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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	93-4958665
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 5, 2024, the registrant had 58,513,198 shares of common stock, $0.00001 par value per share, outstanding, comprising 45,026,556 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.

APOGEE THERAPEUTICS, INC.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly 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 Quarterly 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 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 Quarterly 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, 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;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012; 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 Quarterly 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 Quarterly 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 Quarterly 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 Quarterly 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 Quarterly Report apply only as of the date made and are expressly qualified in their entirety by this and other cautionary statements included in this Quarterly 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 Quarterly 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 trademarks. This Quarterly 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 Quarterly Report, including logos, artwork and other visual displays, may appear without the ®, ^{SM}, or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

PART I – FINANCIAL INFORMATION

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except unit/share data)

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 118,780	$ 118,316
Marketable securities	407,269	277,143
Prepaid expenses and other current assets	8,434	2,950
Total current assets	534,483	398,409
Long-term marketable securities	227,746	—
Property and equipment, net	1,417	377
Right-of-use asset, net	12,126	2,217
Other non-current assets	514	401
Total assets	$ 776,286	$ 401,404
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,216	$ 2,143
Lease liability	2,867	1,101
Accrued expenses	27,528	17,314
Total current liabilities	32,611	20,558
Long-term liabilities:		
Lease liability, net of current	9,273	933
Total liabilities	41,884	21,491
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common Stock; $0.00001 par value, 400,000,000 authorized, 58,509,583 issued and 56,899,295 outstanding as of September 30, 2024; 400,000,000 authorized, 50,655,671 issued and 48,338,769 outstanding as of December 31, 2023	1	—
Additional paid-in capital	969,829	503,354
Accumulated other comprehensive income	3,270	329
Accumulated deficit	(238,698)	(123,770)
Total stockholders' equity	734,402	379,913
Total liabilities and stockholders' equity	$ 776,286	$ 401,404

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

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(UNAUDITED)
(In thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development [1]	$ 45,714	$ 17,069	$ 107,636	$ 39,470
General and administrative [2]	12,972	7,236	33,353	16,378
Total operating expenses	58,686	24,305	140,989	55,848
Loss from operations	(58,686)	(24,305)	(140,989)	(55,848)
Other income, net:				
Interest income, net	9,668	3,465	26,061	3,598
Total other income, net	9,668	3,465	26,061	3,598
Net loss	$ (49,018)	$ (20,840)	$ (114,928)	$ (52,250)
Net loss per share, basic and diluted	$ (0.86)	$ (0.51)	$ (2.11)	$ (3.04)
Weighted-average common shares outstanding, basic and diluted	56,795,544	41,231,379	54,508,496	17,209,842

(1)Includes related-party amounts of $2,447 and $11,125 for the three and nine months ended September 30, 2024, respectively, and $6,624 and $21,083 for the three and nine months ended September 30, 2023, respectively.

(2)No related-party amounts for the three and nine months ended September 30, 2024, and $9 and $53 for the three and nine months ended September 30, 2023, respectively.

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

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Net loss	$ (49,018)	$ (20,840)	$ (114,928)	$ (52,250)
Change in unrealized gains on marketable securities, net of tax	3,559	135	2,941	135
Comprehensive loss	$ (45,459)	$ (20,705)	$ (111,987)	$ (52,115)

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

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(In thousands, except unit/share data)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2023	48,338,769	$ —	$ 503,354	$ (123,770)	$ 329	$ 379,913
Common stock issued, net of issuance costs of $33,045	7,790,321	1	449,954	—	—	449,955
Vesting of restricted stock	237,665	—	—	—	—	—
Issuance of common stock upon exercise of stock options	1,047	—	24	—	—	24
Equity-based compensation expense	—	—	4,186	—	—	4,186
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	(506)	(506)
Net loss	—	—	—	(32,094)	—	(32,094)
Balance at March 31, 2024	56,367,802	$ 1	$ 957,518	$ (155,864)	$ (177)	$ 801,478
Vesting of restricted stock	292,477	$ —	$ —	$ —	$ —	$ —
Issuance of common stock upon exercise of stock options	628	—	14	—	—	14
Issuance of common stock under employee stock purchase plan	15,558	—	377	—	—	377
Equity-based compensation expense	—	—	5,698	—	—	5,698
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	(112)	(112)
Net loss	—	—	—	(33,816)	—	(33,816)
Balance at June 30, 2024	56,676,465	$ 1	$ 963,607	$ (189,680)	$ (289)	$ 773,639
Vesting of restricted stock	203,465	$ —	$ —	$ —	$ —	$ —
Issuance of common stock upon exercise of stock options	19,365	—	383	—	—	383
Equity-based compensation expense	—	—	5,839	—	—	5,839
Change in unrealized gain on marketable securities, net of tax	—	—	—	—	3,559	3,559
Net loss	—	—	—	(49,018)	—	(49,018)
Balance at September 30, 2024	56,899,295	$ 1	$ 969,829	$ (238,698)	$ 3,270	$ 734,402

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

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF PREFERRED UNITS AND STOCKHOLDERS' EQUITY/MEMBERS' DEFICIT
(UNAUDITED)
(In thousands, except unit/share data)

	SERIES A PREFERRED UNITS		SERIES B PREFERRED UNITS		COMMON UNITS		INCENTIVE UNITS		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME	TOTAL MEMBERS' DEFICIT
	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	UNITS	AMOUNT	AMOUNT	AMOUNT	AMOUNT	AMOUNT
Balance at December 31, 2022	20,000,000	$ 71	45,089,212	$ 96	5,000,000	$ 1	1,625,086	$ 2	—	$ —	$ —	$ (39,785)	$ —	$ (35,392)
Equity-based compensation expense	—	—	—	—	—	—	—	1,274	—	—	—	—	—	1,274
Net loss	—	—	—	—	—	—	—	—	—	—	—	(12,525)	—	(12,525)
Balance at March 31, 2023	20,000,000	$ 71	45,089,212	$ 96	5,000,000	$ 1	1,625,086	$ 6	—	$ —	$ —	$ (52,310)	$ —	$ (46,643)
Vesting of incentive units	—	$ —	—	$ —	—	$ —	856,457	$ —	—	$ —	$ —	$ —	$ —	$ —
Equity-based compensation expense	—	—	—	—	—	—	—	1,113	—	—	—	—	—	1,113
Net loss	—	—	—	—	—	—	—	—	—	—	—	(18,885)	—	(18,885)
Balance at June 30, 2023	20,000,000	$ 71	45,089,212	$ 96	5,000,000	$ 1	2,481,543	$ 9	—	$ —	$ —	$ (71,195)	$ —	$ (64,415)
Vesting of incentive units	—	$ —	—	$ —	—	$ —	65,881	$ —	—	$ —	$ —	$ —	$ —	$ —
Exchange of preferred, common, and incentive units into common stock	(20,000,000)	(71)	(45,089,212)	(96)	(5,000,000)	(1)	(2,547,424)	(6)	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 common stock	—	—	—	—	—	—	—	—	122,683	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	—	—	157	—	—	1,348	—	—	1,505
Change in unrealized gain on marketable securities, net of tax	—	—	—	—	—	—	—	—	—	—	—	—	135	135
Net loss	—	—	—	—	—	—	—	—	—	—	—	(20,840)	—	(20,840)
Balance at September 30, 2023	—	$ —	—	$ —	—	$ —	—	$ —	48,017,621	$ —	$ 501,143	$ (92,035)	$ 135	$ 409,243

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

APOGEE THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(UNAUDITED)
(In thousands)

	NINE MONTHS ENDED SEPTEMBER 30, 2024	2023
Cash flows from operating activities:		
Net loss	$ (114,928)	$ (52,250)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation expense	113	—
Equity-based compensation expense	15,723	3,892
Amortization of discounts on marketable securities	(9,255)	(232)
Non-cash lease expense	933	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,484)	(3,402)
Other non-current assets	(113)	—
Accounts payable	73	577
Operating lease liability	(736)	—
Accrued expenses	10,214	6,408
Net cash used in operating activities	(103,460)	(45,007)
Cash flows from investing activities:		
Purchases of marketable securities	(588,866)	(234,218)
Maturities of marketable securities	243,190	—
Purchases of property and equipment	(1,153)	—
Net cash used in investing activities	(346,829)	(234,218)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	449,955	315,604
Proceeds from exercise of options and employee stock purchase plan purchases	798	—
Net cash provided by financing activities	450,753	315,604
Increase in cash, cash equivalents and restricted cash	464	36,379
Cash, cash equivalents and restricted cash, beginning of period	118,610	151,890
Cash, cash equivalents and restricted cash, end of period	$ 119,074	$ 188,269
Supplemental disclosures of non-cash activities:		
Exchange of 72,570,755 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	$ —
Deferred financing issuance costs in accounts payable	$ —	$ 213
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 118,780	$ 188,269
Restricted cash	294	$ —
Total	$ 119,074	$ 188,269

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

APOGEE THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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, 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 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-4Rα, and was subsequently amended in November 2022 to include an additional selected target, OX40L. Under the 2022 Option Agreement, the Company has the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's 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-4Rα 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-4Rα, 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.

On July 18, 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, APG808, APG990 and APG333, 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 $238.7 million as of September 30, 2024. Further, the Company incurred a net loss of $114.9 million and experienced negative cash flows from operations of $103.5 million for the nine months ended September 30, 2024. Based on the Company's current operating plan, it estimates that its existing cash and cash equivalents of $118.8 million, marketable securities of $407.3 million and long-term marketable securities of $227.7 million as of September 30, 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

There have been no material changes to the significant accounting policies as disclosed in Note 2 to the Company consolidated financial statements for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2024, except as noted below.

Basis of Presentation

The condensed consolidated financial statements prior to the Reorganization include the accounts of Apogee Therapeutics, LLC and its wholly-owned subsidiary. The condensed consolidated financial statements subsequent to the Reorganization include the accounts of Apogee Therapeutics, Inc. and its wholly-owned subsidiaries, Apogee Biologics, Inc. and Apogee Therapeutics Securities Corporation, which was formed as a Massachusetts security corporation in September 2024.

These condensed 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 unaudited condensed 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 interim 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. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

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 September 30, 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:

	ESTIMATED USEFUL LIFE
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.

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 condensed consolidated statements of operations and 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 condensed 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 condensed 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 condensed 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 September 30, 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 September 30, 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 one third-party contract manufacturer to produce and process its programs, APG777, APG808, APG990 and APG333 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 September 30, 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 condensed 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 SEPTEMBER 30, 2024			
	COST	UNREALIZED GAINS	UNREALIZED LOSSES	FAIR VALUE
Marketable securities				
Maturities within one year:				
U.S. treasury securities	$ 166,651	$ 554	$ —	$ 167,205
Debt securities issued by U.S. government agencies	158,505	338	—	158,843
Commercial paper	30,217	98	—	30,315
Corporate debt securities	50,651	255	—	50,906
Total maturities within one year	406,024	1,245	—	407,269
Maturities between one and two years:				
U.S. treasury securities	$ 98,184	$ 744	$ (8)	$ 98,920
Debt securities issued by U.S. government agencies	98,131	1,190	—	99,321
Corporate debt securities	29,406	100	(1)	29,505
Total maturities between one and two years	225,721	2,034	(9)	227,746
Total marketable securities	$ 631,745	$ 3,279	$ (9)	$ 635,015

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

As of September 30, 2024, the Company had four securities with a total fair market value of $28.1 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 September 30, 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 nine months ended September 30, 2024 and 2023.

4.Fair Value Measurements

The Company estimated the fair value of the Tranche Options, as defined below (see Note 10), at the time of issuance and subsequently remeasured them at each reporting period and prior to settlement, which occurred prior to December 31, 2022. The fair value of the Tranche Options was determined using a contingent forward model, which considered as inputs the estimated fair value of the preferred units as of each valuation date, the risk-free interest rate, probability of achievement, salvage value and estimated time to each tranche closing. The most significant assumptions in the contingent forward model impacting the fair value of the Tranche Options is the fair value of the Company's Series A Preferred Unit, probability of achievement and time to the tranche closing as of each measurement date. The Company determined the fair value per share of the underlying preferred unit by taking into consideration the most recent sales of its preferred units, results obtained from third-party valuations and additional factors the Company deems relevant.

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

	AS OF SEPTEMBER 30, 2024			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Cash equivalents:				
Money market funds	$ 111,924	$ —	$ —	$ 111,924
U.S. treasury securities	—	—	—	—
Commercial paper	—	—	—	—
Debt securities issued by U.S. government agencies	—	—	—	—
Marketable securities:				
U.S. treasury securities	266,125	—	—	266,125
Debt securities issued by U.S. government agencies	—	258,164	—	258,164
Commercial paper	—	30,315	—	30,315
Corporate debt securities	—	80,411	—	80,411
Total	$ 378,049	$ 368,890	$ —	$ 746,939

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

5.Prepaids and Other Assets

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

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Prepaid expenses	$ 3,265	$ 1,736
Interest receivable	4,773	1,214
Other current assets	396	—
Total	$ 8,434	$ 2,950

As of September 30, 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 September 30, 2024 and December 31, 2023.

6.Property and Equipment, net

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Lab equipment	$ 1,285	$ 377
Leasehold improvements	245	—
Less: Accumulated depreciation	(113)	—
Total	$ 1,417	$ 377

The Company recognized an immaterial amount of depreciation expense for the three months ended September 30, 2024 and $0.1 million of depreciation expense for the nine months ended September 30, 2024. The Company recognized an immaterial amount of depreciation expense for the three and nine months ended September 30, 2023.

7.Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Accrued external research and development expenses	$ 5,242	$ 6,685
Accrued manufacturing expenses	13,676	9,219
Accrued other	1,693	1,243
Accrued employee compensation	6,917	167
Total	$ 27,528	$ 17,314

8.Other Significant Agreements

Paragon Option and License Agreements

For the three and nine months ended September 30, 2024, the Company recognized $2.4 million and $11.1 million, respectively, of research and development expense in connection with services provided by Paragon under the Option and License Agreements. For the three and nine months ended September 30, 2023, the Company recognized $6.6 million and $21.1 million, respectively, 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 the 2022 Option Agreement. Under the terms of the 2022 Option Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. The 2022 Option Agreement initially included two selected targets, IL-13 and IL-4Rα, and was subsequently amended in November 2022 to include an additional selected target, OX40L. Under the 2022 Option Agreement, the Company has the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture and commercialize the antibodies and products directed to the selected targets (each, an "Option"). From time to time, the Company can choose to add additional targets to the collaboration by mutual agreement with Paragon.

Pursuant to the terms of the 2022 Option Agreement, the parties initiated certain research programs that generally focus 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 and Paragon agreed on an initial Research Plan that outlined the services that will be performed commencing at inception of the arrangement related to IL-13 and IL-4Rα. The Research Plan for OX40L was agreed to prior to December 31, 2022. The Company's exclusive option with respect to each Research Program is exercisable at its 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 Tranche Options of the Series A Preferred Unit financing (see Note 10). Through September 30, 2024, the Company had

issued a total of 5,000,000 common units to Paragon with an aggregate fair value of $2.2 million on the grant date. 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. The Company expenses the service fees as the associated costs are incurred when the underlying services are rendered. Such amounts are classified within research and development expenses in the accompanying condensed consolidated statement of operations and comprehensive loss.

The Company concluded that the rights obtained under the 2022 Option Agreement represent an asset acquisition whereby the underlying assets comprise in-process research and development assets with no alternative future use. The 2022 Option Agreement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license options, which represent a group of similar identifiable assets. Therefore, the aggregate acquisition cost of $3.5 million, related to the upfront cash and equity payments, was recognized as acquired in-process research and development expense, which is reported as a component of research and development expense during the period from February 4, 2022 (inception) to December 31, 2022. Amounts paid as on-going development cost reimbursements associated with services being rendered under the related Research Programs is recognized as research and development expense when incurred.

In November 2023, the Company entered the 2023 Option Agreement. 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 is 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 outlined the services that will be performed commencing at inception of the arrangement related to TSLP. The Company's exclusive option with respect to each Research Program is exercisable at its 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.

Unless terminated earlier, the 2023 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 "2023 Term"). Upon the expiration of the 2023 Term for all then-existing Research Programs, under the 2023 Option Agreement, the 2023 Option Agreement will automatically expire in its entirety. The Company may terminate the 2023 Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that the Company must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Each party has the right to terminate the 2023 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.

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.

License Agreements

In November 2022, the Company exercised its option available under the 2022 Option Agreement with respect to the IL-13 Research Program. Upon such exercise, the parties entered into an associated license agreement (the "IL-13 License Agreement"). In April 2023, the Company exercised its option available under the 2022 Option Agreement with respect to the IL- 4Rα Research Program and the OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the "IL-4Rα License Agreement" and the "OX40L License Agreement," respectively. In August 2024, the Company exercised its option available under the

2023 Option Agreement with respect to the TSLP Research Program (the "TSLP License Agreement" and collectively with the IL-13 License Agreement, the IL-4Rα License Agreement and the OX40L License Agreement, the "License Agreements"). Under the terms of each 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 target 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 license. The Company is solely responsible for the continued development, manufacture and commercialization of products at its own cost and expense for each licensed target.

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

Upon execution of the IL-13 License Agreement, the Company paid Paragon a $1.0 million fee for the nomination of a development candidate. In August 2023, the Company announced the dosing of its first participant in the Phase 1 trial of APG777 and incurred a milestone payment of $2.0 million to Paragon in the third quarter of 2023. In November 2023, the Company finalized the nomination of a development candidate under the IL-4Rα License Agreement and made a milestone payment of $1.0 million to Paragon in the fourth quarter of 2023. In March 2024, the Company announced the dosing of its first participant in the Phase 1 trial of APG808 in healthy volunteers 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 in healthy volunteers 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 expects to pay a $3.0 million milestone payment to Paragon 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 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 APG777, APG990, APG808 and APG333 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 busy 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 three and nine months ended September 30, 2024, the Company recognized $14.7 million and $27.9 million, respectively, of research and development expense in connection with the WuXi Biologics MSA, compared to $6.4 million and $9.6 million for the three and nine months ended September 30, 2023, respectively.

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's 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, APG808, APG990 and APG333 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, it 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 its 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.

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 September 30, 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 September 30, 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 June 30, 2023, 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 September 30, 2024, 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 beings 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 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 "ATM Facility"). 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. As of September 30, 2024, the Company has made no sales pursuant to the Sale Agreement.

As of September 30, 2024, 58,509,583 and 56,899,295 shares of common stock were issued and outstanding, respectively. The 58,509,583 shares of common stock issued are comprised of 45,022,941 shares of voting common stock and 13,486,642 shares of non-voting common stock. As of September 30, 2024, there were 1,610,288 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:

	NINE MONTHS ENDED SEPTEMBER 30, 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% - 90%

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 nine months ended September 30, 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	(706,614)	$ 5.42
Unvested restricted common stock as of September 30, 2024	1,610,288	$ 5.27

The fair value of restricted stock vested during the three and nine months ended September 30, 2024 was $0.9 million and $3.8 million, respectively.

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 September 30, 2024, the number of shares of common stock available for future grants under the 2023 Plan is equal to 5,778,639 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:

	THREE MONTHS ENDED SEPTEMBER 30, 2024	NINE MONTHS ENDED SEPTEMBER 30, 2024
Common stock fair value	$40.49 - $58.74	$33.50 - $66.45
Risk-free interest rate	3.6% - 4.0%	3.6% - 4.7%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0 - 6.25	5.5 - 6.25
Expected volatility	94.7% - 95.4%	94.7% - 96.4%

The following table provides a summary of stock option activity during the nine months ended September 30, 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	828,513	$ 44.64	—	—
Exercised	(21,040)	$ 20.05	—	—
Forfeited	(34,284)	$ 19.57	—	—
Outstanding as of September 30, 2024	3,279,206	$ 27.37	9.28	102,974
Vested and expected to vest as of September 30, 2024	3,279,206	$ 27.37	9.28	102,974
Exercisable as of September 30, 2024	497,473	$ 21.91	9.13	18,324

The fair value of options vested during the three and nine months ended September 30, 2024 was $5.1 million and $9.8 million, respectively.

The following table provides a summary of the unvested restricted stock unit activity under the 2023 Plan during the nine months ended September 30, 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
Vested	(26,993)	22.86
Unvested restricted stock units as of September 30, 2024	117,097	$ 22.86

The fair value of restricted stock units vested during the three and nine months ended September 30, 2024 was $0.2 million and $0.6 million, respectively.

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. The first purchase period ended in January 2024. As of September 30, 2024, 15,558 shares have been issued under the ESPP and 946,832 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):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Research and development expense	$ 2,464	$ 417	$ 6,548	$ 755
General and administrative expense	3,375	1,088	9,175	3,137
Total	$ 5,839	$ 1,505	$ 15,723	$ 3,892

As of September 30, 2024, the total unrecognized compensation expense related to the Company's stock options, unvested restricted stock and ESPP was $71.3 million, which the Company expects to recognize over a weighted-average period of approximately 2.7 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 September 30, 2024 and December 31, 2023, $0.5 million and $5.2 million were due to Paragon, respectively. For the three and nine months ended September 30, 2024, the Company incurred research and development expenses of $2.4 million and $11.1 million, respectively. For the three and nine months ended September 30, 2023, the Company incurred research and development expenses of $6.6 million and $21.1 million, respectively, 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):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (49,018)	$ (20,840)	$ (114,928)	$ (52,250)
Net loss attributable to common stockholders, basic and diluted	$ (49,018)	$ (20,840)	$ (114,928)	$ (52,250)
Denominator:				
Weighted average shares of common stock outstanding, basic and diluted	56,795,544	41,231,379	54,508,496	17,209,842
Net loss per share attributable to common stockholders, basic and diluted	$ (0.86)	$ (0.51)	$ (2.11)	$ (3.04)

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:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Stock options	3,279,206	637,546	3,279,206	637,546
Unvested restricted common stock	1,610,288	2,656,675	1,610,288	2,656,675
Unvested restricted stock units	117,097	—	117,097	—
Total	5,006,591	3,294,221	5,006,591	3,294,221

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. As of September 30,

2024, the remaining lease term was 2.2 years and the incremental borrowing rate used to determine the operating lease liability was 10%.

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. The incremental borrowing rate used to determine the operating lease liability for this space was 6%.

As of September 30, 2024, the current and non-current operating lease liabilities were $2.9 million and $9.3 million, respectively. The Company incurred lease expense of $0.6 million and $1.3 million for the three and nine months ended September 30, 2024, respectively.

16.Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the financial statements as of September 30, 2024 and events which occurred subsequently but not recognized in the financial statements. No subsequent events have occurred that require disclosure, except as disclosed below.

In October 2024, the Company finalized the nomination of a development candidate under the TSLP License Agreement and expects to pay a $3.0 million milestone payment to Paragon in the fourth quarter of 2024.

Item 2. 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 condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report, as well as our audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"). 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 Quarterly Report, particularly in the section titled "Risk Factors." We urge you to consider these factors carefully in evaluating the forward-looking statements contained in this Quarterly 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 potential for differentiated efficacy and dosing in the largest inflammatory and immunology ("I&I") markets, including for the treatment of atopic dermatitis ("AD"), asthma, 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. We commenced our operations in February 2022 as a Delaware limited liability company named Apogee Therapeutics, LLC. We were founded by leading healthcare investors, Fairmount Funds and Venrock Healthcare Capital Partners, and have 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. Apogee Therapeutics, Inc., a successor to Apogee Therapeutics, LLC, was formed as a Delaware corporation in June 2023 in preparation for our initial public offering ("IPO"). 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. In addition, we engage significantly with third parties, including Paragon Therapeutics, Inc. ("Paragon"), who is also a related party, to perform ongoing research and development activities and other services on our behalf.

Our pipeline comprises four antibody programs being developed initially for the treatment of I&I indications as monotherapies and combinations. Our most advanced program is APG777, which we are initially developing for the treatment of AD, the largest and least penetrated I&I market. Our other programs include APG808, APG990 and APG333. With four validated targets in its 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

In August 2023, we announced the dosing of our first participant in our first clinical trial for APG777 in Australia. The APG777 Phase 1 trial is a double-blind, placebo-controlled study in healthy volunteers and consists of a single-ascending dose ("SAD") component and a multiple-ascending dose ("MAD") component. The trial enrolled 40 healthy adult subjects into three SAD and two MAD cohorts. The primary endpoint is safety and a key secondary endpoint is pharmacokinetics ("PK"). The Phase 1 trial is ongoing and in March 2024, we announced positive interim safety and PK data from this trial. PK data showed a half-life of approximately 75 days across doses tested and pharmacodynamic ("PD") data showed deep and sustained inhibition of key AD biomarkers pSTAT6 and TARC for approximately three months (longest available follow-up, with inhibition still ongoing at time of the data cut for the March 2024 announcement). APG777, in single doses up to 1,200 mg and multiple doses of 300 mg, was well tolerated and showed a favorable safety profile, in line with the existing body of third-party evidence for the safety of the anti-IL-13 class. In October 2024 we announced positive updated data from the Phase 1 trial. PK data was consistent with what was previously reported and the PD profile showed near complete inhibition of pSTAT6 and sustained TARC inhibition up to 9 months. In the first quarter of 2024, we filed an investigational new drug application ("IND") in support of a Phase 1 trial in healthy volunteers in the United States for subjects of Japanese descent and have completed dosing in that trial.

In May 2024, we commenced dosing in the Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD with 16-week topline data from Part A expected in the second half of 2025. The trial is designed to combine the typical Phase 2a and 2b portions

of a clinical trial into a single protocol. Part A is expected to enroll approximately 110 patients randomized 2:1 to APG777 and placebo with primary endpoint of mean percentage changes in EASI score from baseline to week 16. Part B of the Phase 2 trial is a randomized, placebo-controlled dose optimization with approximately 360 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 continue to APG777 maintenance treatment, which will evaluate three- to six-month dosing intervals. Enrollment in the Phase 2 trial is progressing globally.

APG990 – anti-OX40L antibody, same mechanism of action as amlitelimab

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 Australia. APG990 utilizes advanced antibody engineering to target OX40L, which we are initially developing for the treatment of AD. OX40L is located further upstream in the inflammatory pathway than IL-13 or IL-4Rα and targeting it could potentially have broader impact on the inflammatory cascade by inhibiting Type 1, Type 2 and Type 3 pathways. AD is a heterogeneous patient population and varies by age, severity and ethnicity. With current approved biologics only targeting two mechanisms of action (IL-13 and IL-4Rα) in AD, OX40L could represent another therapeutic option for patients, especially the portion of patients who do not benefit from currently available treatments. 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. In our head-to-head studies of APG990 and amlitelimab in non-human primates ("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. We plan to develop APG777 and APG990 together 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. We believe these combined mechanisms offer the potential for improved clinical responses over monotherapy while our planned approach of coformulating two extended half-life monoclonal antibodies ("mAbs") holds the potential for best-in-class dosing. We plan to initiate the first clinical trial of this combination in 2025.

APG808 – anti-IL4Rα antibody, same mechanism of action as DUPIXENT

In November 2023, we finalized the nomination of a development candidate for APG808 and in March 2024, we commenced dosing of the first healthy volunteer participants in the Phase 1 trial in Australia and in September 2024, we commenced dosing of the first asthma patients as a cohort in that Phase 1 trial. APG808 is an SQ extended half-life mAb targeting IL-4Rα, a target with clinical validation across eight different Type 2 allergic diseases. APG808 has similar binding as a first generation mAb, DUPIXENT, with femtomolar affinity for IL-4Rα and has demonstrated similar inhibition to DUPIXENT across 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). Additionally, in our head-to-head studies of APG808 and DUPIXENT in non-human primates, 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. Based on these preclinical studies, we believe that the longer half-life could support dosing either every 6 weeks or every 2 months in the clinic, which, if future clinical trials are successful, would represent a significant improvement compared to DUPIXENT, which is approved for every 2-week dosing in COPD. We expect interim Phase 1 PK and safety data from our Phase 1 trial in healthy volunteers in the fourth quarter of 2024 and initial proof-of-concept data in asthma in the first half of 2025.

APG333 – anti-TSLP antibody, same mechanism of action as TEZPIRE

In October 2024, we finalized the nomination of a development candidate for 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 I&I indications, 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 and has demonstrated similar potency to TEZSPIRE across our head-to-head preclinical assays. Additionally, in our head-to-head studies of APG333 and TEZSPIRE in non-human primates, 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 3 months in the clinic. We expect to initiate a Phase 1 APG333 clinical trial in healthy volunteers in late 2024 or early 2025. Pending the Phase 1 data, we have the opportunity to study APG777 in combination with APG333 to drive potential best in class efficacy in respiratory conditions.

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 $114.9 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $238.7 million. We expect to continue to incur significantly increased expenses for the foreseeable future if and as we:

- advance our programs, APG777, APG808, APG990 and APG333 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 the programs we may develop;
- 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 $118.8 million, marketable securities of $407.3 million and long-term marketable securities of $227.7 million as of September 30, 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, 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, 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.

Collaboration, License and Services Agreements

Paragon Option Agreements

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

Pursuant to the terms of the 2022 Option Agreement, the parties initiated certain research programs that generally focused on a particular target (each, a “Research Program”). Each Research Program will be aimed at discovering, generating, identifying and/or characterizing antibodies directed to the respective target. For each Research Program, the parties established a research plan that sets forth the activities that will be conducted, and the associated research budget (each, a “Research Plan”). Upon execution of the 2022

Option Agreement, we agreed with Paragon on an initial Research Plan that outlined the services that will be performed commencing at inception of the arrangement related to IL-13 and IL-4Rα. The Research Plan for OX40L was agreed to prior to December 31, 2022. Our exclusive option with respect to 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 (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. Through September 30, 2024, we had issued a total of 5,000,000 common units to Paragon with an aggregate fair value of $2.2 million on the grant date, which subsequently were exchanged for common stock following the IPO. 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. We expense the service fees as the associated costs are incurred when the underlying services are rendered. Such amounts are classified within research and development expenses in our consolidated statement of operations and comprehensive loss.

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 is 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. In the first quarter of 2024, we paid Paragon a $2.0 million fee for a Research Program for TSLP. 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.

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

Paragon License Agreements

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

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

Upon execution of the IL-13 License Agreement, we paid Paragon a $1.0 million fee for the nomination of a development candidate. In August 2023, we announced the dosing of our first participant in the Phase 1 trial of APG777 and have accordingly recorded research and development expense for the milestone payment of $2.0 million to Paragon in the year ended December 31, 2023. In November 2023, we finalized the nomination of a development candidate under the IL-4Rα License Agreement and made a milestone payment of $1.0 million to Paragon in the fourth quarter of 2023. In March 2024, we announced the first dosing of a human patient in a Phase 1 trial of APG808, and accordingly have recorded research and development expense of $2.0 million for the milestone payment 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 expect to make a milestone payment of $3.0 million to Paragon 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, APG808, APG990, and APG333 programs, as well as some of our other 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's 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, APG808, APG990 and APG333 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.

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

Overview of Financial Results

Revenue

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

Operating Expenses

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

Research and Development

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

- 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, 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 incur increased 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 tax credit carryforwards will not be realized.

As of December 31, 2023, we had U.S. federal NOL carryforwards of approximately $23.6 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 $6.5 million, which will begin to expire in 2043 for state tax purposes. As of December 31, 2023, we also had U.S. federal and research and development tax credit carryforwards of approximately $2.7 million, which may be available to reduce future tax liabilities. We also had California research and development credit carryforwards of approximately $0.7 million. The U.S. federal research and development tax credit carryforwards expire at various dates beginning in 2042 and the state 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.

Comparison of the Three Months Ended September 30, 2024 and 2023

Results of Operations

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

	THREE MONTHS ENDED SEPTEMBER 30,		
	2024	2023	$ CHANGE
Operating expenses:			
Research and development	$ 45,714	$ 17,069	$ 28,645
General and administrative	12,972	7,236	5,736
Total operating expenses	58,686	24,305	34,381
Loss from operations	(58,686)	(24,305)	(34,381)
Other income, net:			
Interest income	9,668	3,465	6,203
Total other income, net	9,668	3,465	6,203
Net loss	$ (49,018)	$ (20,840)	$ (28,178)

Research and Development Expense

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

	THREE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
External research and development costs by program:		
APG777	$ 14,928	$ 5,369
APG808 [1]	2,093	—
APG990 [2]	4,694	—
Unallocated research and development costs:		
External-discovery related costs and other [3]	11,979	8,698
Personnel-related (including equity-based compensation)	12,020	3,002
Total research and development expenses	$ 45,714	$ 17,069

(1)External research and development costs for APG808 for the three months ended September 30, 2023 were recorded as unallocated external discovery related costs as the development candidate for APG808 was nominated in November 2023.

(2)External research and development costs for APG990 for the three months ended September 30, 2023 were recorded as unallocated external discovery related costs as the development candidate for APG990 was nominated in May 2024.

(3)External research and development costs for APG333 for the three months ended September 30, 2024 and 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 three months ended September 30, 2024 and 2023 were $45.7 million and $17.1 million, respectively. The increase of $28.6 million was primarily driven by further development of our APG777, APG808, APG990 and APG333 programs and advancement of our pipeline into clinical trials, as well as increases in personnel costs, including equity-based compensation expense, associated with the growth in our research and development team.

Research and development expense related to the APG777 program increased by $9.6 million in the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily driven by an increase in clinical trial-related expenses and clinical manufacturing activities to support our Phase 1 and Phase 2 clinical trials. Research and development expense related to the APG808 and APG990 programs were $2.1 million and $4.7 million for the three months ended September 30, 2024, respectively. No such expenses were recorded in the three months ended September 30, 2023, as APG808 and APG990 expenses were recorded as unallocated external-discovery related costs until the program candidates were nominated in November 2023 and May 2024, respectively. Other external-discovery related costs increased by $3.3 million in the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily driven by the advancement of our APG333 program. Personnel-related expenses increased $9.0 million in the three months ended September 30, 2024, compared to the three months ended September 30, 2023, primarily due to increased headcount and equity-based compensation.

General and Administrative Expense

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

	THREE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
Personnel-related (including equity-based compensation)	$ 7,195	$ 3,483
Legal and professional fees	2,031	2,022
Other	3,746	1,731
Total general and administrative expenses	$ 12,972	$ 7,236

General and administrative expenses for the three months ended September 30, 2024 were $13.0 million, compared to $7.2 million for the three months ended September 30, 2023. The increase of $5.7 million was primarily due to an increase in personnel costs of $3.7 million, driven by increased headcount and equity-based compensation. Additionally, other expenses increased $2.0 million, primarily due to increases in IT related costs, directors and officers 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 $6.2 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023, which was primarily related to interest on our cash, cash equivalents and marketable securities.

Comparison of the Nine Months Ended September 30, 2024 and 2023

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

	NINE MONTHS ENDED SEPTEMBER 30, 2024	2023	$ CHANGE
Operating expenses:			
Research and development	$ 107,636	$ 39,470	$ 68,166
General and administrative	33,353	16,378	16,975
Total operating expenses	140,989	55,848	85,141
Loss from operations	(140,989)	(55,848)	(85,141)
Other income, net:			
Interest income	26,061	3,598	22,463
Total other income, net	26,061	3,598	22,463
Net loss	$ (114,928)	$ (52,250)	$ (62,678)

Research and Development Expense

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

	NINE MONTHS ENDED SEPTEMBER 30, 2024	2023
External research and development costs by program:		
APG777	$ 29,022	$ 17,663
APG808 [1]	8,265	—
APG990 [2]	15,577	—
Unallocated research and development costs:		
External-discovery related costs and other [3]	24,983	16,961
Personnel-related (including equity-based compensation)	29,789	4,846
Total research and development expenses	$ 107,636	$ 39,470

(1)External research and development costs for APG808 for the nine months ended September 30, 2023 were recorded as unallocated external discovery related costs as the development candidate for APG808 was nominated in November 2023.

(2)External research and development costs for APG990 for the nine months ended September 30, 2023 were recorded as unallocated external discovery related costs as the development candidate for APG990 was nominated in May 2024.

(3)External research and development costs for APG333 for the nine months ended September 30, 2024 and 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 nine months ended September 30, 2024 and 2023 were $107.6 million and $39.5 million, respectively. The increase of $68.2 million was primarily driven by further development of our APG777, APG808, APG990 and APG333 programs and advancement of our pipeline into clinical trials, as well as increases in personnel costs, including 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 nine months ended September 30, 2024 and 2023 were $29.0 million and $17.7 million, respectively. The increase of $11.4 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 nine months ended September 30, 2024, we recorded $8.3 million of research and development expense related to the APG808 program, which included a $2.0 million milestone payment related to the first dosing of a human patient in a Phase 1 clinical trial in March 2024. No such expense was recorded in the nine months ended September 30, 2023, as APG808 expenses were recorded as unallocated external-discovery related costs until the program candidate was nominated in November 2023. For the nine months ended September 30, 2024, we recorded $15.6 million of research and development expense related to the APG990 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 human

participants in a Phase 1 clinical trial in August 2024, respectively. No such expense was recorded in the nine months ended September 30, 2023, as APG990 expenses were recorded as unallocated external-discovery related costs until the program candidate was nominated in 2024. Other external-discovery related costs increased by $8.0 million in the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, primarily driven by a one-time non-refundable payment of $2.0 million to Paragon in January 2024 for finalizing the Research Plan for TSLP, and advancement of our APG333 program. Personnel-related expenses increased $24.9 million in the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, primarily due to increased headcount and equity-based compensation.

General and Administrative Expense

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
Personnel-related (including equity-based compensation)	$ 19,627	$ 7,669
Legal and professional fees	5,208	5,446
Other	8,518	3,263
Total general and administrative expenses	$ 33,353	$ 16,378

General and administrative expenses for the nine months ended September 30, 2024 were $33.4 million, compared to $16.4 million for the nine months ended September 30, 2023. The increase of $17.0 million was primarily due to an increase in personnel costs of $12.0 million, driven by increased headcount and share-based compensation. Additionally, other general and administrative expenses increased $5.3 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 $22.5 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 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 and our March 2024 Offering. As of September 30, 2024, we had cash and cash equivalents of $118.8 million, marketable securities of $407.3 million and long-term marketable securities of $227.7 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”). As of September 30, 2024, we have made no sales pursuant to the Sale Agreement.

Cash Flows

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023
Net cash, cash equivalents, and restricted cash provided by (used in):		
Operating activities	$ (103,460)	$ (45,007)
Investing activities	(346,829)	(234,218)
Financing activities	450,753	315,604
Net increase in cash equivalents, and restricted cash	$ 464	$ 36,379

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 nine months ended September 30, 2024, operating activities used $103.5 million of cash, primarily due to a net loss of $114.9 million and amortization of discounts on marketable securities of $9.3 million. This was partially offset by a non-cash charge of $15.7 million for equity-based compensation and net changes in our operating assets and liabilities of $4.0 million.

For the nine months ended September 30, 2023, operating activities used $45.0 million of cash, primarily due to a net loss of $52.3 million, partially offset by non-cash charges of $3.9 million for equity-based compensation and net changes in our operating assets and liabilities of $3.6 million.

Net Cash used in Investing Activities

For the nine months ended September 30, 2024, net cash used in investing activities of $346.8 million was primarily related to the $588.9 million purchase of marketable securities and $1.2 million purchase of property and equipment. This was partially offset by $243.2 million in maturities of marketable securities.

During the nine months ended September 30, 2023, net cash used in investing activities of $234.2 million was entirely related to purchases of marketable securities.

Net Cash provided by Financing Activities

For the nine months ended September 30, 2024, financing activities provided $450.8 million of cash, primarily related to the issuance and sale of 7,790,321 shares of common stock, net of paid issuance costs, in our March 2024 Offering.

For the nine months ended September 30, 2023, financing activities provided $315.6 million of cash related to the issuance and sale of common stock in 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, APG808, APG990 and APG333 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 September 30, 2024, we had $118.8 million of cash and cash equivalents, $407.3 million of marketable securities and $227.7 million of long-term marketable securities. Based on our current operating plan, as of the date of this Quarterly 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 Quarterly 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 September 30, 2024, we have incurred $9.0 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 condensed 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 condensed 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 Quarterly Report, we believe that our most critical accounting policies are those relating to Research and Development Expenses, Asset Acquisitions and Acquired In-Process Research and Development Expenses, and Equity-Based Compensation, which are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgment and Estimates" in our Annual Report on Form 10-K. There have been no material changes to our critical accounting policies from those described in the Annual Report on Form 10-K.

JOBS Act Transition Period and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (i) providing an auditor's attestation report on our system of internal controls over financial

reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (A) following the fifth anniversary of the completion of our IPO, (B) in which we have total annual gross revenues of at least $1.235 billion or (C) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock and non-voting common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company," as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), meaning that the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Based on the aggregate market value of our common stock held by non-affiliates as of June 30, 2024, we believe we will become a "large accelerated filer" and no longer qualify as an emerging growth company or smaller reporting company as of December 31, 2024. Because we believe our emerging growth company and non-accelerated filer status will expire on December 31, 2024, we expect to be required, pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, to include in our Annual Report on Form 10-K for the year ending December 31, 2024, an attestation report as to the effectiveness of our internal control over financial reporting that is issued by our independent registered public accounting firm. In addition, beginning with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2025, we expect to no longer be permitted to take advantage of the reduced reporting requirements applicable to smaller reporting companies.

For more information, see the section titled "Risk Factors—Risks Related to Our Common Stock—*We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.*"

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 condensed consolidated financial statements included elsewhere in this Quarterly 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 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act for this reporting period and are not required to provide the information required under this Item.

Item 4. 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, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures. Based on this evaluation of our disclosure controls and procedures as of September 30, 2024, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level. 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 are 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, as appropriate to allow timely decisions

regarding required disclosure. 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

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 Quarterly Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed 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 Quarterly Report. 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 Quarterly 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 most advanced programs, APG777, APG808, APG990, and APG333, and our anticipated clinical trials of these 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 most advanced programs, APG777, APG808, APG990, and APG333, and advance our other 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. 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 a net loss of $114.9 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $238.7 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 complete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific 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” in our Annual Report on Form 10-K 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 European Union ("EU").

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a program if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our 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 most advanced programs, APG777, APG808, APG990, and APG333, and our ongoing and anticipated trials of APG777, APG808, APG990, and APG333, including in combination, may not be successful.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our most advanced programs, APG777, APG808, APG990, and APG333, 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 initiated our Phase 2 clinical trial for APG777 in patients with moderate-to-severe AD and commenced the dosing of patients in May 2024, initiated our Phase 1 clinical trial for APG808 in March 2024, and initiated our Phase 1 clinical trial for APG990 in August 2024. 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, APG808, APG990, or APG333, 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 in AD, PK, and safety data from our Phase 1 trial in healthy volunteers, and initial proof-of-concept data in asthma, 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.

We may ultimately discover that utilizing half-life extension technologies for our specific targets and indications and any programs resulting therefrom do not possess certain properties required for therapeutic effectiveness. We currently have only preclinical data regarding the increased half-life properties of our programs and the same results may not be seen in humans. In addition, programs using half-life extension technologies may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. This technology and any programs resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways.

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 cost 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 ongoing 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, 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 most advanced programs, APG777, APG808, APG990, and APG333, 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 and EBGLYSS, both 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 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 APG777 and APG777 in combination with APG990 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. APG777 in combination with APG990 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 APG777, APG808, and APG990 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 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 Funds Management LLC, which beneficially owns more than 5% of Paragon, beneficially owns more than 5% of our capital stock and has two seats on our Board of Directors (the "Board").

Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our collaborators or licensors experiences delays in performance of, or fails to perform its obligations under their agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, our pipeline and programs and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our 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, 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 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 proposed 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, APG808, APG990, and APG333, and are working to establish a relationship for clinical and commercial scale supply of APG777. If there should be any disruption in such supply arrangement, including any adverse events affecting our 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” in our Annual Report on Form 10-K 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 experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, 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" in our Annual Report on Form 10-K 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, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, 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 is considering legislation that would 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 platform 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 United States Patent and Trademark Office ("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 would 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, the United States Supreme Court in Amgen, Inc. v. Sanofi (Amgen) recently 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 or applications, if we obtain such patents and applications 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 generics or 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, APG808, and APG990, 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.

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, 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 risk evaluation and mitigation strategy 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" in our Annual Report on Form 10-K 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" in our Annual Report on Form 10-K 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 unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such programs at competitive prices 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" in our Annual Report on Form 10-K 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, if any.

In some countries, particularly member states of the European Union, 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” in our Annual Report on Form 10-K 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 Quarterly 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 Quarterly 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 investors purchase their shares, investors may not realize any return on their investment in us and may lose some or all of their 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.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

We cannot predict what effect, if any, future 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 substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect 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.

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 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.

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. As an emerging growth company, we are only required to provide two years of audited financial statements (in addition to any required unaudited interim financial statements) and correspondingly reduced management discussion and analysis of financial condition and results of operations disclosure. In addition, we are not required to obtain auditor attestation of reporting on internal control over financial reporting, we have reduced disclosure obligations regarding executive compensation and we are not required to hold non-binding advisory votes on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations in this Quarterly Report. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. These provisions allow an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of such extended transition period. We cannot predict whether investors will find our common stock less attractive as a result of its reliance on these exemptions. If some investors find our common stock to be less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile than the current trading market and price of our common stock.

Further, there is no guarantee that the exemptions available under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, we will incur additional compliance costs, which may impact our financial condition.

We will remain an emerging growth company until the earliest of: (i) the end of the fiscal year in which we have a total annual gross revenue of $1.235 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our IPO; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the end of the fiscal year in which the market value of common stock held by non-affiliates exceeds $700 million as of the prior June 30. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, for so long as we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

Based on the aggregate market value of our common stock held by non-affiliates as of June 30, 2024, we believe we will become a “large accelerated filer” and no longer qualify as an emerging growth company or smaller reporting company as of December 31, 2024.

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. 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, and particularly after we are no longer an “emerging growth company” or a “smaller reporting 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 will be required to report upon the effectiveness of our internal control over financial reporting beginning with our annual report for our fiscal year ending December 31, 2024. By losing our previous status as an “emerging growth company” and becoming an “accelerated filer” or a “large accelerated filer,” we will be 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 such as the COVID-19 pandemic, 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 has raised interest rates multiple times in response to concerns about inflation and it may 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 Israel and Hamas, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from IPO of Common Stock

On July 18, 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 Prospectus.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

N/A.

Item 5. Other Information

Trading Plans

During the fiscal quarter ended September 30, 2024, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (in each case, as defined in Item 408(a) of Regulation S-K), except as described below.

On August 21, 2024, Dr. Michael Henderson, the Company's Chief Executive Officer, adopted a trading plan intended to satisfy Rule 10b5-1(c) to sell up to 210,000 shares of our common stock over a period ending August 14, 2025, subject to certain conditions.

On August 21, 2024, Dr. Carl Dambkowski, the Company's Chief Medical Officer, adopted a trading plan intended to satisfy Rule 10b5-1(c) to sell up to 109,035 shares of our common stock over a period ending December 31, 2025, comprising exercises of vested stock options and sales of shares of our common stock, subject to certain conditions.

On September 27, 2024, Jane Pritchett Henderson, the Company's Chief Financial Officer, adopted a trading plan intended to satisfy Rule 10b5-1(c) to sell up to 10,500 shares of our common stock over a period ending December 31, 2025, subject to certain conditions.

Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report are set forth below.

Exhibit Number	Description of Exhibit
2.1	Contribution and Exchange Agreement, effective July 13, 2023, by and among the Company and the Unit Holders named therein (filed with the SEC as Exhibit 2.1 to the Company's Form 10-Q filed on August 28, 2023).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed with the SEC as Exhibit 3.1 to the Company's Form 10-Q filed on August 28, 2023).
3.2	Amended and Restated Bylaws of the Registrant (filed with the SEC as Exhibit 3.2 to the Company's Form 10-Q filed on August 28, 2023).
4.1	Form of Common Stock Certificate of the Registrant (filed with the SEC as Exhibit 4.1 to the Company's Form S-1/A filed on July 3, 2023).
4.2	Registration Rights Agreement, dated July 13, 2023, by and among the Company and the Investors named therein (filed with the SEC as Exhibit 4.2 to the Company's Form 10-Q filed on August 28, 2023).
10.1	Open Market Sale Agreement℠ dated August 12, 2024 between Apogee Therapeutics, Inc. and Jefferies LLC (filed with the SEC as Exhibit 1.2 to the Company's Form S-3 filed on August 12 2024).
31.1*	Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934
31.2*	Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934
32.1*(1)	Certification of the principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) under the Securities Exchange Act of 1934
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

(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.

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: November 12, 2024

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

Date: November 12, 2024

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

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Henderson, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q 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)) 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)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

(c)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: November 12, 2024

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jane Pritchett Henderson, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q 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)) 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)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

(c)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: November 12, 2024

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Apogee Therapeutics, Inc. (the "Company") for the period ending September 30, 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 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: November 12, 2024

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

Date: November 12, 2024

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.