,143
Prepaid expenses and other current assets	9,060	2,950
Total current assets	529,713	398,409
Long-term marketable securities	210,416	—
Property and equipment, net	1,959	377
Right-of-use asset, net	11,365	2,217
Other non-current assets	498	401
Total assets	<u>\$ 753,951</u>	<u>\$ 401,404</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,071	\$ 2,143
Lease liability	3,234	1,101
Accrued expenses and other current liabilities	24,255	17,314
Total current liabilities	28,560	20,558
Long-term liabilities:		
Lease liability, net of current	8,597	933
Total liabilities	<u>37,157</u>	<u>21,491</u>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common Stock; \$0.00001 par value, 400,000,000 authorized, 59,478,725 issued and 58,062,898 outstanding as of December 31, 2024; 400,000,000 authorized, 50,655,671 issued and 48,338,769 outstanding as of December 31, 2023	1	—
Additional paid-in capital	1,021,794	503,354
Accumulated other comprehensive income	915	329
Accumulated deficit	(305,916)	(123,770)
Total stockholders' equity	<u>716,794</u>	<u>379,913</u>
Total liabilities and stockholders' equity	<u>\$ 753,951</u>	<u>\$ 401,404</u>

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,	
	2024	2023
Operating expenses:		
Research and development <sup>(1)</sup>	\$ 167,865	\$ 68,424
General and administrative <sup>(2)</sup>	49,005	24,579
Total operating expenses	216,870	93,003
Loss from operations	(216,870)	(93,003)
Other income, net:		
Interest income, net	34,742	9,018
Total other income, net	34,742	9,018
Net loss before taxes	(182,128)	(83,985)
Provision for income taxes	(18)	—
Net loss after taxes	\$ (182,146)	\$ (83,985)
Net loss per share, basic and diluted	\$ (3.30)	\$ (3.36)
Weighted-average common shares outstanding, basic and diluted	55,193,971	25,005,774

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

(2) No related party amounts for the year ended December 31, 2024 and \$33 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)

	<b>YEAR ENDED DECEMBER 31,</b>	
	<b>2024</b>	<b>2023</b>
Net loss	\$ (182,146)	\$ (83,985)
Change in unrealized gains on marketable securities, net of tax	586	329
Comprehensive loss	<u>\$ (181,560)</u>	<u>\$ (83,656)</u>

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 AMOUNT	ACCUMULATED DEFICIT AMOUNT	ACCUMULATED OTHER COMPREHENSIVE INCOME AMOUNT	TOTAL STOCKHOLDERS' EQUITY/MEMBERS' DEFICIT AMOUNT
	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	SHARES	AMOUNT				
<b>Balance at December 31, 2022</b>	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
Change in unrealized gain on marketable securities, net of tax	—	—	—	—	—	—	—	—	—	—	—	—	329	329
Net loss	—	—	—	—	—	—	—	—	—	—	—	(83,985)	—	(83,985)
<b>Balance at December 31, 2023</b>	—	\$ —	—	\$ —	—	\$ —	—	\$ —	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 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)
<b>Balance at December 31, 2024</b>	—	\$ —	—	\$ —	—	\$ —	—	\$ —	58,062,898	\$ 1	\$ 1,021,794	\$ (305,916)	\$ 915	\$ 716,794

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

**APOGEE THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	<b>YEAR ENDED DECEMBER 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (182,146)	\$ (83,985)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation expense	189	—
Equity-based compensation expense	23,332	6,103
Amortization of discounts on marketable securities	(12,241)	(3,071)
Non-cash lease expense	1,694	87
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(6,080)	(2,785)
Other assets	(97)	(107)
Accounts payable	(1,072)	1,613
Operating lease liability	(1,045)	(270)
Accrued expenses	6,292	7,654
Net cash used in operating activities	<u>(171,174)</u>	<u>(74,761)</u>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(649,450)	(303,743)
Maturities of marketable securities	350,140	30,000
Purchases of property and equipment	(1,152)	(167)
Net cash used in investing activities	<u>(300,462)</u>	<u>(273,910)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock, net of issuance costs	449,955	315,391
Proceeds from issuance of common stock under ATM equity offering program, net of issuance costs	43,528	—
Proceeds from exercise of options and employee stock purchase plan purchases	1,626	—
Net cash provided by financing activities	<u>495,109</u>	<u>315,391</u>
Increase (decrease) in cash, cash equivalents and restricted cash	23,473	(33,280)
Cash, cash equivalents and restricted cash, beginning of period	118,610	151,890
Cash, cash equivalents and restricted cash, end of period	<u>\$ 142,083</u>	<u>\$ 118,610</u>
<b>Supplemental disclosures of non-cash activities:</b>		
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	\$ 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
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>		
Cash and cash equivalents	\$ 141,789	\$ 118,316
Restricted cash	\$ 294	\$ 294
Total	<u>\$ 142,083</u>	<u>\$ 118,610</u>

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 subsidiaries (collectively, “Apogee” or the “Company”), a successor to Apogee Therapeutics, LLC, is a clinical-stage biotechnology company advancing novel biologics with 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.

The Company commenced its operations in February 2022 as a Delaware limited liability company named Apogee Therapeutics, LLC. The Company was founded by leading healthcare investors, Fairmount Funds Management LLC and Venrock Healthcare Capital Partners and has since assembled a management team of drug developers and an executive team with significant experience in clinical development, manufacturing of biologics and leading public biopharmaceutical company operations, financing and transactions. As a result of the Reorganization (as defined below) and in connection with the Company’s initial public offering (“IPO”) in July 2023, the Company directly wholly owns the assets of Apogee Therapeutics, LLC, including the stock of its subsidiary. In addition, the Company engages third parties, including Paragon Therapeutics, Inc. (“Paragon”), who is also a related party, to perform ongoing research and development and other services on its behalf.

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-4R $\alpha$ , 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 rights, 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. In November 2023, the Company entered into an additional antibody discovery and option agreement for the thymic stromal lymphopoietin (“TSLP”) target 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.

In November 2022, the Company exercised its option available under the 2022 Option Agreement with respect to the IL-13 Research Program (as defined below) and, in April 2023, the Company exercised its options available under the 2022 Option Agreement with respect to the IL-4R $\alpha$  Research Program and the OX40L Research Program. Upon such exercises, the parties entered into associated license agreements for each target. Under the terms of each license agreement, 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. In August 2024, the Company exercised its option under the 2023 Option Agreement with the respect to the TSLP Research Program. The Company is solely responsible for the development, manufacture and commercialization of IL-13, IL-4R $\alpha$ , OX40L and TSLP product candidates and products at its own cost and expense.

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. On March 12, 2024, the Company issued and sold an aggregate of 7,790,321 shares of its 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 aggregate net proceeds of \$450.0 million after deducting underwriting discounts and commissions and other offering expenses.

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, APG777, APG990, 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 \$305.9 million as of December 31, 2024. Further, the Company incurred a net loss of \$182.1 million and experienced negative cash flows from operations of \$171.2 million for the year ended December 31, 2024. Based on the Company's current operating plan, it estimates that its existing cash and cash equivalents of \$141.8 million, marketable securities of \$378.9 million and long-term marketable securities of \$210.4 million as of December 31, 2024, 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 subsidiaries. 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, 2024 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:

	<b>ESTIMATED USEFUL LIFE</b>
Laboratory equipment	5 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.

### ***Preferred Units***

The Company has classified the preferred units as temporary equity because the units could become effectively settled for cash or other assets due to certain contingent event clauses that are outside of the Company’s control. The preferred units are not currently settleable, but are entitled to a distribution of available proceeds upon a change of control or a sale event which is a bona fide, negotiated transaction in which the Company has determined to affect a change of control. Because the occurrence of a change of control and a sale event is not currently probable, the carrying values of the preferred units are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the preferred units would be made only when the change of control or sale event becomes probable. All outstanding preferred units were exchanged for shares of common stock (or non-voting common stock in lieu therefor) in connection with the IPO in July 2023.

### ***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.

### **Equity-Based Compensation**

Prior to the Reorganization, the Company issued equity-based awards to employees, managers, executives, non-employees and service providers in the form of common units and incentive units. Subsequent to the Reorganization, the Company issued 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* ("ASC 718").

Due to the absence of an active market for the Company's common units or incentive units prior to the completion of the IPO, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common units and incentive units. The estimated fair value of the common units and incentive units was determined at each grant date based upon a variety of factors, including the illiquid nature of the common units, arm's-length sales of the Company's equity units (including preferred units), the effect of the rights and preferences of the preferred unit unitholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could have resulted in different fair values of the common units and incentive units at each valuation date.

Subsequent to the completion of the IPO, 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, 2024, 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, 2024 and December 31, 2023, 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 contract manufacturers to produce and process its programs, APG777, APG990, APG333 and APG808, for preclinical and clinical 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, 2024 and December 31, 2023, 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 follows the two-class method when computing net loss per share. Prior to the Reorganization, the Company issued units that met the definition of participating securities, including the Company's Series A Preferred Units, the Series B Preferred Units, and vested incentive units (each a participating security), and subsequent to the Reorganization, 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. The two-class method determines net loss per unit and net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income for the period to be allocated between common and participating securities based upon their respective rights to share in the income as if all income for the period had been distributed. Prior to the Reorganization, during periods of loss, there was no allocation required under the two-class method since the participating securities did not have a contractual obligation to fund the losses of the Company. Subsequent to the Reorganization, 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. 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, 2024			
	COST	UNREALIZED		FAIR VALUE
		GAINS	LOSSES	
<b>Marketable securities</b>				
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
<b>Total maturities within one year</b>	<b>378,096</b>	<b>833</b>	<b>(65)</b>	<b>378,864</b>
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
<b>Total maturities between one and two years</b>	<b>210,269</b>	<b>579</b>	<b>(432)</b>	<b>210,416</b>
<b>Total marketable securities</b>	<b>\$ 588,365</b>	<b>\$ 1,412</b>	<b>\$ (497)</b>	<b>\$ 589,280</b>

	AS OF DECEMBER 31, 2023			
	COST	UNREALIZED		FAIR VALUE
		GAINS	LOSSES	
<b>Marketable securities:</b>				
U.S. treasury securities	\$ 123,836	\$ 140	\$ (2)	\$ 123,974
Debt securities issued by U.S. government agencies	152,978	199	(8)	153,169
	<b>\$ 276,814</b>	<b>\$ 339</b>	<b>\$ (10)</b>	<b>\$ 277,143</b>

As of December 31, 2024, the Company had 20 securities with a total fair market value of \$130.3 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, 2024 and December 31, 2023. 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, 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 recurring basis and indicates the level of fair value hierarchy utilized to determine such values (in thousands):

	AS OF DECEMBER 31, 2024			TOTAL
	LEVEL 1	LEVEL 2	LEVEL 3	
<b>Cash equivalents:</b>				
Money market funds	\$ 132,491	\$ —	\$ —	\$ 132,491
<b>Marketable securities:</b>				
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	<u>\$ 381,426</u>	<u>\$ 340,345</u>	<u>\$ —</u>	<u>\$ 721,771</u>

	AS OF DECEMBER 31, 2023			TOTAL
	LEVEL 1	LEVEL 2	LEVEL 3	
<b>Cash equivalents:</b>				
Money market funds	\$ 110,655	\$ —	\$ —	\$ 110,655
<b>Marketable securities:</b>				
U.S. treasury securities	123,974	—	—	123,974
Debt securities issued by U.S. government agencies	—	153,169	—	153,169
Total	<u>\$ 234,629</u>	<u>\$ 153,169</u>	<u>\$ —</u>	<u>\$ 387,798</u>

#### 5. Property and Equipment, net

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

	DECEMBER 31, 2024	DECEMBER 31, 2023
Lab equipment	\$ 1,285	\$ 377
Leasehold improvements	863	—
Less: Accumulated depreciation	(189)	—
Total	<u>\$ 1,959</u>	<u>\$ 377</u>

The Company recognized \$0.2 million of depreciation expense for the year ended December 31, 2024. The Company recognized an immaterial amount of depreciation expense for the year ended December 31, 2023.

#### 6. Prepaids and Other Assets

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

	DECEMBER 31, 2024	DECEMBER 31, 2023
Prepaid expenses	\$ 2,621	\$ 1,736
Interest receivable	4,697	1,214
Other current assets	1,742	—
Total	<u>\$ 9,060</u>	<u>\$ 2,950</u>

As of December 31, 2024 and December 31, 2023, 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 and December 31, 2023.

## 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	DECEMBER 31, 2024	DECEMBER 31, 2023
Accrued external research and development expenses	\$ 4,957	\$ 6,685
Accrued manufacturing expenses	15,505	9,219
Accrued employee compensation	1,895	167
Accrued other	1,898	1,243
Total	<u>\$ 24,255</u>	<u>\$ 17,314</u>

## 8. Other Significant Agreements

### Paragon Option and License Agreements

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

#### *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-4R $\alpha$ , 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-4R $\alpha$ . 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.

Unless terminated earlier, the 2022 Option Agreement 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 “2022 Term”). Upon the expiration of the 2022 Term for all then-existing Research Programs, under the 2022 Option Agreement, the 2022 Option Agreement will automatically expire in its entirety. The Company may terminate the 2022 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 the 2022 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.

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 (see Note 10). 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 that outlines 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 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 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.

### *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- 4R $\alpha$  Research Program and the OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the “IL-4R $\alpha$  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-4R $\alpha$  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-4R $\alpha$  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 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-4R $\alpha$  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.

The Company concluded that each of the License Agreements constitutes an asset acquisition of in-process research and development assets with no alternative future use. Each of the arrangements did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the license which comprises a single identifiable asset. Therefore, the aggregate acquisition cost for each license was recognized as research and development expense.

#### **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 our APG777, APG990, APG333 and APG808 programs, as well as potential future programs, 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 year ended December 31, 2024, the Company recognized \$31.8 million of research and development expense in connection with the WuXi Biologics MSA, compared to \$20.2 million for the year ended December 31, 2023.

#### **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 a component of the Company's APG777, APG990, APG333 and APG808 programs.

In consideration for the license, the Company 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 Company's 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.

#### **Letter of Intent — Samsung Biologics Limited**

In the fourth quarter of 2024, the Company executed a letter of intent for the manufacturing of drug product with Samsung Biologics, under which the Company recognized \$9.9 million of research and development expense.

### **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, 2024, 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, 2024 and December 31, 2023.

#### ***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. Preferred Shares**

As of December 31, 2022, the Company had authorized, issued and outstanding an aggregate of 65,089,212 preferred units, of which 20,000,000 units had been designated as Series A Preferred Units and 45,089,212 units had been designated as Series B Preferred Units. All outstanding preferred units were exchanged for 24,987,750 shares of common stock (or non-voting common stock in lieu thereof) in connection with the IPO in July 2023. As of December 31, 2024 and 2023, the Company did not have any outstanding preferred units.

#### ***Series A Preferred Units***

On February 24, 2022, the Company executed the Series A Preferred Unit Purchase Agreement (the "Series A Agreement") to issue and sell up to 20,000,000 Series A Preferred Units at a purchase price of \$1.00 per unit. In the initial closing on February 24, 2022, the Company issued 5,000,000 Series A Preferred Units at a purchase price of \$1.00, resulting in gross cash proceeds to the Company of \$5.0 million, and incurred \$0.2 million of issuance costs.

The Series A Agreement provided for three tranche option closings following the initial closing (the “Tranche Options”), which Tranche Option closings were subject to approval of the Board of Managers of Apogee Therapeutics, LLC (the “Board of Managers”), which was controlled by the holders of the Series A Preferred Units. The Board of Managers approved all such subsequent closings resulting in investors purchasing 5,000,000 Series A Preferred Units in each of the three subsequent Tranche Option closings throughout 2022. As a result, the Company received an aggregate of \$20.0 million in gross proceeds associated with the Series A Agreement.

The Company assessed the Tranche Options and concluded that they met the definition of a freestanding financial instrument, as the Tranche Options were legally detachable and separately exercisable from the Series A Preferred Units. Therefore, the Company allocated the proceeds between the Tranche Options and the Series A Preferred Units sold at the initial closing. As the Series A Preferred Units are contingently redeemable upon an event that is not completely within the control of the Company, the Tranche Options are classified as an asset or liability and are initially recorded at fair value. The Tranche Options are measured at fair value at each reporting period, through the settlement of the instrument. Since the Tranche Options are subject to fair value accounting, the Company allocated \$1.1 million of the initial proceeds to the Tranche Options based on the fair value at the date of issuance with the remaining proceeds being allocated to the Series A Preferred Units. Upon the Tranche Option closings in August and October 2022, the respective Tranche Option value was remeasured at fair value and then reclassified to Series A Preferred Units upon settlement.

### ***Series B Preferred Units***

On November 15, 2022, the Company executed the Series B Preferred Unit Purchase Agreement (the “Series B Agreement”) to issue and sell 45,089,212 Series B Preferred Units in a single closing at a purchase price of \$3.30456 per unit, resulting in gross cash proceeds to the Company of \$149.0 million. The Company incurred \$0.5 million of issuance costs in connection with the issuance of the Series B Preferred Units.

### ***Embedded Securities Evaluation***

The Company assessed the Series A Preferred Units and the Series B Preferred Units for any features that may require separate accounting under FASB ASC Topic 815- *Derivatives and Hedging* (“ASC 815”). The Company concluded that none of the features required separate accounting as a derivative.

## **11. Common Stock**

In July 2023, the Company completed its IPO, selling an aggregate 20,297,500 shares of common stock. All outstanding preferred units were exchanged into 24,987,750 shares of common stock in connection with the IPO. Following the IPO, 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.

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. The Sales Agent will be entitled to compensation at a commission of up to 3.0% of the aggregate gross sales price per share sold under the Sale Agreement, unless otherwise agreed to by the Sales Agent and the Company under the Sale Agreement. In December 2024, the Company sold 926,049 shares of common stock under the ATM at a price per share of \$48.50. As of December 31, 2024, \$255.1 million remained available for sale under the Sale Agreement.

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 are 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.

As of December 31, 2023, 50,655,671 and 48,338,769 shares of common stock were issued and outstanding, respectively. The 50,655,671 shares of common stock issued are comprised of 37,169,029 shares of voting common stock and 13,486,642 shares of non-voting common stock. As of December 31, 2023, there were 2,316,902 shares of unvested restricted common stock included within the shares of common stock issued.

## **12. Equity-Based Compensation**

### ***Incentive Units***

Prior to the Reorganization, the Company periodically granted incentive units to employees, managers and executives, as well as to consultants and service providers of the Company. The incentive units represent a separate substantive class of members' equity with defined rights. The incentive units represent profits interest in the increase in the value of the entity over a threshold value, or strike price, as determined at the time of grant. The strike price is established for tax compliance purposes related to Internal Revenue Service Revenue Procedure 93-27 and 2001-43 where the Company allocates equity value to separate classes of equity in a hypothetical liquidation transaction as of the date of grant. Each incentive unit issued includes a strike price determined by the Board of Managers. The strike price is based on an estimate of the amount a common unit would receive on the date of issuance of such incentive units in a hypothetical liquidation of the Company in which the Company sold its assets for their fair market value, satisfied its liabilities, and distributed the net proceeds to the holders of units in liquidation of the Company.

The Company accounts for equity-based compensation in accordance with ASC 718. In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award. The service-based incentive unit grants generally vest over a four-year service period, with the first 25% vesting on the 12-month anniversary of the vesting start date and the remaining vesting in equal monthly installments over the following 36 months. The service-based and performance-based incentive unit grant, which the Company has one such award, vests in the same manner as the service-based award upon the achievement of the performance condition. The Company had one incentive unit grant which vested immediately upon issuance. The holders of vested incentive units are entitled to distributions and are not required to purchase or "exercise" their incentive units in order to receive such distributions. However, distributions to incentive unit holders began only after the cumulative amount distributed to common unit holders exceeds the strike price with respect to such incentive unit.

The Company determined that incentive units issued to employees, managers, executives, non-employees and service providers are equity-based service payments and, as such, the Company measures and recognizes the related compensation expense in a manner consistent with its accounting policy for equity-based awards.

The fair value of each incentive unit grant was estimated on the grant date using either an option pricing method (“OPM”), or a hybrid method, both of which used market approaches to estimate the Company’s enterprise value. The OPM treats common units, incentive units and preferred units as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company’s securities changes. Under this method, the incentive units have value only if the funds available for distribution to unitholders exceed the value of the preferred and common unit distribution preferences and the strike price with respect to such incentive unit at the time of the liquidity event. The hybrid method is a probability-weighted expected return method (“PWERM”), where the equity value is allocated in one or more of the scenarios using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of each unit based upon an analysis of future values, assuming various outcomes. The incentive unit value is based on the probability-weighted value across the scenarios, considering the OPM to estimate the value within each scenario given the rights of each class of unit. A discount for lack of marketability of the incentive unit is then applied to arrive at an indication of fair value for the incentive unit.

The following assumptions were used in determining the fair value of incentive units granted during the period:

	YEAR ENDED DECEMBER 31, 2023
Risk-free interest rate	4.1% - 4.9%
Expected dividend yield	0.0%
Expected term (in years)	0.17 - 2.00
Expected volatility	84.0% - 90.0%

### **Restricted Common Stock**

Concurrent with the Reorganization, all of the outstanding incentive units were exchanged into 3,469,546 shares of common stock, of which 2,779,358 were unvested restricted common stock. The following table provides a summary of the unvested restricted common stock award activity during the year ended December 31, 2024:

	NUMBER OF SHARES	WEIGHTED- AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested restricted common stock as of December 31, 2023	2,316,902	\$ 5.31
Vested	(901,075)	\$ 5.32
Unvested restricted common stock as of December 31, 2024	1,415,827	\$ 5.30

The fair value of restricted stock vested during the year ended December 31, 2024 was \$4.8 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 the date of the effectiveness of the registration statement for the IPO. 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, 2024, the number of shares of common stock available for future grants under the 2023 Plan is equal to 3,720,964 shares of common stock. The number of shares available for grant and issuance under the 2023 Plan will be 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, 2024
Risk-free interest rate	3.6% - 4.7%
Expected dividend yield	0.0%
Expected term (in years)	5.5 - 6.25
Expected volatility	74.9% - 96.4%

The following table provides a summary of stock option activity during the year ended December 31, 2024:

	OPTIONS	WEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2023	2,506,017	\$ 21.49	9.80	\$ 16,154
Granted	2,726,734	\$ 47.21	—	\$ —
Exercised	(43,025)	\$ 19.81	—	\$ —
Forfeited	(34,312)	\$ 19.59	—	\$ —
Outstanding as of December 31, 2024	<u>5,155,414</u>	\$ 35.12	9.37	\$ 61,506
Exercisable as of December 31, 2024	<u>704,323</u>	\$ 22.06	8.89	\$ 16,434

The fair value of options vested during the year ended December 31, 2024 was \$14.1 million.

The following table provides a summary of the unvested restricted stock unit activity under the 2023 Plan during the year ended December 31, 2024:

	NUMBER OF SHARES	WEIGHTED- AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested restricted stock units as of December 31, 2023	144,090	\$ 22.86
Granted	159,482	49.07
Vested	(36,008)	22.86
Unvested restricted stock units as of December 31, 2024	<u>267,564</u>	<u>\$ 38.48</u>

The fair value of restricted stock units vested during the year ended December 31, 2024 was \$0.8 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, 2024, 27,651 shares have been issued under the ESPP and 934,739 shares remain available for issuance.

The following table presents the classification of equity-based compensation expense related to equity awards granted to employees, managers, executives, and service providers (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Research and development expense	\$ 9,964	\$ 1,574
General and administrative expense	13,368	4,529
Total	\$ 23,332	\$ 6,103

As of December 31, 2024, the total unrecognized compensation expense related to the Company's stock options, unvested restricted stock and ESPP was \$134.5 million, which the Company expects to recognize over a weighted-average period of approximately 3.1 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.

### 13. Related Parties

Under the Option Agreements and the License Agreements, Paragon, a stockholder of the Company that was founded by a Series A Preferred Unit investor, 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, 2024 and December 31, 2023, \$0.1 million and \$5.2 million were due to Paragon, respectively. For the year ended December 31, 2024, the Company incurred research and development expenses with Paragon of \$19.2 million. For the year ended December 31, 2023, the Company incurred research and development expenses with Paragon of \$26.3 million, and immaterial general and administrative expenses with Paragon.

#### 14. 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,	
	2024	2023
Numerator:		
Net loss	\$ (182,146)	\$ (83,985)
Net loss attributable to common stockholders, basic and diluted	<u>\$ (182,146)</u>	<u>\$ (83,985)</u>
Denominator:		
Weighted average shares of common stock outstanding, basic and diluted	55,193,971	25,005,774
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (3.30)</u>	<u>\$ (3.36)</u>

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,	
	2024	2023
Stock options	5,155,414	2,506,017
Unvested restricted common stock	1,415,827	2,316,902
Unvested restricted stock units	267,564	144,090
Total	<u>6,838,805</u>	<u>4,967,009</u>

#### 15. 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 lab space and extend the lease term through November 2026, with the option to extend for one year.

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, 2024, the current and non-current operating lease liabilities were \$3.2 million and \$8.6 million, respectively. The Company incurred lease expense of \$2.3 million for the year ended December 31, 2024. As of December 31, 2024, the weighted average remaining lease term was 3.9 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 7%.

As of December 31, 2024, 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
2025	\$ 3,909
2026	3,475
2027	2,049
2028	2,110
2029	1,618
Thereafter	—
Total undiscounted lease payments	<u>13,161</u>
Present value adjustment	(1,330)
Total net lease liabilities	<u>\$ 11,831</u>

## 16. Income Tax

Apogee Therapeutics, Inc. and its U.S. subsidiaries, 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 the respective period.

The provision for income taxes consists of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Current:		
Federal	\$ —	\$ —
State	18	—
Total Current	18	—
Deferred:		
Federal	—	—
State	—	—
Total Deferred	—	—
Total Provision	\$ 18	\$ —

The difference between the effective tax rate and the U.S. federal tax rate were as follows:

	YEAR ENDED DECEMBER 31,	
	2024	2023
U.S. federal statutory tax rate	(21.0)%	(21.0)%
State and local income taxes, net of federal income tax benefit	(3.7)%	(4.9)%
Change in state effective income rate	1.2%	(1.8)%
Nondeductible items	1.5%	1.5%
Change in valuation allowance	25.2%	27.9%
Tax credits	(3.2)%	(1.9)%
Other	—%	0.2%
Effective tax rate	—%	—%

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,	
	2024	2023
Deferred tax assets:		
Capitalized license and research and development payments	\$ 46,240	\$ 21,034
Net operating loss carryforwards	16,095	5,370
Research and development credits	9,947	2,415
Intangible assets	1,342	1,244
Stock compensation	2,352	186
Lease liability	2,849	502
Other	13	1
<b>Total deferred tax assets</b>	<b>78,838</b>	<b>30,752</b>
Deferred tax liabilities:		
Fixed asset basis differences	(18)	—
Right-of-use asset	(2,737)	(574)
<b>Total deferred tax liabilities</b>	<b>(2,755)</b>	<b>(574)</b>
Valuation allowance	(76,083)	(30,178)
<b>Net deferred tax assets</b>	<b>\$ —</b>	<b>\$ —</b>

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, 2024. The change in the valuation allowance for the years ended December 31, 2024 and 2023 was \$45.9 million and \$23.5 million, respectively. Management reevaluates the positive and negative evidence at each reporting period.

As of December 31, 2024 and 2023, the Company had U.S. federal net operating loss carryforwards of approximately \$68.1 million and \$23.6 million, respectively, which have no expiration for federal tax purposes. As of December 31, 2024 and 2023, the Company also had state net operating loss carryforwards of approximately \$28.5 million and \$6.5 million, respectively, which will begin to expire in 2043.

As of December 31, 2024 and 2023, the Company had federal research and development credit carryforwards of approximately \$10.5 million and \$2.7 million, respectively, which will begin to expire in 2042. The Company also had California research and development credit carryforwards of approximately \$1.5 million and \$0.7 million as of December 31, 2024 and 2023, respectively, which will not expire. Additionally, the Company had Massachusetts research and development credit carryforwards of approximately \$2.1 million, 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):

Beginning balance as of December 31, 2023	\$ 904
Changes related to tax positions taken in the prior year	28
Changes related to tax positions taken in the current year	2,671
<b>Ending balance as of December 31, 2024</b>	<b>\$ 3,603</b>

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, 2024 and 2023, the Company had no accrued interest or penalties related to uncertain tax positions. The Company does not expect that its uncertain tax positions will materially change in the next twelve months.

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). The Company has evaluated the current legislation at this time and prepared the provision by following the treatment of research and development expenditures for tax purposes under Section 174.

## 17. Segment Information

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.

	YEAR ENDED DECEMBER 31,	
	2024	2023
Operating expenses <sup>(1)</sup> :		
Research and development personnel-related (excluding equity-based compensation)	\$ 39,013	\$ 9,387
External research and development costs - APG777	49,241	21,644
External research and development costs - APG990 / APG279	20,000	—
External research and development costs - APG333 / APG777 + APG333	28,095	—
External research and development costs - APG808	10,311	20,801
External-discovery related costs and other	11,064	15,019
General and administrative personnel-related (excluding equity-based compensation)	16,935	8,047
General and administrative operations <sup>(2)</sup>	18,690	12,002
Equity-based compensation	23,332	6,103
Depreciation expense	189	—
Interest income	(34,742)	(9,018)
Provision for income taxes	18	—
Consolidated net loss	\$ 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 overhead expenses

## 18. 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, 2024 and events which occurred subsequently but 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, 2024. 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, 2024. 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, 2024, 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, 2024.

Our independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of our internal control over financial reporting as of December 31, 2024, 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, 2024, 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, 2024, 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 2024 consolidated financial statements of the Company and our report dated March 3, 2025 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 3, 2025

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

Not applicable.

**Trading Plans**

During the quarter ended December 31, 2024, 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 2025 Proxy Statement, including under headings “Executive Compensation,” “Election of Directors,” and “Corporate Governance,” and “Insider Trading Policy.”

### **Item 11. Executive Compensation**

The information required by this item is incorporated by reference to the 2025 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 2025 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 2025 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 2025 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 122 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.

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
2.1	<a href="#">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).</a>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
4.1	<a href="#">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).</a>
4.2	<a href="#">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).</a>
4.3*	<a href="#">Description of the Company's Securities.</a>
10.1+	<a href="#">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).</a>
10.2+	<a href="#">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).</a>
10.3+	<a href="#">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).</a>
10.4+	<a href="#">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).</a>
10.5+	<a href="#">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).</a>
10.6+	<a href="#">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).</a>
10.7+	<a href="#">2023 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.15 of the Company's Registration Statement on Form S-1/A filed on July 10, 2023).</a>

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- 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-4R \$\alpha\$  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 [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 \(incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 filed on June 22, 2023\).](#)
- 10.16# [Biologics Master Services Agreement, dated June 20, 2022 by and between Paragon Therapeutics, Inc. and WuXi Biologics \(Hong Kong\) Limited \(incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 filed on June 22, 2023\).](#)
- 10.17# [Cell Line License Agreement, effective as of June 20, 2022, by and between Paragon Therapeutics, Inc. and WuXi Biologics \(Hong Kong\) Limited \(incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 filed on June 22, 2023\).](#)
- 10.18+ [First Amendment to the Apogee Therapeutics 2023 Employee Stock Purchase Plan \(incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024\).](#)
- 10.19 [License Agreement, dated November 22, 2023, by and between the Company and MIL 6T, LLC \(incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024\).](#)
- 10.20 [First Amendment to License Agreement, dated December 4, 2023, by and between the Company and MIL 6T, LLC \(incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 12, 2024\).](#)

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10.21	<a href="#"><u>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).</u></a>
10.22	<a href="#"><u>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).</u></a>
10.23	<a href="#"><u>Open Market Sale Agreement<sup>SM</sup> 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).</u></a>
19*	<a href="#"><u>Insider Trading Policy.</u></a>
21.1*	<a href="#"><u>Subsidiaries of the Registrant.</u></a>
23.1*	<a href="#"><u>Consent of Ernst &amp; Young LLP.</u></a>
31.1*	<a href="#"><u>Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.</u></a>
31.2*	<a href="#"><u>Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.</u></a>
32.1*(1)	<a href="#"><u>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.</u></a>
97.1*	<a href="#"><u>Incentive Compensation Clawback Policy.</u></a>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation LinkbaseDocument
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)

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\* 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 3, 2025

By: /s/ Michael Henderson, M.D.  
Michael Henderson, M.D.  
*Director and Chief Executive Officer*  
*(principal executive officer)*

Date: March 3, 2025

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael Henderson, M.D.</u> Michael Henderson, M.D.	Director and Chief Executive Officer ( <i>principal executive officer</i> )	March 3, 2025
<u>/s/ Jane Pritchett Henderson</u> Jane Pritchett Henderson	Chief Financial Officer ( <i>principal financial and accounting officer</i> )	March 3, 2025
<u>/s/ Mark C. McKenna</u> Mark C. McKenna	Chair and Director	March 3, 2025
<u>/s/ Peter Harwin</u> Peter Harwin	Director	March 3, 2025
<u>/s/ Jennifer Fox</u> Jennifer Fox	Director	March 3, 2025
<u>/s/ Andrew Gottesdiener, M.D.</u> Andrew Gottesdiener, M.D.	Director	March 3, 2025
<u>/s/ Tomas Kiselak</u> Tomas Kiselak	Director	March 3, 2025
<u>/s/ William Jones, Jr.</u> William Jones, Jr.	Director	March 3, 2025
<u>/s/ Nimish Shah</u> Nimish Shah	Director	March 3, 2025
<u>/s/ Lisa Bollinger</u> Lisa Bollinger	Director	March 3, 2025

**DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934****General**

The following is a summary of the material terms of the capital stock of Apogee Therapeutics, Inc. (“we,” “us,” “our” or the “Company”) as well as other material terms of our amended and restated certificate of incorporation and amended and restated bylaws and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K, to which this exhibit is also appended.

Our authorized capital stock consists of 386,513,358 shares of voting common stock, \$0.00001 par value per share, 13,486,642 shares of non-voting common stock, \$0.00001 par value per share, and 10,000,000 shares of “blank check” preferred stock, \$0.00001 par value per share. Unless otherwise noted, all references to our “common stock” herein refers to our voting common stock.

**Common Stock and Non-Voting Common Stock**

Our amended and restated certificate of incorporation authorizes the issuance of up to 386,513,358 shares of our common stock and 13,486,642 of our non-voting common stock. All outstanding shares of our common stock and non-voting common stock are validly issued, fully paid and nonassessable.

The holders of our common stock and our non-voting common stock have identical rights, provided that, (i) except as otherwise expressly provided in our amended and restated certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the right to convert each share of our non-voting common stock into one share of common stock at such holder’s election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 9.99% of our common stock immediately prior to and following such conversion (the “Beneficial Ownership Limitation”), unless otherwise as expressly provided for in our amended and restated certificate of incorporation. However, the Beneficial Ownership Limitation may be increased or decreased to any other percentage (not to exceed 19.99%) designated by such holder of non-voting common stock upon 61 days’ notice to us.

**Voting Rights.** Our common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders, except on matters relating solely to terms of preferred stock, and our non-voting common stock is not entitled to any votes per share. However, as long as any shares of non-voting common stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of non-voting common stock, (i) alter or change adversely the powers, preferences or rights given to the non-voting common stock, alter, amend or repeal any provision of, or add any provision to, our amended and restated certificate of incorporation or our amended and restated bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the non-voting common stock, regardless of whether any of the foregoing actions shall be by means of amendment to our amended and restated certificate of incorporation or by merger, consolidation or otherwise, (ii) issue further shares of non-voting common stock or increase or decrease the number of authorized shares of non-voting common stock, (iii) prior to the Stockholder Approval (as defined in our amended and restated certificate of incorporation) or at any time while at least 6,061,821 shares of non-voting common stock remain issued and outstanding, consummate either: (A) any Fundamental Transaction (as defined in our amended and restated certificate of incorporation) or (B) 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 or (iv) enter into any agreement with respect to any of the foregoing.

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of common stock and non-voting common stock have the same rights and privileges and rank equally, share ratably, and are identical in all respects for all matters, including those described below. Our amended and restated certificate of incorporation does not provide for cumulative voting in the election of directors.

**Dividends.** Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock and non-voting common stock are entitled to receive ratably any dividends declared by the Board of Directors of the Company (the “Board”) out of funds legally available therefor if our Board, in its discretion, determines to issue dividends and then only at the times and in the amounts that our Board may determine to issue dividends and then only at the times and in the amounts that our Board may determine.

**Liquidation Rights.** In the event of our liquidation, dissolution or winding-up, the holders of our common stock and non-voting common stock will be entitled to share equally, identically, and ratably in all assets remaining after payment of or provision for any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

**Other Rights.** The holders of our common stock and non-voting common stock have no preemptive rights. There are no redemption or sinking fund provisions applicable to our common stock and non-voting common stock.

### Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our Board has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers, preferences, and relative, participating, optional or other rights, if any, and the qualifications, limitations or restrictions, if any, of the shares of each such series.

Our Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock and non-voting common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of our common stock and non-voting common stock and the voting and other rights of the holders of our common stock and non-voting common stock. We have no current plans to issue any shares of preferred stock.

### Registration Rights

We have entered into a registration rights agreement with the holders of 24,987,750 shares of our common stock (including shares of common stock issuable upon conversion of our non-voting common stock). The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable holders to sell these shares without restriction under the Securities Act of 1933, as amended (the “Securities Act”), when the registration statement is declared effective. We will pay all expenses related to any demand, piggyback or Form S-3 registration described below, with the exception of underwriting discounts, selling commissions, and stock transfer taxes.

The registration rights described below will expire upon the earliest to occur of: (i) July 18, 2026; (ii) the closing of a merger or consolidation in which (A) we are constituent party or (B) a subsidiary of ours is a constituent party and we issue shares of our capital stock pursuant to such merger or consolidation; or (iii) with respect to any particular holder, at such time that such holder can sell its shares, under Rule 144 or another similar exemption under the Securities Act, during any three-month period without registration.

**Form S-1 Demand Registration Rights**

The holders of registrable securities who are party to the registration rights agreement (the “Registration Rights Holders”) are entitled to certain demand registration rights. The Registration Rights Holders who hold a majority of the registrable securities then outstanding may request that we file a Form S-1 registration statement for which the anticipated aggregate offering price would exceed \$20,000,000.

**Form S-3 Demand Registration Rights**

Subject to limitations and conditions, Registration Rights Holders who hold at least 30% of the registrable securities then outstanding may make a written request that we prepare and file a registration statement on Form S-3 under the Securities Act covering their shares, so long as the aggregate price to the public, net of the underwriters’ discounts and commissions, is at least \$5,000,000. We will prepare and file the Form S-3 registration statement as requested, unless, in the good faith judgment of our Board, such registration would be materially detrimental to the Company and its stockholders and filing should be deferred. We may defer only once in any 12-month period, and such deferral shall not exceed 90 days after receipt of the request. In addition, we are not obligated to prepare or file any of these registration statements (i) during the period that is 30 or 60 days, as the case may be, before our good faith estimate of the date of filing of, and ending on a date that is 180 days after the effective date of, a Company-initiated registration or (ii) if two of these registrations have been completed within any 12-month period.

**Piggyback Registration Rights**

Subject to certain specified exceptions, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the Registration Rights Holders are entitled to notice and certain “piggyback” registration rights allowing them to include their shares in our registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, in their sole discretion, to limit the number of shares included in any such offering under certain circumstances, but not below 30% of the total amount of securities included in such offering.

**Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law**

Our amended and restated certificate of incorporation and our amended and restated bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our Board rather than pursue non-negotiated takeover attempts.

- **Issuance of undesignated preferred stock:** Under our amended and restated certificate of incorporation, our Board has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board. The existence of authorized but unissued shares of preferred stock enables our Board to make it more difficult to attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.
- **Classified board:** Our amended and restated certificate of incorporation establishes a classified Board consisting of three classes of directors, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders to succeed the directors of the same class whose terms are then expiring, with the other classes continuing for the remainder of their respective three-year terms. This provision may have the effect of delaying a change in control of our Board.
- **Election and removal of directors and board vacancies:** Our amended and restated bylaws provide that directors will be elected by a plurality vote. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our Board has the right to increase or decrease the size of the Board and to fill vacancies on the Board. Directors may be removed only for cause by the affirmative vote of at least 66 2/3% of the voting power of the stock outstanding and entitled to vote thereon (which, for the avoidance of doubt, does not include non-voting common stock). Only our Board is authorized to fill vacant directorships. In addition, the number of directors constituting our Board may be set only by

resolution adopted by a majority vote of the directors then in office. These provisions prevent stockholders from increasing the size of our Board and gaining control of our Board by filling the resulting vacancies with its own nominees.

- **Requirements for advance notification of stockholder nominations and proposals:** Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors that specify certain requirements as to the timing, form and content of a stockholder's notice. Business that may be conducted at an annual meeting of stockholders are limited to those matters properly brought before the meeting. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.
- **No written consent of stockholders:** Our amended and restated certificate of incorporation provides that all stockholder actions be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the removal of directors by our stockholders without holding a meeting of stockholders.
- **No stockholder ability to call special meetings:** Our amended and restated certificate of incorporation and amended and restated bylaws provide that only our Board may be able to call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders.
- **Amendments to certificate of incorporation and bylaws:** Any amendment to our amended and restated certificate of incorporation is required to be approved by a majority of our Board as well as, if required by law or our amended and restated certificate of incorporation, a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of provisions to Board classification, stockholder action, certificate amendments and liability of directors and officers must be approved by not less than 66 2/3% of the outstanding shares entitled to vote on the amendment, voting together as a single class. Any amendment to our amended and restated bylaws is required to be approved by either a majority of our Board or not less than 66 2/3% of the outstanding shares entitled to vote on the amendment, voting together as a single class (which, for the avoidance of doubt, does not include non-voting common stock).

These provisions are designed to enhance the likelihood of continued stability in the composition of our Board and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of our company and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

#### ***Delaware General Corporation Law Section 203***

As a Delaware corporation, we are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the DGCL could also have the effect of delaying or preventing a change of control of us.

***Exclusive Forum Selection Clause***

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum to the fullest extent permitted by law for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed by any director, officer or other employee to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee arising pursuant to the DGCL; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (v) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. 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 but the forum selection provisions will not apply to claims brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of imposing additional costs on stockholders in pursuing any such claims or limiting a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits against us or our directors or officers. It is possible that a court could find that such provisions are inapplicable for a particular claim or action or that such provisions are unenforceable. In addition, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

**Transfer Agent and Registrar**

Computershare Trust Company, N.A. serves as the transfer agent and registrar for our common stock. The address of the transfer agent and registrar is 150 Royall Street, Canton, MA 02021.

**Listing**

Our common stock is listed on The Nasdaq Global Market under the symbol "APGE." Our non-voting common stock is not listed on any securities exchange.



## INSIDER TRADING POLICY

(dated June 5, 2024)

### 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 in possession 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, 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 controlled, influenced or managed by them or their Family Members, 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 or restricted stock units or any other type of securities that 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 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 in possession 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. *General Prohibition.* You may not buy, sell, gift or otherwise transact in securities of the Company or a Company Counterparty when you are in possession of MNPI about that company.
2. *No Tipping.* You may not convey MNPI about the Company or a Company Counterparty to anyone else, including family members. You also may not suggest that anyone purchase or sell any company’s securities while you are aware of MNPI about that company.

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. This policy against “tipping” applies to information about the Company and its securities, as well as to information about Company Counterparties. 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 including Company securities in a margin account 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:
- a) purchases and/or sales of securities in public markets;
  - b) sales of securities obtained through the exercise of stock options or vesting of other equity awards granted by the Company;
  - c) making gifts of securities; and
  - d) 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 General Counsel ("GC")<sup>1</sup> 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, GC and outside counsel, and, if required or advisable, approval by the Board of Directors or appropriate board committee.

## **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 GC or attorneys designated by the GC 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 developments, innovations or discoveries (including new targets);
- pending U.S. Food and Drug Administration, European Medicines Agency or other regulatory action;
- clinical data or significant interactions, filings, approval or rulings by a regulatory agency relating to the Company or a Company product;
- clinical trial enrollment status and results (including interim results) and status of pre-clinical or clinical studies;
- changes in intellectual property status, including patent filings, issuances or potential interference and infringement proceedings
- changes in research and/or business strategies

- financial and operating results, estimates, forecasts and projections, including earnings, cash runway, revenue or similar financial information;

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<sup>1</sup> At any time when the Company does not have an active GC, the duties and responsibilities assigned to the GC under this Policy shall be fulfilled by the Chief Financial Officer (“**CFO**”). At any time when the Company does not have an active CFO, the duties and responsibilities assigned to the CFO under this Policy shall be fulfilled by the principal financial officer.

- unpublished financial reports or projections, including knowledge of changes of research analyst views/ratings;
- extraordinary borrowing or liquidity problems;
- 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 regarding an important 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;
- information about major contracts;
- gain or loss of a significant customer or supplier;
- significant product pricing or reimbursement changes;
- a new cybersecurity risk or cybersecurity incident, whether known to be critical or potentially significant;
- product recalls;
- impending financial problems such as impending bankruptcy or liquidity problems;
- the interruption of production or other aspects of a company’s business as a result of an accident, fire, natural disaster or breakdown of labor negotiations;
- major environmental incidents;
- institution of, or developments in, major actual or threatened litigation, investigations, or regulatory actions or proceedings;
- information about Company 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.

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 deciding that the information is material and not trade. 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 GC.

## 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, a filing with the SEC or a widely disseminated statement from a senior officer); 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 GC 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 GC 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 in the possession of MNPI. 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 GC 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. All requests must be submitted to the GC at least two business days in advance of the proposed transaction.<sup>2</sup> **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 GC 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.

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<sup>2</sup> Transactions by the GC (or the GC's Family Members and Controlled Entities) are required to be approved in advance by the Chief Executive Officer (“*CEO*”) or CFO.

#### 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 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 in possession 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 GC.*

**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 GC 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 GC 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 GC (or, in the case of the GC, 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:
  - 2.1. when you are not aware of any MNPI; and
  - 2.2. 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:
  - 3.1. specify the amount, price and date of the sales (or purchases) of Company securities to be effected;
  - 3.2. 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
  - 3.3. 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:
  - 7.1. 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.
  - 7.2. 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 GC 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 GC 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 GC in accordance with the pre-clearance procedures set forth in the Policy and these guidelines. Except in limited circumstances, the GC 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.

**Subsidiary**

Apogee Therapeutics Securities Corporation

**Country of Origin**

United States

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**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 and
- 4) Registration Statement (Form S-8 No. 333-281477) pertaining to the Non-Plan Stock Option Grant of Apogee Therapeutics, Inc.;

of our reports dated March 3, 2025, 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, 2024.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 3, 2025

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**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 3, 2025

By: /s/ Michael Henderson, M.D.  
Michael Henderson, M.D.  
Chief Executive Officer  
(principal executive officer)

**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 3, 2025

By: /s/ Jane Pritchett Henderson  
Jane Pritchett Henderson  
Chief Financial Officer  
*(principal financial and accounting officer)*

**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, 2024, 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 3, 2025

By: /s/ Michael Henderson, M.D.

Michael Henderson, M.D.  
Chief Executive Officer  
*(principal executive officer)*

Date: March 3, 2025

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.

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