#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

#### **FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2023 OR

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

For the transition period from to Commission File Number: 001-41740

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

Delaware (State or other jurisdiction incorporation or organizat

88-0588063 (I.R.S. Employer entification Numl

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	$\boxtimes$	Smaller reporting company	X
		Emerging growth company	X

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 6, 2023, the registrant had 50,674,296 shares of common stock, \$0.00001 par value per share, outstanding, comprised of 37,187,654 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.

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 estimates and assumptions. All statements, other than statements of historical facts included in this Quarterly Report on Form 10-Q, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital requirements or financing needs, plans or intentions relating to product candidates and markets and business trends and other information referred to 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 are not historical facts and reflect our current views with respect to future events. Given the significant 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 on Form 10-Q. Such risks, uncertainties and other factors include, among others, the following risks, uncertainties and factors:

- 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, and marketable securities will be sufficient to fund our future operating expenses and capital expenditure requirements; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012.

There may be other factors that may cause our actual results to differ materially from the forward-looking statements expressed or implied in this Quarterly Report on Form 10-Q, 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 on Form 10-Q 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 on Form 10-Q may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will 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 and you should not place undue reliance on our forward-looking statements.

All forward-looking statements in this Quarterly Report on Form 10-Q apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this Quarterly Report on Form 10-Q. Except as required by law, we disclaim any intent to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changes in assumptions or otherwise.

In addition, statements that "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 on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such 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.

#### PART I – FINANCIAL INFORMATION

#### APOGEE THERAPEUTICS, INC.

### CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(UNAUDITED)
(In thousands, except unit/share data)

	SEP	TEMBER 30, 2023	DE	CEMBER 31, 2022
Assets				
Current assets:				
Cash and cash equivalents	\$	188,269	\$	151,890
Marketable securities		234,585		_
Prepaid expenses and other current assets		3,567		165
Total current assets		426,421		152,055
Total assets	\$	426,421	\$	152,055
Liabilities, preferred units and stockholders' equity/members' deficit				
Current liabilities:				
Accounts payable	\$	1,208	\$	418
Accrued expenses		15,970		9,562
Total current liabilities		17,178		9,980
Total liabilities		17,178		9,980
Commitments and contingencies (Note 8)				
Series A Preferred Units; no units authorized, issued and outstanding at September 30, 2023; 20,000,000				
units authorized, issued and outstanding as of December 31, 2022		—		28,971
Series B Preferred Units; no units authorized, issued and outstanding at September 30, 2023; 45,089,212				
units authorized, issued and outstanding as of December 31, 2022		_		148,496
Stockholders' equity/members' deficit:				
Common Units; no units authorized, issued and outstanding at September 30, 2023; 5,000,000 units				
authorized, issued and outstanding as of December 31, 2022		_		2,251
Incentive Units; no units authorized, issued and outstanding at September 30, 2023; 12,412,473 units				
authorized, 9,648,374 issued and 1,625,086 outstanding as of December 31, 2022				2,142
Preferred Stock; 10,000,000 authorized, \$0.00001 par value, no shares issued and outstanding September				
30, 2023; No shares authorized, issued and outstanding at December 31, 2022		_		_
Common Stock; 400,000,000 authorized, \$0.00001 par value, 50,674,296 issued and 48,017,621				
outstanding as of September 30, 2023; No shares authorized, issued and outstanding at December 31, 2022				
Additional paid-in capital		501,143		_
Accumulated other comprehensive income		135		
Accumulated deficit		(92,035)		(39,785)
Total stockholders' equity/members' deficit		409,243		(35,392)
1 5	\$	409,243	\$	152,055
Total liabilities, preferred units and stockholders' equity/members' deficit	φ	420,421	ф —	152,055

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

#### CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

(UNAUDITED)

(In thousands, except share and per share data)

TH	REE MONTHS EN	DED SI	EPTEMBER 30,	NI	NE MONTHS ENDED	PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO			
	2023		2022	SEPT	EMBER 30, 2023	SEP	TEMBER 30, 2022		
\$	17,069	\$	9,885	\$	39,470	\$	15,578		
	7,236		622		16,378		1,050		
	24,305		10,507		55,848		16,628		
	(24,305)		(10,507)	_	(55,848)		(16,628)		
	3,465				3,598		—		
			(9,150)		—		(9,150)		
	3,465		(9,150)		3,598		(9,150)		
\$	(20,840)	\$	(19,657)	\$	(52,250)	\$	(25,778)		
\$	(0.51)	\$	(9.46)	\$	(3.04)	\$	(17.00)		
		-		-					
	41,231,379		2,078,804		17,209,842		1,516,736		
		2023 \$ 17,069 7,236 24,305 (24,305) 3,465 3,465 \$ (20,840) \$ (0.51)	2023         \$ 17,069       \$         7,236       24,305         24,305       (24,305)         3,465       3,465         \$ (20,840)       \$         \$ (0.51)       \$	\$       17,069       \$       9,885         7,236       622         24,305       10,507         (24,305)       (10,507)         3,465          -       (9,150)         3,465       (9,150)         \$       (20,840)       \$       (19,657)         \$       (0.51)       \$       (9.46)	THREE MONTHS ENDED SEPTEMBER 30,           2023         2022         SEPT           \$         17,069         \$         9,885         \$           7,236         622         2         2         2           24,305         10,507         1         2         2         2           24,305         10,507         1         2 <t< td=""><td><math display="block">\begin{array}{c c c c c c c c c c c c c c c c c c c </math></td><td>THREE MONTHS ENDED SEPTEMBER 30, 2023         NINE MONTHS ENDED         FEI (II SEPTEMBER 30, 2023           \$ 17,069         \$ 9,885         \$ 39,470         \$           \$ 17,069         \$ 9,885         \$ 39,470         \$           7,236         622         16,378        </td></t<>	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	THREE MONTHS ENDED SEPTEMBER 30, 2023         NINE MONTHS ENDED         FEI (II SEPTEMBER 30, 2023           \$ 17,069         \$ 9,885         \$ 39,470         \$           \$ 17,069         \$ 9,885         \$ 39,470         \$           7,236         622         16,378		

Includes related-party amounts of \$6,624 for the three months ended September 30, 2023, \$9,596 for the three months ended September 30, 2022, \$21,083 for the nine months ended September 30, 2023 and \$15,219 for the period from February 4, 2022 (inception) to September 30, 2022.

(2) Includes related-party amounts of \$9 for the three months ended September 30, 2023, none for the three months ended September 30, 2022,
 \$53 for the nine months ended September 30, 2023 and \$273 for the period from February 4, 2022 (inception) to September 30, 2022.

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

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

	THR	EE MONTHS EN	DED S			INE MONTHS ENDED		PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO		
		2023		2022	SEPTEMBER 30, 2023			SEPTEMBER 30, 2022		
Net loss	\$	(20,840)	\$	(19,657)	\$	(52,250)	\$	(25,778)		
Change in unrealized gains on marketable securities,										
net of tax		135		_		135		—		
Comprehensive loss	\$	(20,705)	\$	(19,657)	\$	(52,115)	\$	(25,778)		

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

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

	SERII PREFEI UNI UNITS	RRED	SERII PREFE UNI UNITS	RRED	COMN UNI UNITS		INCEN UNI UNITS		COMN STO UNITS		ADI	DITIONAL PAID-IN A CAPITAL AMOUNT		ACCUMULATED OTHER COMPREHENSIVE INCOME AMOUNT	TOTAL STOCKHOLDERS EQUITY / MEMBERS' DEFICIT AMOUNT
Balance at December 31, 2022	20,000,000	\$ 28,971	45,089,212	\$ 148,496	5,000,000	\$ 2,251	1,625,086	\$ 2,142	_	s —	\$	_ \$	(39,785)	s —	\$ (35,392
Equity-based compensation															
expense	_	_	_	_	_	_	_	1,274	_	_		_	_	_	1,274
Net loss	_	_	_	_	_	_	_		_	_		_	(12,525)	_	(12,525
Balance at															
March 31, 2023	20,000,000	\$ 28,971	45,089,212	\$ 148,496	5,000,000	\$ 2,251	1,625,086	\$ 3,416	_	s —	\$	- 9	5 (52,310)	s —	\$ (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	\$ 28,971	45,089,212	\$ 148,496	5,000,000	\$ 2,251	2,481,543	\$ 4,529	_	s —	\$	- \$	6 (71,195)	\$ —	\$ (64,415
Vesting of incentive															
units	—	—	—	—		—	65,881	—	—	—		—	—	—	—
Exchange of															
preferred, common,															
and incentive units	(20,000,000)	(20.071)	(45,000,010)	(1.40,400)	(5.000.000)	(2.251)	(0.545.404)	(4.606)	27 507 420			104.404			177.467
into common stock Common stock	(20,000,000)	(28,971)	(45,089,212)	(148,496)	(5,000,000)	(2,251)	(2,547,424)	(4,686)	27,597,438	_		184,404	-	_	177,467
Common stock issued in IPO, net of															
issuance costs of												245 204			245 204
\$29,666	_	_	—	_	_	_	_	_	20,297,500	_		315,391	—	_	315,391
Vesting of restricted common stock									122,683	_					
Share-based		_		_			_	_	122,005			_	_	_	
compensation															
expense								157				1.348			1,505
Change in					_			137				1,540			1,305
unrealized gain on															
marketable															
securities, net of tax	_	_	_	_	_	_	_	_	_	_		_	_	135	135
Net loss	_	_	_	_	_	_	_	_	_	_		_	(20,840)		(20,840
Balance at													(20,010)		(20,040
September 30, 2023	_	s —	_	s —	_ :	5 —	_	s —	48,017,621	s —	\$	501,143	6 (92,035)	\$ 135	\$ 409,243
					'						-		(. ,000)		

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

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

	SERIE PREFEI UNI UNITS	RRED	PREF	IES B ERRED NTS AMOUNT	UN	IMON ITS AMOUNT	INCENT UNIT UNITS AN	rs	COMI STO	ск	CA	DNAL PAID-IN A APITAL AOUNT	CCUMULATED DEFICIT AMOUNT	ACCUMULATED OTHER COMPREHENSIVE INCOMI AMOUNT	TOTA MEMBE DEFIC	ERS' IT
Balance at February 4, 2022 (inception)		s _		s —	_	s —	- \$			_	s	— \$	_	s —	s	_
Issuance of Common Units - initial closing	_	_	_	_	1,250,000	1,688	_	_	_	_	9		_		1,	,688
Issuance of Series A Preferred Units – initial closing, net of tranche rights of \$1,050 and issuance costs of \$179	5,000,000	3,771	_	_	_	_	_	_	_	_		_	_	_		_
Net loss	_	_	_	_	-	_	—	_	_	_		-	(4,305)	_	(4,	,305)
Balance at March 31, 2022	5,000,000	3,771		_	1,250,000	1,688	_	_		_		_	(4,305)		(2,	,617)
Net loss		_	_	_		_	_	_	_	_		_	(1,816)			,816)
Balance at June 30, 2022	5,000,000	\$ 3,771	_	s —	1,250,000	\$ 1,688	— \$	_	— \$	—	\$	— \$	(6,121)	\$	\$ (4,-	,433)
Issuance of Common Units - 2nd closing	_	_	_	_	1,250,000	_	_	_	_	_		_	_	_		_
Issuance of Series A preferred units - subsequent closings	5,000,000	5,000	_	_	_	_	_	_	_	_		_	_	_		_
Reclassification of tranche rights upon issuance of preferred units	_	(600)	_	_	_	_	_	_	_	_		_	_	_		_
Net loss		—	_	_		_		—		—		_	(19,657)		(19,	,657)
Balance at September 30, 2022	10,000,000	\$ 8,171		\$ —	2,500,000	\$ 1,688	— \$	_	— \$	_	\$	— \$	(25,778)	\$	\$ (24,	,090)

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

#### CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

## (UNAUDITED) (In thousands)

	 NE MONTHS ENDED EMBER 30, 2023	FEBRU (INCE	OD FROM JARY 4, 2022 PTION) TO IBER 30, 2022
Cash flows from operating activities:	 		
Net loss	\$ (52,250)	\$	(25,778)
Adjustments to reconcile net loss to net cash used in operating activities:			
Equity-based compensation expense	3,892		—
Loss on remeasurement of tranche option liability	—		9,150
Non-cash research and development license expense	—		1,688
Amortization of discounts on marketable securities	(232)		—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,402)		—
Accounts payable	577		36
Accrued expenses	 6,408		7,666
Net cash used in operating activities	(45,007)		(7,238)
Cash flows from investing activities:			
Purchase of marketable securities	(234,218)		—
Net cash used in investing activities	 (234,218)		
Cash flows from financing activities:	 i i		
Proceeds from issuance of Series A Preferred Units and the tranche option, net	—		9,821
Proceeds from issuance of common stock, net of issuance costs	315,604		_
Net cash provided by financing activities	 315,604		9,821
Increase in cash and cash equivalents	36,379		2,583
Cash and cash equivalents, beginning of period	151,890		
Cash and cash equivalents, end of period	\$ 188,269	\$	2,583
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	\$	—
Settlement of Series A Preferred Units tranche obligation	\$ _	\$	600
Deferred financing issuance costs in accounts payable	\$ 213	\$	_

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

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### (UNAUDITED)

#### 1. Nature of the Business

Apogee Therapeutics, Inc., together with its consolidated subsidiary (collectively, "Apogee" or the "Company"), a successor to Apogee Therapeutics, LLC, is a biotechnology company seeking to develop differentiated biologics for the treatment of atopic dermatitis, asthma, chronic obstructive pulmonary disease and related inflammatory and immunology indications with high unmet need. The Company's antibody programs are designed to overcome limitations of existing therapies by leveraging clinically validated mechanisms and incorporating advanced antibody engineering to optimize half-life and other properties designed.

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 with significant experience in clinical development. 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. The Company operates as a virtual company and, thus, does not maintain a corporate headquarters or other significant facilities. 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 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. In November 2023, the Company entered into an additional antibody discovery and option agreement with Paragon (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.

In November 2022, the Company exercised its option available under the 2022 Option Agreement with respect to the IL-13 Research Program (as defined below) and, in April 2023, the Company exercised its options available under the 2022 Option Agreement with respect to the IL-4R $\alpha$  Research Program and 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. The Company is solely responsible for the development, manufacture and commercialization of IL-13, IL-4R $\alpha$  and OX40L 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. and Apogee Therapeutics, LLC became a wholly-owned subsidiary 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, including \$0.2 million in deferred financing issuance costs in accounts payable as of September 30, 2023. The shares of Apogee Therapeutics, Inc. began trading on the Nasdaq Global Market on July 14, 2023 under the ticker symbol APGE.

The Company is subject to risks and uncertainties common to early stage companies in the biotechnology industry, including, but not limited to, completing preclinical studies and clinical trials, obtaining regulatory approval for its programs, market acceptance of products, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, and the ability to raise additional capital to fund operations. The Company's two most advanced programs currently under development, APG777 and APG808, as well as other programs, 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 condensed consolidated financial statements are issued. The Company had an accumulated deficit of \$92.0 million as of September 30, 2023. Further, the Company incurred a net loss of \$52.3 million and experienced negative cash flows from operations of \$45.0 million for the nine months ended September 30, 2023. Based on the Company's current operating plan, it estimates that its existing cash and cash equivalents of \$188.3 million, and marketable securities of \$234.6 million as of September 30, 2023 will be sufficient to enable the Company to fund its operating expenses and capital requirements through at least the next twelve months from the issuance of these condensed 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's consolidated financial statements for the period from February 4, 2022 (inception) to December 31, 2022 included in the Company's final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"), on July 17, 2023, 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 subsidiary.

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

#### 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 and U.S. treasury securities.

#### Available-For-Sale Securities

The Company's investments are comprised of U.S. government agency securities and U.S. treasury 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 as current assets on the condensed consolidated balance sheets as they mature within one year from the balance sheet date.



#### 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 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 Company generally issues equity awards that are subject to either service-based vesting conditions and in limited instances, servicebased 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 equitybased compensation awards granted. As of September 30, 2023, 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 condensed 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 and cash equivalents. The Company maintains its cash and cash equivalents 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, 2023 and December 31, 2022, 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 relies on one third-party contract manufacturer to produce and process its two most advanced programs, APG777 and APG808, for preclinical and clinical activities. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs could be adversely affected by a significant interruption in the supply of the necessary materials. A significant amount of the Company's research and development activities are performed under its agreements with Paragon (see Note 7).

#### **Off-Balance Sheet Risk**

As of September 30, 2023 and December 31, 2022, 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 available-for-sale 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, including the three and nine months ended September 30, 2023, the weightedaverage shares of common stock outstanding include the weighted average number of common units outstanding prior to the Reorganization.



#### 3. Available-For-Sale Securities

The Company did not hold any available-for-sale securities as of December 31, 2022. The following is a summary of the Company's investing portfolio as of September 30, 2023 (in thousands):

	AN	AORTIZED COST	 AS OF SEPTE UNRE/ GAINS	FAIR VALUE		
Cash equivalents:				 		
U.S. treasury securities	\$	59,685	\$ 8	\$ _	\$	59,693
Marketable securities						
U.S. treasury securities		117,635	6	(13)		117,628
Debt securities issued by U.S. government agencies		116,823	148	(14)		116,957
	\$	294,143	\$ 162	\$ (27)	\$	294,278

As of September 30, 2023, the Company had seven securities with a total fair market value of \$71.4 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, 2023. All securities held by the Company have a maturity date of one year or less.

Securities are evaluated at the end of each reporting period. The Company did not record any impairment related to its available-for-sale securities during the three and nine months ended September 30, 2023.

#### 4. Fair Value Measurements

The Company estimated the fair value of the Tranche Options, as defined below (see Note 9), 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 as of September 30, 2023 (in thousands):

AS OF SEPTEMBER 30, 2023												
	LEVEL 1	_	LEVEL 2	]	LEVEL 3	3 TOTA						
\$	103,776	\$		\$		\$	103,776					
	59,693						59,693					
	117,628						117,628					
	—		116,957				116,957					
\$	281,097	\$	116,957	\$	_	\$	398,054					
	_	59,693 117,628 —	\$ 103,776 \$ 59,693 117,628	LEVEL 1         LEVEL 2           \$ 103,776         \$ —           59,693         —           117,628         —            116,957	LEVEL 1     LEVEL 2       \$ 103,776     \$       59,693        117,628         116,957	LEVEL 1         LEVEL 2         LEVEL 3           \$ 103,776         \$         \$           59,693             117,628              116,957	LEVEL 1     LEVEL 2     LEVEL 3       \$ 103,776     \$     \$       59,693         117,628          116,957					

The following table provides a reconciliation of all assets and liabilities measured at fair value using Level 3 significant unobservable inputs which were settled during the period from February 4, 2022 (inception) to September 30, 2022 (in thousands):

	TRANCI	RRED UNIT HE OPTION SSET	PREFERRED UNIT TRANCHE OPTION (LIABILITY)	PREFERRED UNIT TRANCHE OPTION, NET
Balance as of February 4, 2022 (inception)	\$		\$ —	\$ —
Issuance		650	(1,700)	(1,050)
Change in fair value		(50)	(9,100)	(9,150)
Transfer to temporary equity upon settlement		(600)		(600)
Balance as of September 30, 2022	\$	_	\$ (10,800)	\$ (10,800)

#### 5. Prepaids and Other Current Assets

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

	SEPTEME 202		DEC	EMBER 31, 2022
Prepaid expenses	\$	2,156	\$	108
Other current assets		1,411		57
Total	\$	3,567	\$	165

#### 6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	SEPT	EMBER 30, 2023	DEC	EMBER 31, 2022
Accrued external research and development expenses	\$	13,057	\$	8,847
Accrued other		692		200
Accrued employee compensation		2,221		515
Total	\$	15,970	\$	9,562

#### 7. Other Significant Agreements

#### **Paragon Option Agreements**

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

Pursuant to the terms of the 2022 Option Agreement, the parties initiated certain research programs that generally 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 9). Through December 31, 2022, 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 \$2.9 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 September 30, 2022. Amounts paid as on-going development expense when incurred.

In November 2023, the Company entered into an additional antibody discovery and option agreement with Paragon (the "2023 Option Agreement," and together with the 2022 Option Agreement, collectively the "Option Agreements"). Under the terms of the 2023 Option Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. The 2023 Option Agreement initially includes one undisclosed target. 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 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 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. The Company and Paragon will agree on an initial Research Plan that outlines the services that will be performed commencing at inception of the arrangement related to the undisclosed target. 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. There is no payment due upon exercise of an Option pursuant to the 2023 Option Agreement. Following entry into the 2023 Option Agreement, the Company and Paragon will negotiate a form of License Agreement to be entered into in the event that the Company exercises its exclusive option with respect to each Research Program, which License Agreement will include certain pre-agreed economic and other business terms.

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 223 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.

For the three months ended September 30, 2022 and for the period from February 4, 2022 (inception) to September 30, 2022, the Company recognized \$9.6 million and \$15.5 million, respectively, and for the three and nine months ended September 30, 2023, the Company recognized \$4.4 million and \$12.1 million, respectively, of research and development expense in connection with services provided by Paragon under the Option Agreements, including nonrefundable fees following the finalization of a Research Plan.

#### **Paragon License Agreements**

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

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. 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 dosed 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. The nomination of a development candidate under the IL-4Rα License Agreement and the OX40L License Agreement had not yet occurred as of September 30, 2023. Except for the two milestone payments totaling an aggregate of \$3.0 million, no other milestone or royalty payments have become due to Paragon through September 30, 2023. In November 2023, the Company finalized the nomination of a development candidate under the IL-4Rα License Agreement and will make a milestone payment of \$1.0 million to Paragon in the fourth quarter of 2023.

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 the 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 productby-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. No expense was recognized for the three months ended September 30, 2022 and for the period from February 4, 2022 (inception) to September 30, 2022, as a program candidate was not nominated until November 2022. For the three and nine months ended September 30, 2023, the Company recognized \$2.3 million and \$9.1 million, respectively, of research and development expense in connection with services provided by Paragon under the License Agreements.

#### 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 and APG808 programs, as well as the Company's other 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, 2023, the Company recognized \$6.4 million and \$9.6 million, respectively, of research and development expense in connection with the WuXi Biologics MSA subsequent to novation. As of September 30, 2023, there were no non-cancelable obligations under the WuXi Biologics MSA.

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

In June 2022, Paragon and WuXi Biologics entered into a cell line license agreement (the "Cell Line License Agreement"), which was subsequently novated to the Company by Paragon in the second quarter of 2023. Under the Cell Line License Agreement, the Company received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics'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 and APG808 programs.

In consideration for the license, the Company agreed to pay WuXi Biologics a non-refundable license fee of \$150,000 for each licensed cell line. 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.

#### 8. Commitments and Contingencies

#### Other Contracts

Currently, all of the Company's preclinical and clinical drug manufacturing, storage, distribution or quality testing are outsourced to thirdparty 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. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never 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, 2023 and December 31, 2022.

#### 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.

#### 9. Preferred Shares

As of December 31, 2022, the Company had authorized, issued and outstanding an aggregate of 65,089,212 preferred units, of which 20,000,000 units had been designated as Series A Preferred Units and 45,089,212 units had been designated as Series B Preferred Units. All outstanding preferred units were exchanged for 24,987,750 shares of common stock (or non-voting common stock in lieu thereof) in connection with the IPO in July 2023. As of September 30, 2023, the Company did not have any outstanding preferred units.

#### Series A Preferred Units

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

Company of \$5.0 million, and incurred \$0.2 million of issuance costs. The Series A Agreement provided for three tranche option closings following the initial closing (the "Tranche Options"), which Tranche Option closings were subject to approval of the Board of Managers of Apogee Therapeutics, LLC (the "Board of Managers"), which was controlled by the holders of the Series A Preferred Units. The Board of Managers approved all such subsequent closings resulting in investors purchasing 5,000,000 Series A Preferred Units in each of the three subsequent Tranche Option closings throughout 2022. As a result, the Company received an aggregate of \$20.0 million in gross proceeds associated with the Series A Agreement.

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

The Company's preferred units as of December 31, 2022 consisted of the following (in thousands, except unit amounts):

	PREFERRED UNITS AUTHORIZED	PREFERRED UNITS ISSUED AND OUTSTANDING	C	ARRYING VALUE	UIDATION EFERENCE
Series A Preferred Units	20,000,000	20,000,000	\$	28,971	\$ 20,000
Series B Preferred Units	45,089,212	45,089,212		148,496	149,000
Total	65,089,212	65,089,212	\$	177,467	\$ 169,000

#### 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.

#### 10. 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. As of September 30, 2023, 50,674,296 and 48,017,621 shares of common stock were issued and outstanding, respectively. The 50,674,296 shares of common stock issued is comprised of 37,187,654 shares of voting common stock, and 13,486,642 shares of non-voting common stock, respectively. As of September 30, 2023, there are 2,656,675 shares of unvested restricted common stock included within the shares of common stock issued.

As of December 31, 2022, the Company had 5,000,000 common units authorized, issued and outstanding.

#### 11. 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 equitybased 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 is estimated on the grant date using either an option pricing method ("OPM"), or a hybrid method, both of which use 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
Expected volatility	84% - 90%



The following table summarizes the Company's unvested incentive unit activity:

	NUMBER OF UNITS	AV GRAN	EIGHTED- VERAGE T DATE FAIR VE PER UNIT
Unvested incentive units as of December 31, 2022	8,023,288	\$	1.20
Granted	4,621,901	\$	1.32
Vested	(922,338)	\$	1.54
Exchanged for unvested restricted common stock	(11,722,851)	\$	1.22
Unvested incentive units as of September 30, 2023		\$	—

#### **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, 2023:

	NUMBER OF SHARES	AVE GRANT I	HTED- RAGE DATE FAIR ER SHARE
Unvested restricted common stock as of December 31, 2022	_	\$	
Exchange of incentive units	2,779,358	\$	5.16
Vested	(122,683)	\$	3.78
Unvested restricted common stock as of September 30, 2023	2,656,675	\$	5.22

#### 2023 Equity Incentive Plan

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. The number of shares of common stock reserved for issuance under the 2023 Plan is equal to 6,706,037 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, 2023
Common stock fair value	\$17.00 - \$23.60
Risk free interest rate	1.8% - 2.1%
Expected dividend yield	0.0%
Expected term (in years)	5.75 - 6.25
Expected volatility	96.8% - 99.9%

The following table provides a summary of stock option activity under the 2023 Plan during the nine months ended September 30, 2023:

	OPTIONS	VEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM		AGGREGATE INTRINSIC VALUE I THOUSANDS)
Outstanding as of December 31, 2022		\$ _		\$	—
Granted	637,546	\$ 20.28	9.84	\$	_
Outstanding as of September 30, 2023	637,546	\$ 20.28	9.84	\$	1,317
Vested and expected to vest as of September 30, 2023	637,546	\$ 20.28	9.84	\$	1,317
Exerciseable as of September 30, 2023	1,389	\$ 23.60	9.89	\$	

#### 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. A total of 479,003 shares of common stock were reserved for issuance under the ESPP. As of September 30, 2023, no shares have been issued under the ESPP.

#### **Equity-Based Compensation Expense**

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 MON ENDED SEPTEM 2023		NINE M ENDED SEPT 202	EMBER 30,	FEBRUARY 4, 2022 (INCEPTION) to SEPTEMBER 30, 2022		
Research and development expense	\$	417	\$	755	\$	—	
General and administrative expense		1,088		3,137		—	
Total	\$	1,505	\$	3,892	\$		

As of September 30, 2023, the total unrecognized compensation expense related to the Company's unvested restricted stock and stock options was \$21.4 million, which the Company expects to recognize over a weighted-average period of approximately 3.0 years. For the period from February 4, 2022 (inception) to September 30, 2022, the Company recognized an additional \$1.7 million of equity-based compensation expense, in connection with the additional common units issued under the 2022 Option Agreement with Paragon.

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 is 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 will result in the forfeiture of the award. Prior to receiving stockholder approval for the second option, neither a grant date nor a service inception date will occur, and no compensation cost is recognized for the award. Should stockholder approval be received at the 2024 Annual Meeting of Stockholders, a cumulative catch-up in equity-based compensation for the second option will be recognized on the date of stockholder approval.

#### 12. Related Parties

Under the Option Agreements and the License Agreements, Paragon, a member of the Company which was founded by a Series A 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 7). As of September 30, 2023 and December 31, 2022, \$6.6 million and \$8.0 million was due to Paragon, respectively. The Company incurred \$6.6 million and \$21.1 million of research and development expenses for the three and nine months ended



September 30, 2023, respectively. The Company incurred \$9.6 million and \$15.2 million of research and development expenses for the three months ended September 30, 2022 and for the period from February 4, 2022 (inception) to September 30, 2022, respectively.

#### 13. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

Numerator:	THREE MONTHS ENDED SEPTEMBER 30, 2023 2022				EN	NINE MONTHS IDED SEPTEMBER 30, 2023	PERIOD FROM FEBRUARY 4 (INCEPTION) TO SEPTEMBER 30, 2022		
Net loss	\$	(20,840)	\$	(19,657)	\$	(52,250)	\$	(25,778)	
Net loss attributable to common stockholders,	. <u> </u>		<u> </u>		<u> </u>	<u> </u>	-	<u> </u>	
basic and diluted	\$	(20,840)	\$	(19,657)	\$	(52,250)	\$	(25,778)	
Denominator:	-								
Weighted average shares of common stock									
outstanding, basic and diluted		41,231,379		2,078,804		17,209,842		1,516,736	
Net loss per share attributable to common							-		
stockholders, basic and diluted	\$	(0.51)	\$	(9.46)	\$	(3.04)	\$	(17.00)	

The following potential common shares, presented based on amounts outstanding 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 END 2023	ED SEPTEMBER 30, 2022	NINE MONTHS ENDED SEPTEMBER 30, 2023	PERIOD FROM FEBRUARY 4 (INCEPTION) TO SEPTEMBER 30, 2022
Series A Preferred Units		10,000,000	<u></u>	10,000,000
Stock options	637,546		637,546	
Unvested restricted common stock	2,656,675	_	2,656,675	_
Total	3,294,221	10,000,000	3,294,221	10,000,000

#### 14. 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, 2023 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 November 2023, the Company finalized the nomination of a development candidate under the IL-4Rα License Agreement and will make a milestone payment of \$1.0 million to Paragon in the fourth quarter of 2023.

In November 2023, the Company entered into the 2023 Option Agreement with Paragon. 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.

#### 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 on Form 10-Q (this "Quarterly Report"), as well as our audited consolidated financial statements and the related notes included in our final prospectus for our initial public offering ("IPO") filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act") on July 17, 2023 (the "Prospectus"). The following discussion contains forward-looking statements that reflect our current plans, estimates and beliefs. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Our actual results 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 subsidiary.

#### Overview

We are a biotechnology company seeking to develop differentiated biologics for the treatment of atopic dermatitis ("AD"), asthma, chronic obstructive pulmonary disease ("COPD"), and related inflammatory and immunology ("I&I") indications with high unmet need. Our antibody programs leverage clinically validated mechanisms and incorporate advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. 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 with significant experience in clinical development. Apogee Therapeutics, ILC, was formed as a Delaware corporation in June 2023 in preparation for our initial public offering ("IPO"). We operate as a virtual company and, thus, do not maintain a corporate headquarters or other significant facilities. 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 programs being developed initially for the treatment of I&I indications. Our two most advanced programs, APG777 and APG808, which we are initially developing for the treatment of AD and COPD, respectively, target the same mechanism of action as lebrikizumab and DUPIXENT (dupilumab), respectively. Moreover, we are evaluating APG777 in additional I&I indications, including asthma, alopecia areata, chronic rhinosinusitis with nasal polyps, chronic spontaneous urticaria, eosinophilic esophagitis and prurigo nodularis. Our earlier-stage programs, APG990 and APG222, utilize advanced antibody engineering to target OX40L and both IL-13 and OX40L, respectively. 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.

In August 2023, we dosed our first participant in our first clinical trial for APG777. The APG777 Phase 1 trial is a double-blind, placebocontrolled study in healthy volunteers and consists of a single-ascending dose ("SAD") component and a multiple-ascending dose ("MAD") component. The study is expected to enroll approximately 40 healthy adult subjects into three SAD and two MAD cohorts. The primary endpoint is safety and a key secondary endpoint is pharmacokinetic ("PK"). The Phase 1 trial is ongoing and we expect initial safety and PK data from this trial in mid-2024. Pending data from the Phase 1 trial, Apogee plans to initiate a randomized, placebo-controlled, 16-week Phase 2 clinical trial in patients with moderate-to-severe AD in 2024.

In November 2023, we finalized the nomination of a development candidate for APG808, a subcutaneous, extended half-life mAb targeting IL-4R $\alpha$ , a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding femtomolar affinity for IL-4R $\alpha$  as a first generation mAb, DUPIXENT, 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 the Company's 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 26 days, as compared to 12 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 currently being investigated with every 2-week dosing in COPD. APG808 remains on track to enter the clinic in healthy volunteers in 2024 followed by a Phase 2 trial in COPD (pending data from the Phase 1 trial and following the submission of an IND to support the Phase 2 trial).

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 sale of our preferred units and common stock. Through September 30, 2023, 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 Registration Statement), relating to our IPO were declared effective by the SEC. Pursuant to the Registration Statement, we issued and sold an aggregate 20,297,500 shares of common stock (inclusive of 2,647,500 shares pursuant to the exercise of the underwriters' overallotment option in full) at a price of \$17.00 per share for gross proceeds of \$345.1 million in gross proceeds, and net proceeds of \$315.4 million, after deducting underwriting discounts and commissions and other offering expenses, including \$0.2 million in deferred financing issuance costs in accounts payable as of September 30, 2023.

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 net losses of \$52.3 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of \$92.0 million. We expect to continue to incur significantly increased expenses for the foreseeable future if and as we:

- advance our most advanced programs, APG777 and APG808, into and through clinical trials and regulatory approval prior to commercialization;
- continue our research and development and preclinical development of our other programs, including APG990 and APG222;
- 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 \$188.3 million, and marketable securities of \$234.6 million as of September 30, 2023 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026. 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 will initiate certain research programs that will generally be 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-4R $\alpha$ . The Research Plan for OX40L was agreed to prior to December 31, 2022. Our exclusive option with respect to any future Research Program is exercisable at our sole discretion, at any time during the period beginning on the initiation of activities under the associated Research 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. As of September 30, 2023, 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 undisclosed target. 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. We and Paragon will agree on an initial Research Plan that outlines the services that will be performed commencing at inception of the arrangement related to the undisclosed target. 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. Following entry into the 2023 Option Agreement, we and Paragon will negotiate a form of License Agreement to be entered into in the event that we exercise our exclusive option with respect to each Research Program, which License Agreement will include certain pre-agreed economic and other business terms.

Under the 2023 Option Agreement, on a Research Program-by-Research Program basis following the finalization of the Research Plan for each respective Research Program, we are required to pay Paragon a nonrefundable fee in cash of \$2.0 million. We are also obligated to compensate Paragon on a quarterly basis for its services performed under each Research Program based on the actual costs incurred. We expense the service fees as the associated costs are incurred when the underlying services are rendered.

Unless terminated earlier, the 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 we exercise our Option with respect to such Research Program (the "Term"). Upon the expiration of the Term for all then-existing 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 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 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 Option Agreement with respect to the IL-4R $\alpha$  Research Program and OX40L Research Program. Upon such exercise, the parties entered into associated license agreements (the "IL-4R $\alpha$  License Agreement" and the "OX40L License Agreement," respectively and collectively with the IL-13 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 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.

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. 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, the Company dosed its first participant in the Phase 1 trial of APG777 and accordingly have accrued research and development expense for the milestone payment of \$2.0 million to Paragon in the three months ended September 30, 2023. The nomination of a development candidate under the IL-4R $\alpha$  License Agreement and the OX40L License Agreement had not yet occurred as of September 30, 2023. Except for the two milestone payments totaling an aggregate of \$3.0 million, no other milestone or royalty payments had become due to Paragon through September 30, 2023. In November 2023, we finalized the nomination of a development candidate under the IL-4R $\alpha$  License Agreement and will make a milestone payment of \$1.0 million to Paragon in the fourth quarter of 2023.

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 APG777 and APG808 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 and APG808 programs.

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of \$150,000 for each licensed cell line. 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 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 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.

#### **Financial Operations Overview**

#### 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 Agreement, 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 Agreement, and the IL-13 License Agreement. 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 begin 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 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.

We operate as a virtual company. Therefore, we do not incur material operating expenses for the rent, maintenance and insurance of facilities or for depreciation of fixed assets.

#### 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, 2022, we had U.S. federal NOL carryforwards of approximately \$3.0 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. As of December 31, 2022, we also had U.S. federal and state research and development tax credit carryforwards of

approximately \$0.6 million and \$0.1 million, respectively, which may be available to reduce future tax liabilities. 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 Three Months Ended September 30, 2023 and 2022

#### **Results of Operations**

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

	THREE MONTHS ENDED SEPTEMBER 30,					
	2023		2022		\$ CHANGE	
Operating expenses:						
Research and development	\$	17,069	\$	9,885	\$	7,184
General and administrative		7,236		622		6,614
Total operating expenses		24,305		10,507	_	13,798
Loss from operations		(24,305)		(10,507)		(13,798)
Other income (expense), net:						
Interest income		3,465		—		3,465
Other financing expense				(9,150)		9,150
Total other income (expense), net		3,465		(9,150)		12,615
Net loss	\$	(20,840)	\$	(19,657)	\$	(1,183)

#### **Research and Development Expense**

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

	THRE	E MONTHS EN 2023	DED SEPTEMBER 30, 2022		
External research and development costs by program:					
APG777	\$	5,369	\$		
Unallocated research and development costs:					
External-discovery related costs and other		8,698	\$	9,648	
Personnel-related (including equity-based compensation)		3,002		237	
Total research and development expenses	\$	17,069	\$	9,885	

Research and development expenses for the three months ended September 30, 2023 were \$17.1 million, compared to \$9.9 million for the three months ended September 30, 2022. In the three months ended September 30, 2023, we recorded \$5.4 million of external research and development expense related to the APG777 program, which includes a \$2.0 million milestone payable upon the first dosing of a human patient in a Phase 1 trial in August 2023, and no such expense was recorded in the three months ended September 30, 2022, as APG777 expenses were recorded as unallocated external-discovery related costs until the program candidate was nominated in November 2022. Other external-discovery related costs decreased from \$9.6 million for the three months ended September 30, 2022 to \$8.7 million for the three months ended September 30, 2023, primarily due to the breakout of APG777 costs beginning in the fourth quarter of 2022. Our personnel related expenses were \$3.0 million for the three months ended September 30, 2022. The increase in personnel costs was attributable to an increase in headcount and share-based compensation in the three months ended September 30, 2023 compared to the three months ended September 30, 2022.

#### General and Administrative Expense

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

THREE MONTHS ENDED SEPTEMBER 30,

	 2023	2022		
Personnel-related (including equity-based compensation)	\$ 3,483	\$	202	
Legal and professional fees	2,022		102	
Other	1,731		318	
Total general and administrative expenses	\$ 7,236	\$	622	

General and administrative expenses for the three months ended September 30, 2023 were \$7.2 million compared to \$0.6 million for the three months ended September 30, 2022. The increase of \$6.6 million was primarily due to an increase in personnel costs of \$3.3 million, an increase in legal and professional services of \$1.9 million and an increase of other expenses of \$1.4 million, all of which were the result of the expansion of our operations to support growth in our business and the cost of operating as a public company.

#### Other Income (Expense), net

Interest income was \$3.5 million for the three months ended September 30, 2023, which was primarily related to interest on our cash, cash equivalents and marketable securities.

Other financing expense was \$9.2 million for the three months ended September 30, 2022, which was related to the change in fair value for the tranche options associated with the Series A Preferred Unit financing.

#### Comparison of Nine Months Ended September 30, 2023 to the Period from February 4, 2022 (inception) to September 30, 2022

#### **Results of Operations**

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

	E MONTHS SEPTEMBER 30, 2023	PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO SEPTEMBER 30, 2022	\$ CHANGE	
Operating expenses:				
Research and development	\$ 39,470	\$ 15,578	\$ 23,892	
General and administrative	16,378	1,050	15,328	
Total operating expenses	 55,848	16,628	39,220	
Loss from operations	 (55,848)	(16,628)	(39,220)	
Other income (expense), net:				
Interest income	3,598	—	3,598	
Other financing expense		(9,150)	9,150	
Total other income (expense), net	 3,598	(9,150)	12,748	
Net loss	\$ (52,250)	\$ (25,778)	\$ (26,472)	

### 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, 2023		PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO SEPTEMBER 30, 2022	
External research and development costs by program:				
APG777	\$	17,663	\$	—
Unallocated research and development costs:				
In-process research and development acquisitions		—		2,942
External-discovery related costs and other		16,961		12,360
Personnel-related (including equity-based compensation)		4,846		276
Total research and development expenses	\$	39,470	\$	15,578

Research and development expenses for the nine months ended September 30, 2023 were \$39.5 million, compared to \$15.6 million for the period from February 4, 2022 (inception) to September 30, 2022. In the nine months ended September 30, 2023, we recorded \$17.7 million of external research and development expense related to the APG777 program, which includes a \$2.0 million milestone payable upon the first dosing of a human patient in a Phase 1 trial in August 2023, and no such expense was recorded for the period from February 4, 2022 (inception) to September 30, 2022, as APG777 expenses were recorded as unallocated external-discovery related costs until the program candidate was nominated in November 2022. Other external-discovery related costs increased from \$12.4 million for the period from February 4, 2022 (inception) to September 30, 2022 to \$17.0 million of in-process research and development acquisition costs in the period from February 4, 2022 (inception) to September 30, 2022. Our personnel related expenses were \$4.8 million for the nine months ended September 30, 2023, and \$0.3 million was recorded for the period from February 4, 2022 (inception) to September 30, 2022. The increase in personnel costs was attributable to an increase in headcount and share-based compensation in the nine months ended September 30, 2023 compared to the period from February 4, 2022 (inception) to September 30, 2023.

### General and Administrative Expense

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

	NINE MONTHS ENDED SEPTEMBER 30, 2023		PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO SEPTEMBER 30, 2022	
Personnel-related (including equity-based compensation)	\$	7,669	\$	246
Legal and professional fees		5,446		655
Other		3,263		149
Total general and administrative expenses	\$	16,378	\$	1,050

General and administrative expenses for the nine months ended September 30, 2023 were \$16.4 million, compared to \$1.1 million for the period from February 4, 2022 (inception) to September 30, 2022. The increase of \$15.3 million was primarily due to an increase of personnel costs of \$7.4 million, an increase in legal and professional services of \$4.8 million and an increase of other expenses of \$3.1 million, all of which were the result of the expansion of our operations to support our growth in our business and the cost of operating as a public company.

### Other Income (Expense), Net

Interest income increased \$3.6 million for the nine months ended September 30, 2023, which was primarily related to interest on our cash, cash equivalents and marketable securities.

Other financing expense was \$9.2 million for the period from February 4, 2022 (inception) to September 30, 2022, which was related to the change in fair value for the tranche options associated with the Series A Preferred Unit financing.

### 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. From inception through September 30, 2023, we have raised \$484.4 million in aggregate cash proceeds from such transactions, net of issuance costs. As of September 30, 2023, we had cash and cash equivalents of \$188.3 million and \$234.6 million of marketable securities.

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 of the underwriters' overallotment option in full) at a price of \$17.00 per share. We received net proceeds of \$315.4 million, after deducting underwriting discounts and commissions and other offering expenses, including \$0.2 million in deferred financing issuance costs in accounts payable as of September 30, 2023.

### Cash Flows

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

	NINE MONTHS ENDED SEPTEMBER 30, 2023		PERIOD FROM FEBRUARY 4, 2022 (INCEPTION) TO SEPTEMBER 30, 2022	
Net cash provided by (used in):				
Operating activities	\$ (45,007)	\$	(7,238)	
Investing activities	(234,218)			
Financing activities	315,604	\$	9,821	
Net increase in cash	\$ 36,379		2,583	

### Net Cash used in Operating Activities

The 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, 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.

For the period from February 4, 2022 (inception) to September 30, 2022, operating activities used \$7.2 million, primarily due to a net loss of \$25.8 million, partially offset by non-cash charges of \$9.2 million for the loss on remeasurement of tranche option liability and \$1.7 million of research and development license expense, and net changes in our operating assets and liabilities of \$7.7 million.

### Net Cash used in Investing Activities

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, 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.

For the period from February 4, 2022 (inception) to September 30, 2022, financing activities provided \$9.8 million of cash from the issuance and sale of our Series A preferred units.

### 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 and APG808 programs and other development 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

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 your ownership interest.

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, 2023, we had \$188.3 million of cash and cash equivalents and \$234.6 million of marketable securities. Based on our current operating plan, we estimate that our existing cash, cash equivalents, and marketable securities as of the date of this Quarterly Report will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve 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 expension and capital expenditure requirements into the fourth quarter of 2026. 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 did not have any contractual obligations as of September 30, 2023.

We operate as a virtual company and, thus, we do not maintain a corporate headquarters or other significant facilities.

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. The maximum aggregate potential milestone payments payable by us total approximately \$9.0 million. As of September 30, 2023, we have incurred \$3.0 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.

### 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 (GAAP). 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 included in the Prospectus, 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 the Prospectus. There have been no material changes to our critical accounting policies from those described in the Prospectus.

### 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 \$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 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.

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

### Effects of Inflation

Inflation generally affects or will affect us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our condensed consolidated financial statements included elsewhere in this Quarterly Report.

### **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, 2023, 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, 2023 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 have not completed any 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 two most advanced programs, AGP777 and APG808, and our anticipated clinical trials of such programs may not be successful.

- Our approach to the discovery and development of our programs is unproven, and we may not be successful in our efforts to build a pipeline of programs with commercial value.
- Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.
- If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We rely on collaborations and licensing arrangements with third parties. If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.
- We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our programs.
- We currently rely, and expect to rely in the future, on the use of manufacturing suites in third-party facilities or on third parties to manufacture our 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.
- 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 have not completed any 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 no significant experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our planned clinical trials will begin or 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 and APG808, 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 currently anticipate. Because the design and outcome of our 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 fourth quarter of 2026. 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 net losses of \$25.8 million and \$52.3 million for the period from February 4, 2022 (inception) to September 30, 2022 and the nine months ended September 30, 2023, respectively. We generated net losses of \$19.6 million and \$20.8 million for the three months ended September 30, 2022 and for the three months ended September 30, 2023, respectively. As of September 30, 2023, we had an accumulated deficit of \$92.0 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 Paragon 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
- 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 the Prospectus 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 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 initiate or complete any clinical trials, obtain regulatory approvals, manufacture a clinical development or 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 clinical trials, the start of our first 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 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 two most advanced programs, AGP777 and APG808, and our anticipated clinical trials of such programs may not be successful.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our two most advanced programs, APG777 and APG808. We are investing a majority of our efforts and financial resources into the research and development of these programs. We initiated our Phase 1 clinical trial for APG777 in healthy volunteers and dosed our first participant in August 2023. We finalized the nomination of a development candidate for APG808 in the fourth quarter of 2023 and plan to initiate a Phase 1 clinical trial in 2024 in healthy volunteers, subject to the filing of an IND or foreign equivalent and regulatory approval. The success of our programs is dependent on observing a longer half-life of our programs in humans than other monoclonal antibodies 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 non-human primates ("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, 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 or APG808, 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 completion of our Phase 1 clinical trial in AD



and expected initiation of and topline data from our planned Phase 2 clinical trial in AD, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. 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 and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly and, if the shortage continues, could also result in delays to our development 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 plan to use the data from our ongoing Phase 1 trial of APG777 in healthy volunteers to support Phase 2 trials in AD and other I&I indications. If the FDA requires us to conduct additional trials or enroll additional patients, 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.

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

We may experience difficulties in patient enrollment in our 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 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 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. Our preclinical studies in NHPs have not shown any such characteristics to date. 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 and APG808. 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. There are several approved products and product candidates in later stages of development for the treatment of AD, including DUPIXENT, a wellestablished treatment for moderate-to-severe AD. However, our programs incorporate advanced antibody engineering to optimize half-life of antibodies targeting IL-13, IL-4Ra 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 halflife 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, APG990 and APG222 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. APG990 and APG222 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 trial for APG777 in Australia 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 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 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 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.

# 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 to develop and manufacture 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 clinical supply of APG777 and APG808. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, it could have a negative effect on the clinical development of our programs and other operations while we work to identify and qualify an alternate supply source. 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 the Prospectus 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 financial resources and the experience of our management team working together in managing a 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. We have adopted a code of conduct, but 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 computer 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.

Despite the implementation of security measures in an effort 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. 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 fully-remote workforce may create additional risks for our information technology systems and data because 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 the Prospectus 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 recently 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 knowhow, 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 the Company undertakes efforts to protect its 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 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 USPTOadministered 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and 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 European Union. 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 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 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 and APG808, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our programs are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our programs may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our programs could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a program is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our programs; we may be unable to demonstrate that a program's clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our programs may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our programs; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

If we were to obtain approval, regulatory authorities may approve any of our programs for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a program with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that program. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our programs, we will not be able to commercialize, or will be delayed in commercializing, our programs and our ability to generate revenue will be materially impaired.

### 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 the Prospectus 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 the Prospectus 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 the Prospectus 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 costeffectiveness 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 lifethreatening 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 the Prospectus 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 is likely to be highly volatile and could be subject to wide fluctuations 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 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. 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, 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.

Following the IPO, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 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 significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, 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. Certain other shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times following our IPO. 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 also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section titled "Underwriting" in the Prospectus.

## 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 completion 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, if 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.

# 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 nonvoting 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 Prospectus for a more detailed description of these provisions.

# 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 Prospectus for a more detailed description of these choice of forums provisions.

## 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, we expect that maintaining customary public company director and officer liability insurance will require 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 revisi

# 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 annual report for our fiscal year ending December 31, 2024. When we lose our status as an "emerging growth company" and become 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 will be engaged in a process to document and evaluate our internal control over financial reporting. 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, the ongoing military conflict 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, including \$0.2 million in deferred financing issuance costs in accounts payable as of September 30, 2023. 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 APG900 program and fund our preclinical studies of our APG222 program. 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

None.

# Item 6. Exhibits

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q 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+	Employment Agreement, dated August 25, 2023, by and between Apogee Therapeutics, Inc. and Michael Henderson, M.D (filed with the SEC as Exhibit 10.2 to the Company's Form 10-Q filed on August 28, 2023).
10.2+	Employment Agreement, dated August 25, 2023, by and between Apogee Therapeutics, Inc. and Jane Pritchett Henderson (filed with the SEC as Exhibit 10.3 to the Company's Form 10-Q filed on August 28, 2023).
10.3+	Employment Agreement, dated August 25, 2023, by and between Apogee Therapeutics, Inc. and Carl Dambkowski, M.D. (filed with the SEC as Exhibit 10.4 to the Company's Form 10-Q filed on August 28, 2023).
10.4+	Form of Indemnification Agreement (filed with the SEC as Exhibit 10.1 to the Company's Form S-1/A filed on July 3, 2023).
10.5+	Equity Incentive Plan (filed with the SEC as Exhibit 10.9 to the Company's Form 10-Q filed on August 28, 2023).
10.6+	2023 Employee Stock Purchase Plan (filed with the SEC as Exhibit 10.15 to the Company's Form S-1/A filed on July 10, 2023).
10.7*#	2023 Option Agreement, dated November 9, 2023, by and between Paragon Therapeutics, Inc. and Apogee Therapeutics, Inc.
31.1*	<u>Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934</u>
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 Document

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101.CAL\* Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF\* Inline XBRL Taxonomy Extension Definition
101.LAB\* Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE\* Inline XBRL Taxonomy Extension Presentation Linkbase Document
104\* The cover page for this report, formatted in Inline XBRL (included in Exhibit 101)

(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.

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<sup>\*</sup> Filed herewith

<sup>+</sup> Indicates management contract or compensatory plan.

<sup>#</sup> Portions of the exhibit have been omitted for confidentiality purposes.

# 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 13, 2023	By: /s/ Michael Henderson, M.D. Michael Henderson, M.D. Chief Executive Officer (principal executive officer)
Date: November 13, 2023	By: /s/ Jane Pritchett Henderson Jane Pritchett Henderson Chief Financial Officer (principal financial and accounting officer)

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#### ANTIBODY DISCOVERY AND OPTION AGREEMENT

**THIS ANTIBODY DISCOVERY AND OPTION AGREEMENT** ("**Agreement**") is entered into and effective as of November 9, 2023 (the "**Effective Date**"), by and between Paragon Therapeutics, Inc., a Delaware corporation ("**Paragon**"), and Apogee Therapeutics, Inc. ("**Apogee**"), a Delaware corporation. Paragon and Apogee are also referred to herein individually as a "**Party**", or collectively as the "**Parties**."

#### RECITALS

**WHEREAS,** Paragon has developed a proprietary platform technology for the discovery and development of antibodies against therapeutically relevant targets;

**WHEREAS,** Apogee desires to engage Paragon to identify, evaluate and develop one or more antibody candidates directed to certain mutually agreed therapeutic targets of interest to Apogee;

WHEREAS, Paragon is willing to perform certain antibody discovery and development activities for Apogee; and

**WHEREAS,** Apogee will have an exclusive option to enter into separate license agreements with Paragon to develop, manufacture and commercialize the resulting antibodies with respect to a given target, all on the terms and subject to the conditions set forth in this Agreement.

**NOW THEREFORE,** in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

### AGREEMENT

#### ARTICLE 1 DEFINED TERMS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 "Active Research Program" shall have the meaning provided in <u>Section 5.2(a)</u>.

**1.2** "Actual Annual Costs" shall have the meaning provided in <u>Section 5.2(c)</u>.

**1.3** "Affiliate" shall mean, with respect to an entity, any other entity controlled by, controlling or under common control with such entity for as long as such control exists. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" or "under common control") means the direct or indirect ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) in the equity of, or the right to appoint more than fifty percent (50%) of the directors or management of, such corporation or other

business entity. Notwithstanding the foregoing, with respect to either Party, Affiliates of such Party do not include the other Party or [\*\*\*] or its Affiliates and other affiliated entities other than such Party and its subsidiaries.

**1.4 "Agreement**" shall have the meaning provided in the first paragraph of this Agreement.

**1.5** "Annual Development Fees" shall have the meaning provided in <u>Section 1.27</u>.

**1.6** "Antibody" shall mean any molecule, including [\*\*\*].

**1.7 "Apogee"** shall have the meaning provided in the first paragraph of this Agreement.

**1.8** "Apogee Indemnitee" shall have the meaning provided in <u>Section 10.2</u>.

**1.9 "Applicable Law**" shall mean any national, supra-national, federal, state or local laws, rules, guidances and regulations, in each case, as applicable to the subject matter and the Party at issue.

**1.10 "Background IP**" shall mean all Patents and Know-How Controlled by a Party (a) as of the Effective Date, or (b) that otherwise arise outside of and independently of this Agreement. Paragon's Background IP includes the Paragon Platform Technology.

**1.11 "Bankruptcy Code"** shall have the meaning provided in <u>Section 9.4</u>.

**1.12 "Bankruptcy Event**" shall have the meaning provided in <u>Section 9.4</u>.

**1.13 "Budget**" shall mean the agreed budget for the activities set forth in the applicable Research Plan.

**1.14 "Business Day**" shall mean any day other than Saturday, Sunday or a national holiday in the United States.

**1.15** "**Calendar Quarter**" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

**1.16 "Calendar Year**" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

**1.17** "**Change of Control**" shall mean, with respect to any entity, any of the following: (a) the sale or disposition of all or substantially all of the assets of such entity or its direct or indirect controlling Affiliate to a Third Party; or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such entity or any of its Affiliates, of more than fifty percent (50%) of the then outstanding shares of voting capital stock of such entity or its direct or indirect parent entity that holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then outstanding shares of voting capital stock of such entity (a "**Parent Entity**"), or (ii) the acquisition,

merger or consolidation of such entity or its Parent Entity with or into another entity, other than, in the case of clause (i) or (ii), an acquisition or a merger or consolidation of such entity or its Parent Entity in which the holders of shares of voting capital stock of such entity or its Parent Entity, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation, and in each case of (a) or (b), whether through a single transaction or a series of related transactions but excluding any and all bona fide financing transactions or internal reorganizations for tax purposes (including the change of place of incorporation or domicile of such entity).

**1.18** "**Commercialize**" or "**Commercializing**" shall mean to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize an Antibody, including any Project Antibody or Derived Antibody, or Product, as applicable. When used as a noun, "**Commercialization**" means any and all activities involved in Commercializing.

**1.19** "**Confidential Information**" of a Party shall mean any and all non-public scientific, business, regulatory or technical information that is disclosed or made available by or on behalf of a Party (the "**Disclosing Party**") to the other Party (a "**Receiving Party**") prior to the Effective Date or in connection with this Agreement, whether in writing, orally, visually or otherwise and whether explicitly marked as confidential or not. Confidential Information may include information of a third party that is in the possession of the Disclosing Party and is disclosed to the Receiving Party under this Agreement. Notwithstanding any provision of this Agreement to the contrary, (a) Paragon Platform Technology shall be the Confidential Information of Paragon, and (b) Project Antibody Technology shall be the Confidential Information of both Parties, and each Party shall be deemed as both the "Disclosing Party" and the "Receiving Party" with respect to Project Antibody Technology; provided that if Apogee does not exercise its Option or the Parties do not enter into a License Agreement in accordance with this Agreement, then the Project Antibody Technology shall thereafter be the Confidential Information of Paragon.

**1.20** "**Control**" (including any variations such as "**Controlled**") shall mean, with respect to any technology, Know-How, Patents, other Intellectual Property Rights, Antibodies or Confidential Information, possession by a Party or its Affiliates, as applicable, and the ability (whether by ownership, license or otherwise) to grant a license or a sublicense to or under such technology, Know-How, Patents, other Intellectual Property Rights, Antibodies or Confidential Information without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding the foregoing, a Party or its Affiliates shall not be deemed to "Control" any technology, Know-How, Patents, other Intellectual Property Rights, Antibodies or Confidential Information that (a) prior to the consummation of a Change of Control of such Party is owned or in-licensed, or (b) after the consummation of a Change of Control of such Party, becomes owned or inlicensed, in each case ((a) or (b)), by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Change of Control or an assignment of this Agreement in connection with a Change of Control unless prior to the consummation of such Change of Control or assignment,

such Party or any of its Affiliates also Controlled such technology, Know-How, Patents, other Intellectual Property Rights, Antibodies or Confidential Information.

**1.21** "Cost Advance" shall have the meaning provided in <u>Section 5.2(b)</u>.

**1.22** "**Cover**" or "**Covering**" shall mean, with respect to a product (including an Antibody or Product), technology, process, method or mode of administration that, in the absence of a license granted under, or ownership of, a particular Patent, the making, using, offering for sale, selling or importation of such product or composition of matter or any formulation thereof, or the practice of such technology, process, method or mode of administration would infringe a Valid Claim of such Patent or, in the case of a Patent claim that has not yet issued, would infringe such claim if it were to issue without change.

**1.23** "**Deliverables**" shall have the meaning provided in <u>Section 2.1(c)</u>.

**1.24 "Derived Antibody**" shall mean any Antibody that (a) is derived from or constitutes a modification of a Project Antibody, including [\*\*\*], and (b) is [\*\*\*]. For avoidance of doubt, any Antibody that [\*\*\*] will be deemed a Derived Antibody, irrespective of origin.

**1.25 "Derived Antibody Patent"** shall mean any Patent that Covers the composition of matter of, or any method of specifically making or using, any Derived Antibody.

**1.26** "**Develop**," "**Developed**," or "**Developing**" shall mean to discover, evaluate, test, research or otherwise develop an Antibody, including a Project Antibody or Derived Antibody, or Product. When used as a noun, "Development" means any and all activities involved in Developing.

**1.27** "**Development Costs**" shall mean, on a Research Program-by-Research Program basis, (a) [\*\*\*] (such amounts, the "**Third Party Costs**"), and (b) [\*\*\*] (such development fees, the "**Development Fees**", and the Development Fees to be paid in any given Calendar Year during the Research Program, the "**Annual Development Fees**"); in each case ((a) and (b)) to the extent consistent with the applicable Research Plan (including [\*\*\*]).

**1.28** "Development Fees" shall have the meaning provided in <u>Section 1.27</u>.

**1.29** "Directed To" shall mean, with regard to an Antibody or Product, that such Antibody or Product is developed or designed to (a) [\*\*\*], and (b) [\*\*\*].

**1.30** "Disclosing Party" shall have the meaning provided in <u>Section 1.19</u>.

**1.31** "**Dispute**" shall have the meaning provided in <u>Section 11.7</u>.

**1.32** "Election Notice" shall have the meaning provided in <u>Section 4.4</u>.

**1.33 "Effective Date"** shall have the meaning provided in the first paragraph of this Agreement.

**1.34 "Field"** shall mean the prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas.

**1.35** "Indemnified Party" shall have the meaning provided in <u>Section 10.3</u>.

**1.36** "**Indemnifying Party**" shall have the meaning provided in <u>Section 10.3</u>.

**1.37** "**Initial Discovery and Option Agreement**" means that certain Antibody Discovery and Option Agreement, effective as of February 24, 2022, by and between Paragon and Apogee, as such agreement may be amended or restated from time to time.

**1.38** "Intellectual Property Rights" shall mean any and all proprietary rights provided under (a) patent law, including any Patents; (b) copyright law; or (c) any other applicable statutory provision or common law principle, including trade secret law, that may provide a right in Know-How, or the expression or use thereof.

**1.39** "**JDC**" shall have the meaning provided in <u>Section 3.1</u>.

**1.40** "Know-How" shall mean all technical information and know-how in any tangible or intangible form, including (a) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (b) all data, instructions, processes, formulae, strategies and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical or otherwise and whether related to safety, quality control, manufacturing or other disciplines. Notwithstanding the foregoing, Know-How excludes Patent claims.

**1.41** "License Agreement" shall have the meaning provided in <u>Section 4.5(b)</u>.

**1.42** "License Template" shall have the meaning provided in <u>Section 4.5(a)</u>.

**1.43** "Losses" shall have the meaning provided in <u>Section 10.1</u>.

**1.44** "Manufacture" or "Manufacturing" shall mean to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store an Antibody, including any a Project Antibody or Derived Antibody, or Product or any component thereof. When used as a noun, "Manufacture" or "Manufacturing" means any and all activities involved in Manufacturing an Antibody, including any Project Antibody or Derived Antibody, or Product or any component thereof.

**1.45** "Monthly Rate" shall have the meaning set forth in <u>Section 5.2(a)</u>.

**1.46** "Notice of Dispute" shall have the meaning provided in <u>Section 11.7(a)</u>.

**1.47 "Option**" shall have the meaning provided in <u>Section 4.1</u>.

**1.48** "Option Period" shall have the meaning provided in <u>Section 4.4</u>.

**1.49 "Paragon**" shall have the meaning provided in the first paragraph of this Agreement.

**1.50 "Paragon Indemnitee**" shall have the meaning provided in <u>Section 10.1</u>.

**1.51 "Paragon Platform Know-How**" shall mean (a) Know-How Controlled by Paragon or its Affiliates prior to or during the Term relating to antibody discovery and development, (b) all methods, materials and other Know-How used in the foregoing Controlled by Paragon or its Affiliates, and (c) platforms embodying, components, component steps and other portions of any of the foregoing in (a) or (b) Controlled by Paragon or its Affiliates.

**1.52 "Paragon Platform Know-How Improvement"** shall mean all Know-How developed or discovered through or as a result of the activities performed by or on behalf of Paragon under a Research Program that constitutes an improvement, enhancement, modification, substitution, or alteration to the Paragon Platform Technology; provided, however, to the extent any of the Know-How developed or discovered during the Term that specifically relates to a Project Antibody will be considered Project Antibody Technology and not Paragon Platform Know-How Improvements.

**1.53 "Paragon Platform Patents**" shall mean all Patents that Paragon or its Affiliates Control prior to or during the Term that Cover Paragon Platform Know-How, including Patents that Cover Paragon Platform Know-How Improvements.

**1.54 "Paragon Platform Technology"** shall mean Paragon Platform Know-How, Paragon Platform Know-How Improvements and Paragon Platform Patents.

**1.55** "**Parent Entity**" shall have the meaning provided in <u>Section 1.17</u>.

**1.56 "Party"** and **"Parties"** shall have their respective meanings provided in the first paragraph of this Agreement.

**1.57** "**Patents**" shall mean (a) unexpired patents and patent applications, (b) any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications, and (c) any and all foreign equivalents of the foregoing.

**1.58** "**Pre-Effective Date Development Costs**" shall have the meaning provided in <u>Section 5.2(b)</u>.

**1.59 "Product**" shall mean any product that comprises or contains (a) any Project Antibody or (b) any Derived Antibody.

**1.60 "Project Antibody**" shall mean any and all Antibodies that are Directed To a particular Selected Target and that are discovered, generated, identified or characterized by Paragon in the course of performing the applicable Research Program.

**1.61 "Project Antibody Invention**" shall mean (a) any invention or discovery, whether or not patentable, that constitutes the composition of matter of, or any method of specifically making or using, any Project Antibody or a Derived Antibody; and (b) all Intellectual Property Rights therein.

**1.62 "Project Antibody Patents**" shall mean all Patents that Cover the composition of matter of, or any method of specifically making or using, any Project Antibody.

**1.63** "**Project Antibody Samples**" shall have the meaning provided in <u>Section 2.1(c)</u>.

**1.64 "Project Antibody Selection Criteria"** shall mean those criteria agreed to by the Parties in the applicable Research Plan that establish that a Project Antibody is suitable for clinical testing.

**1.65 "Project Antibody Technology"** shall mean (a) the Project Antibody Inventions; (b) the Project Antibody Patents, (c) the Sequence Information and Results; and (d) all Intellectual Property Rights therein, that in each case are Controlled by Paragon or its Affiliates as of the Effective Date or during the Term.

**1.66** "**Receiving Party**" shall have the meaning provided in <u>Section 1.19</u>.

**1.67** "**Representatives**" of a Party shall mean such Party's officers, directors, employees, contractors, subcontractors, agents and consultants.

**1.68** "**Research Initiation Fee**" shall have the meaning provided in <u>Section 5.1</u>.

**1.69** "**Research Plan**" shall have the meaning provided in <u>Section 2.1(b)</u>.

**1.70** "**Research Program**" shall mean a research program agreed to by the Parties to identify Project Antibodies with activity against one Selected Target and to perform such additional activities with respect to such Selected Target as set forth in the applicable Research Plan.

**1.71** "**Research Term**" shall mean, on a Research Program-by-Research Program basis, the period of time beginning on the Effective Date and continuing until completion of such Research Program, or such other date mutually agreed upon by the Parties.

**1.72 "Results**" shall mean the data, results, analysis, conclusions, outcomes, information, documentation and reports (in each case, excluding Project Antibody Technology) that are generated by or on behalf of Paragon in performance of a Research Program, excluding Project Antibodies.

**1.73** "Selected Target" shall have the meaning provided in <u>Section 2.1(a)</u>.

**1.74 "Sequence Information**" shall mean electronic files of Paragon containing all Project Antibody sequences generated under a given Research Program.

**1.75 "Target**" shall mean a protein molecule that (a) [\*\*\*], and (b) [\*\*\*].

- **1.76 "Term**" shall have the meaning provided in <u>Section 9.1</u>.
- **1.77 "Term Sheet**" shall have the meaning provided in <u>Section 4.5(a)</u>.
- **1.78 "Territory**" shall mean worldwide.

**1.79 "Third Party**" shall mean any person or entity other than Paragon or Apogee or an Affiliate of any of Paragon or Apogee.

- **1.80 "Third Party Claim"** shall have the meaning provided in <u>Section 10.1</u>.
- **1.81** "Third Party Costs" shall have the meaning provided in <u>Section 1.27</u>.

**1.82 "Valid Claim"** shall mean, with respect to a particular country, a claim (including a process, use or composition of matter claim) of an issued and unexpired Patent (or a supplementary protection certificate thereof) that has not (a) irretrievably lapsed or been abandoned, permanently revoked, dedicated to the public or disclaimed, or (b) been held invalid, unenforceable or not patentable by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, which holding, finding or decision is final and un-appealable or unappealed within the time allowed for appeal.

#### ARTICLE 2 CONDUCT OF RESEARCH PROGRAM

#### 2.1 Research Program.

(a) **Target Selection.** The Parties intend to initiate one or more Research Programs, each focused on a particular Target (each, a "**Selected Target**"). No more than one (1) Selected Target will be included in any Research Program, unless the Parties otherwise agree in writing (e.g., in the case of a Research Program seeking to develop [\*\*\*]). As of the Effective Date, the Parties have agreed to the Selected Targets listed on <u>Exhibit A</u>. Additional Targets may be added to the Selected Targets by mutual written agreement of the Parties, it being understood that each Party may accept or reject a new Selected Targets. The Parties acknowledge that, prior to any agreement with respect to a Selected Target and a Research Plan, it is intended that the Parties may initiate, from time-to-time, "proof-of-concept" studies to decide if a combination of Antibodies or a bispecific Antibody is viable at no up-front Research Plan and associated fees (which may include milestone payments), in each case, as agreed by the Parties.

(b) Research Plan. No later than [\*\*\*] days after the Effective Date (or in the case of any Selected Target added after the Effective Date, no later than [\*\*\*] days after the Parties' written agreement on such additional Selected Target), the Parties will agree on a research plan for the applicable Selected Target that will include design, modeling, synthesis, evaluation and other mutually agreed activities ("Research Plan"). For clarity, if at the end of such [\*\*\*] day period (or any extension thereof mutually agreed in writing) (a) the Parties have not agreed on a Research Plan, or (b) Apogee has not paid Paragon the Research Initiation Fee, the target shall cease to be a Selected Target and Paragon shall have no obligations with respect thereto. Once the Parties agree on a Research Plan and Apogee pays the Research Initiation Fee for the Research Program, Paragon shall conduct research under a Research Program directed to the applicable Selected Target in an effort to produce Project Antibodies against such Selected Target for further Development, Manufacture and Commercialization by Apogee. The Parties may amend the Research Plan upon mutual written agreement. Paragon will use [\*\*\*] to conduct and complete the activities set forth in such Research Plan on the timelines set forth in such Research Plan and in compliance with the Budget.

(c) Deliverables; Project Antibody Samples. Following completion of a Research Program, Paragon will deliver to Apogee a data package that includes Sequence Information for all Project Antibodies and all Results (the "Deliverables"). Additionally, upon request by Apogee, and at [\*\*\*] cost and expense, Paragon shall provide to Apogee samples of proteins corresponding to Project Antibodies that have been expressed in accordance with the Research Plan ("Project Antibody Samples") to enable Apogee to evaluate the Option. During the Option Period, Apogee will review the Deliverables and Project Antibody Samples to determine whether [\*\*\*] Project Antibody meets the Project Antibody Selection Criteria. If Apogee determines that [\*\*\*] Project Antibody meets the Project Antibody Selection Criteria, then Apogee will so notify Paragon prior to the end of the Option Period.

(d) Conduct of Research Program. During the Research Term: (i) Apogee shall cooperate with Paragon [\*\*\*] to ensure the continued performance of the activities described in the applicable Research Plan; and (ii) Paragon shall (1) perform the activities assigned to Paragon under the applicable Research Plan in a professional, diligent and good scientific manner, in compliance with all Applicable Law, and in compliance with the applicable Research Plans; (2) ensure that its Representatives and subcontractors diligently perform the applicable Research Program in a manner in accordance with generally accepted industry practices by appropriately trained personnel who are experienced in the relevant fields and in compliance with Applicable Law; (3) keep Apogee fully informed regarding the progress and Results of the Research Program; (4) promptly provide Apogee with any additional information regarding the Research Program that Apogee reasonably requests; (5) participate in teleconference(s) at a time(s) agreed upon by the Parties to provide an update to Apogee on the performance of the Research Program; and (6) give Apogee prompt written notice with respect to information known or believed by Paragon to be likely to materially impede or otherwise adversely affect the performance of the Research Program.

**2.2 Subcontractors.** Paragon may perform some of the activities under a Research Program through one or more subcontractors, provided that Paragon shall at all times be fully

responsible for the compliance of such subcontractors with this Agreement and for the performance of Paragon's obligations under this Agreement.

**2.3 Research Books and Records; Audit.** Paragon shall maintain complete and accurate records related to the activities performed by Paragon under a Research Program. All such books and records shall be retained by Paragon until the later of: (a) [\*\*\*] after the end of the applicable Research Term; and (b) such longer period as may be required by Applicable Law. Upon Apogee's [\*\*\*] request (no more than [\*\*\*] per Calendar Year during the Term) and at [\*\*\*] expense, Paragon shall provide copies of such records or such records shall be made available for Apogee's reasonable review, audit and inspection upon [\*\*\*] notice and with reasonable frequency.

## ARTICLE 3 GOVERNANCE

**3.1 Joint Development Committee.** The Parties will establish a single Joint Development Committee (the "**JDC**") to oversee and coordinate the activities under all Research Programs in accordance with the remainder of this <u>Article 3</u>. The JDC shall be comprised of two (2) employees from Apogee and two (2) employees from Paragon, with each Party designating one (1) such employee as its JDC co-chairperson. Subject to the foregoing, each Party shall appoint its respective JDC representatives to the JDC from time to time, and may change its JDC representatives, in its sole discretion, effective upon notice to the other Party designating such change. JDC representatives from each Party shall have appropriate technical credentials, experience and knowledge pertaining to and ongoing familiarity with the activities to be performed under the Research Programs.

**3.2 JDC Meetings.** The JDC shall meet in accordance with a schedule established by mutual written agreement of the Parties no less frequently than once every three (3) months, on a Research Program-by-Research Program basis, until the end of the period specified in <u>Section 3.5</u>. The JDC may meet by means of teleconference, videoconference or other similar means, as jointly determined by the Parties. As appropriate, additional employees or consultants may from time to time attend the JDC meetings as nonvoting observers, provided that any such consultant shall agree in writing to comply with the confidentiality obligations under this Agreement; and provided further that no Third Party personnel may attend unless otherwise agreed by both Parties. Each Party shall bear its own expenses related to the attendance of the JDC meetings by its JDC representatives. Each Party may also call for special meetings to resolve particular matters requested by such Party. Paragon shall be responsible for keeping minutes of each JDC meeting that record in writing all decisions made, action items assigned or completed and other appropriate matters. Paragon shall send meeting minutes to all members of the JDC within [\*\*\*] Business Days after a meeting for review. Each member shall have [\*\*\*] Business Days from receipt in which to comment on and to approve/provide comments to the minutes (such approval not to be unreasonably withheld, conditioned or delayed). If a member, within such time period, does not notify the drafting Party that s/he does not approve of the minutes, the minutes shall be deemed to have been approved by such member.

**3.3 JDC Functions.** The JDC's responsibilities are as follows:

(a) Developing, reviewing, overseeing and coordinating the activities under each Research Plan;

**(b)** Periodically reviewing the progress of activities under each Research Plan;

(c) Updating or modifying each Research Plan, provided that such update or modification does not obligate any Party to perform any task or expend any resources outside of or beyond its obligations under the applicable Budget;

(d) Reviewing performance against the Budget and timeline for each Research Program periodically (at least [\*\*\*]), and periodically meeting to review and (subject to mutual approval of the Parties), approving any Budget deviation where such deviation is greater than [\*\*\*] percent ([\*\*\*]%);

(e) Reviewing the reconciliation of Actual Annual Costs against the Cost Advance at the end of each Calendar Year for each Research Program; and

(f) Determining whether the Project Antibody Selection Criteria for a Research Program are not achievable for any reason and therefore such Research Program no longer warrants further research.

**3.4 JDC Decision Making and Disputes.** The JDC will endeavor to make decisions by consensus, with each of Apogee and Paragon having one vote. If consensus is not reached by the Parties' JDC representatives pursuant to such vote, then disputes relating to: (a) the reconciliation of Actual Annual Costs against the Cost Advance, as set forth in <u>Section 5.2(c)</u>, will be resolved in accordance with <u>Section 11.7</u>; (b) technical or scientific decisions in the course of operationalizing each Research Program, including the nature of activities to be performed by Paragon thereunder, shall be finally decided by [\*\*\*]; and the Budget for any Research Program, and all other matters not covered by clauses (a) or (b) shall be finally decided by [\*\*\*]. For clarity, and notwithstanding the creation of the JDC, each Party shall retain the rights, powers and discretion granted to it hereunder, and the JDC shall not be delegated or vested with such rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. The JDC shall not have the power to amend, waive or modify any term of this Agreement, and no decision of the JDC shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the JDC are limited to those specific issues that are expressly provided in this Agreement to be decided by the JDC.

**3.5 Disbandment.** The JDC shall remain in effect from the date on which it is established in accordance with <u>Section 3.1</u> until, on a Research Program-by-Research Program basis, the earlier of (a) expiration of the Term and (b) Apogee's exercise of the Option in accordance with <u>Section 4.4</u>.

#### ARTICLE 4 OPTION; LICENSE

**4.1 Grant of Option.** Subject to the terms and conditions of this Agreement, on a Research Program-by-Research Program basis, Paragon hereby grants to Apogee, during the Term and subject to delivery of the Election Notice in accordance with <u>Section 4.4</u>, an exclusive option ("**Option**"), to be granted an exclusive license to all of Paragon's right, title and interest in and to the Project Antibody Technology under the applicable Research Program to Develop, Manufacture and Commercialize Project Antibodies, Derived Antibodies and Products in the Field in the Territory.

**4.2 Limited License Grant During Option Period.** Subject to the terms and conditions of this Agreement, on a Research Program-by-Research Program basis, and effective only during the Term, Paragon hereby grants to Apogee a limited, exclusive, royalty-free, non-transferable license, without the right to sublicense, under the Project Antibody Technology arising from such Research Program solely to evaluate the Option and for the purpose of allowing Apogee to determine whether to exercise the Option with respect to such Research Program. For clarity, the license set forth in this <u>Section 4.2</u> does not include a license to Develop, Manufacture or Commercialize Project Antibodies, Derived Antibodies or Products.

**4.3 Retained Rights.** Notwithstanding the rights granted to Apogee in <u>Section 4.2</u>, Paragon retains the right for Paragon and its Affiliates to use the Project Antibody Technology to perform its obligations under this Agreement and for any other purpose not expressly licensed to Apogee in <u>Section 4.2</u>.

**4.4 Option Exercise.** On a Research Program-by-Research Program basis, Apogee may, in its sole discretion, exercise the Option at any time during the period beginning on the initiation of activities under such Research Program and ending [\*\*\*] days following Apogee's receipt of the Deliverables for such Research Program, or such longer period as agreed upon by the Parties ("**Option Period**") by delivering written notice of such exercise to Paragon ("**Election Notice**"). If Apogee fails to exercise an Option in accordance with this <u>Section 4.4</u> prior to expiration of the applicable Option Period, then, upon such expiration, such Option shall terminate and be of no further force or effect.

# 4.5 License Template; Execution After Option Exercise.

(a) Within [\*\*\*] days following finalization of the Research Plan for a given Research Program, the Parties shall negotiate [\*\*\*] and use [\*\*\*] to agree upon a form of agreement template ("**License Template**") to be used in connection with Apogee's exercise of its Option with respect to such Research Program. The License Template will be consistent with the economic and other terms set forth in the license agreement term sheet ("**Term Sheet**") attached hereto as <u>Exhibit B</u>, and upon mutual agreement by the Parties on the form of the License Template will be attached to this Agreement and replace the Term Sheet on the existing <u>Exhibit B</u>. If the Parties are unable to reach agreement on the definitive terms of the License Template within such [\*\*\*] period, the matter will be resolved in accordance with Section 11.7.

(b) Within [\*\*\*] days of Apogee's exercise of its Option with respect to a Research Program as set forth in <u>Section 4.4</u>, the Parties shall use [\*\*\*] to finalize and execute a definitive written agreement consistent with the License Template (the "License Agreement")

with respect to such Research Program.

#### ARTICLE 5 PAYMENTS

**5.1 Research Initiation Fee.** Apogee shall pay to Paragon, on a Research Program-by-Research Program basis, a one-time, nonrefundable, noncreditable fee of Two Million Dollars (\$2,000,000.00) (the "**Research Initiation Fee**") no later than [\*\*\*] days following finalization of the Research Plan for such Research Program. For clarity, the Research Initiation Fee is nonrefundable and noncreditable and separate from any Development Costs (including Pre-Effective Date Development Costs) or Cost Advance paid or owing with respect to a particular Research Program.

#### 5.2 Development Costs.

(a) The monthly rate for the Development Fees (the "**Monthly Rate**") shall be determined and charged on a Research Program-by-Research Program and calendar month-by-calendar month basis based on, with respect to any particular calendar month, the total number of (i) [\*\*\*], and (ii) [\*\*\*] (each such Research Program, an "Active Research Program"). [\*\*\*].

(b) On a quarterly basis for each Research Program, Apogee will advance to Paragon any Development Costs contemplated in the Budget, including [\*\*\*], and any [\*\*\*] reasonably expected to be incurred by Paragon in the performance of the Research Program during the upcoming [\*\*\*] (less any pre-payments for [\*\*\*] from earlier [\*\*\*] that Paragon reasonably anticipates will be carried over to such upcoming [\*\*\*]) (the "**Cost Advance**"). For clarity, the Cost Advance and Apogee's responsibility for Development Costs shall apply to any Research Program intended to [\*\*\*]. Apogee will pay the Cost Advance within [\*\*\*] days after receipt of Paragon's invoice for such Development Costs. The Parties acknowledge that Paragon has incurred (i) approximately \$750,055.62 in Development Costs through September 30, 2023, and (ii) certain additional Development Costs between October 1, 2023 and the Effective Date, as a result of work performed by Paragon at risk on one or more Research Programs (the costs described in (i) and (ii), the "**Pre-Effective Date Development Costs**"). Apogee shall reimburse Paragon for the Pre-Effective Date Development Costs on later than [\*\*\*] days after the later of (i) the Effective Date and (ii) Apogee's receipt of a written invoice that details the Pre-Effective Date Development Costs and includes reasonable documentation therefor.

(c) Within [\*\*\*] days after the end of each Calendar Year, Paragon will calculate and provide to Apogee a written reconciliation of its actually incurred Third Party Costs (incurred in a manner consistent with the Budget) for the prior Calendar Year ("Actual Annual Costs") against that portion of the Cost Advance for such Third Party Costs for that Calendar Year, including reasonable documentation of such Actual Annual Costs. The form of such reconciliation shall be subject to JDC review and approval. If the amounts paid for anticipated Third Party Costs in the Cost Advance exceeds the Actual Annual Costs, then Paragon will credit such excess payment against Development Costs contemplated in the Budget and reasonably expected to be incurred by Paragon in the performance of the Research Program during any upcoming Calendar

Year and Apogee will deduct such amount from its next quarterly Cost Advance. If the Cost Advance is less than the Actual Annual Costs, then Paragon will invoice Apogee for the difference and Apogee will pay such amount together with its next quarterly Cost Advance. If no further amounts will be owed to Paragon hereunder, Paragon will refund such amount. For clarity, the above reconciliation will not apply to Annual Development Fees.

**5.3 Financial Records.** Paragon shall keep complete and accurate books of account and records in sufficient detail to enable the Development Costs payable under this Agreement to be determined. Such books and records shall be kept at the principal place of business of Paragon, for at least [\*\*\*] months following the end of the [\*\*\*] to which such books and records pertain and Apogee shall be entitled to inspect such books and records at Paragon's offices upon Apogee's reasonable request.

**5.4 Manner and Method of Payment.** All cash payment amounts hereunder are expressed in U.S. dollars (USD) unless otherwise specified. Each cash payment shall be made by electronic funds transfer in immediately available funds to a bank and account designated in writing by Paragon, unless otherwise specified in writing by Paragon.

**5.5 Tax.** Each Party shall be responsible for paying its own respective taxes in connection with any activities that it performs and any payments that it receives under this Agreement. The Parties will commit [\*\*\*] to provide each other with any tax forms that may be reasonably necessary in order for any Party to not pay or withhold tax or to pay or withhold tax at a reduced rate under an applicable income tax treaty.

**5.6 Late Payments.** In the event that any cash payment due for any undisputed amount under this Agreement is not made when due, then the cash payment shall accrue interest from the date due at a per annum rate equal to [\*\*\*] above the then-current per annum prime rate reported by the *Wall Street Journal* (U.S., Western Edition) or, if lower, the maximum legal annual interest rate.

## ARTICLE 6 INTELLECTUAL PROPERTY RIGHTS

# 6.1 Ownership.

(a) **Background IP.** As between the Parties, each Party will retain all right, title and interest in and to all of its Background IP.

(b) **Project Antibody Technology.** Subject to the rights and licenses granted to Apogee in this Agreement, as between the Parties, Paragon or its Affiliates shall own all right, title and interest in and to all Project Antibody Technology, irrespective of inventorship. Apogee agrees to assign and hereby assigns to Paragon all of Apogee's right, title and interest in and to the Project Antibody Technology, including any and all Intellectual Property Rights therein. Apogee shall execute and deliver, and shall cause its Affiliates to execute and deliver, such additional documents, instruments, conveyances and assurances and take any such further actions as may be [\*\*\*] required to ensure that all right, title and interest in the Project Antibody Technology is

effectively assigned to and held by Paragon. Apogee and its Affiliates shall cause all of its and their employees who, in each case, generated, conceived of or created any Project Antibody Technology to assign [\*\*\*] all ownership rights in such Project Antibody Technology to Paragon.

#### 6.2 Patent Prosecution, Maintenance and Enforcement.

(a) Prior to execution of the License Agreement, Paragon shall have the sole right, but not the obligation, to prepare, file, prosecute, maintain or enforce any Project Antibody Patents at Paragon's sole expense, and Apogee shall reasonably cooperate and assist Paragon in such preparation, filing, prosecution, maintenance and enforcement, at Paragon's request. Following execution of the License Agreement, the Parties' respective rights relating to the preparation, filing, prosecution, maintenance and enforcement of Project Antibody Patents and Derived Antibody Patents shall be as set forth therein and Apogee shall reimburse Paragon for any costs and expenses actually incurred by Paragon in the prosecution and maintenance of any Project Antibody Patents prior to the exercise of the Option by Apogee, in accordance with the terms of the License Agreement.

(b) Apogee covenants and agrees that it will not file or prosecute any Patents Covering any Project Antibody or Derived Antibody (including without limitation any Project Antibody Inventions) during the Term of this Agreement except as permitted under a License Agreement executed by all Parties with respect to a given Research Program.

**6.3 Defense of Claims Brought by Third Parties.** If a Party becomes aware of any actual or potential claim that the research, development, or manufacture of any Project Antibody, Derived Antibody or Product being Developed pursuant to this Agreement or that are contemplated for Development, Manufacture of Commercialization under a License Agreement, infringes the Intellectual Property Rights of any Third Party, such Party will [\*\*\*] notify the other Party. In any such instance, the Parties will [\*\*\*] thereafter meet (which may be through the JDC) to discuss [\*\*\*] regarding the best response to such notice. Certain additional rights and obligations of the Parties with respect to any such claim will be set forth in the applicable License Agreement (to the extent applicable).

**6.4 No Implied Licenses.** Except as expressly set forth herein, no right or license under any Patents, Know-How or Intellectual Property Rights of either Party is granted or shall be granted by implication hereunder. All such rights or licenses are or shall be granted only as expressly provided in this Agreement or the applicable License Agreement.

#### ARTICLE 7 PROTECTION OF CONFIDENTIAL INFORMATION

**7.1 Confidentiality.** Except to the extent expressly authorized by this Agreement, the Receiving Party agrees that, during the Term and for [\*\*\*] years thereafter, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party may disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Representatives who have a need for such

information, provided that the Receiving Party shall advise such Representatives of the confidential nature thereof, shall ensure that each such Representative is bound in writing by obligations of confidentiality and non-use at least as stringent as those contained in this Agreement, and shall be responsible for the compliance of its Representatives with the terms of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information of the Disclosing Party. The Receiving Party shall [\*\*\*] notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the Disclosure On the Disclosure O

**7.2 Exceptions.** The Receiving Party's obligations under <u>Section 7.1</u> shall not apply to any Confidential Information of the Disclosing Party that the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available; (b) is known by the Receiving Party at the time of receiving such information from the Disclosing Party without obligation of confidentiality; (c) is hereafter furnished to the Receiving Party by a Third Party who had the lawful right and authority to furnish such information without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the aid, use or application of any Confidential Information of the Disclosing Party.

**7.3 Authorized Disclosure.** Notwithstanding the provisions of this <u>Article 7</u>, the Receiving Party may disclose Confidential Information, without violating its obligations under this Agreement, to the extent the disclosure is:

(a) required by a valid order of a court or other governmental body of competent jurisdiction or as otherwise required by Applicable Law, rule, regulation (including securities laws and regulations), government requirement or as may be required in connection with any filings made with, or by the disclosure policies of, a stock exchange, provided that the Receiving Party shall give reasonable prior written notice to the Disclosing Party of such required disclosure and, at the [\*\*\*] request and expense, shall cooperate with the Disclosing Party's efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law, rule or regulation required, or to obtain other confidential treatment of such Confidential Information; or

(b) reasonably necessary to file or prosecute patent applications, prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, in each case, in accordance with this Agreement.

**7.4 No Requirement to Disclose Paragon Platform Technology.** Notwithstanding anything to the contrary in this Agreement, Paragon will not be required to disclose any of the Paragon Platform Technology to Apogee other than as required to be included in the Deliverables.

**7.5 Use of Names.** Neither Party shall use the other Party's name or trademarks in any advertising, sales or promotional material or in any publication without the prior written consent of the other Party.

**7.6 Confidentiality of this Agreement.** This Agreement and its terms are considered Confidential Information of both Parties, and each Party shall keep confidential and shall not publish or otherwise disclose the terms of this Agreement without the prior written consent of the other Party, except as expressly permitted by <u>Section 7.3</u> or <u>Section 7.7</u>, and except that both Parties may disclose this Agreement and its terms to actual or potential investors, lenders, and strategic partners in connection with due diligence or similar investigations by such Third Parties or in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this <u>Article 7</u> (provided that the confidentiality term applicable to such Third Party may be shorter so long as it is commercially reasonable).

**7.7 Publicity.** Except to the extent required by Applicable Law or the rules of any stock exchange or listing agency, neither Party shall issue a press release announcing that they have entered into an Antibody discovery partnership, without the other Party's prior written consent, which shall not be unreasonably withheld.

#### ARTICLE 8 REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMER

#### 8.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder;

and

(b)

(c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not and will not conflict with any agreement, instrument or understanding, oral or written, to which it is or may become a party or by which it may be or become bound.

**8.2 Paragon Representations, Warrants and Covenants.** Paragon hereby represents, warrants and covenants to Apogee that:

(a) it will perform its activities under a Research Program with due care and in accordance with (i) Applicable Law, (ii) the terms and conditions contained herein and the applicable Research Plan, and (iii) generally prevailing industry standards;

(b) neither it nor any of its Affiliates have entered or will enter, directly or indirectly, into any contract or any other transaction with any Third Party or Affiliate that conflicts or derogates from its undertakings under this Agreement;

(c) it has the unencumbered right to the Paragon Platform Technology and the right, power and authority to use the Paragon Platform Technology in performance of the Research

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Plans and the performance of its obligations under this Agreement, in each case in accordance with the terms hereof;

(d) each Representative employed or engaged by Paragon or its Affiliate to conduct the activities under a Research Program has assigned and has executed an agreement assigning its entire right, title and interest in and to Project Antibody Technology to Paragon;

(e) there are no claims, actions or proceedings pending or threatened, nor are there any formal inquiries initiated or written notices received that may lead to the institution of any such legal proceedings, in each case (or in aggregate) against Paragon or its properties, assets or business, which would, individually or in the aggregate, have a material adverse effect on, or materially prevent, Paragon's ability to perform under this Agreement or to grant the Option or other rights granted to Apogee under this Agreement; and

none of Paragon, its Representatives, or any other person used by Paragon in the performance of the Agreement has been or is (i) debarred, convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (ii) listed by any government or regulatory agencies as ineligible to participate in any "Federal health care programs" (as that term is defined in 42 U.S.C. 1320a-7b(f)) or government procurement or non-procurement programs, or excluded, debarred, suspended or otherwise made ineligible to participate in any such program, or (iii) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Paragon agrees to inform Apogee in writing promptly if Paragon or any person who is performing activities on its behalf under the Agreement is subject to the foregoing, or if any action, suit, claim, investigation or proceeding relating to the foregoing is pending or threatened.

**8.3 Disclaimer.** EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, DURABILITY, MERCHANTABLE QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

#### ARTICLE 9 TERM AND TERMINATION

**9.1 Term.** The term of this Agreement ("**Term**") shall commence on the Effective Date and, subject to earlier termination of this Agreement in accordance with this <u>Article 9</u>, shall continue in force on a Research Program-by-Research Program basis until the earlier of:

(a) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by Apogee; and

(b) the effective date of the License Agreement for such Research Program if Apogee exercises its Option with respect to such Research Program, unless an extension is mutually agreed between the Parties.

Upon the expiration of the Term for all then-existing Research Programs, this Agreement will automatically expire in its entirety. For clarity, any executed License Agreements shall not be affected by such expiration.

**9.2 Termination of Agreement for Material Breach.** Each Party shall have the right to terminate this Agreement or a Research Program upon thirty (30) days' prior written notice to the other Party upon or after the material breach of any provision of this Agreement by the other Party if the breaching Party has not cured such breach by the end of such thirty (30) day period.

**9.3 Termination for Convenience.** Apogee shall have the right to terminate this Agreement or any Research Program for any reason or no reason upon thirty (30) days' prior written notice to Paragon; provided that Apogee will pay Paragon any unpaid fees due for Development Costs accrued prior to such effective termination date, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program, as evidenced by Paragon's records.

**9.4 Termination for a Bankruptcy Event.** Each Party will have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. **"Bankruptcy Event"** means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended, or under any similar laws or statutes of the United States or any state thereof (the **"Bankruptcy Code**"), where in the case of involuntary proceedings, such proceedings have not been dismissed or discharged within [\*\*\*] days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (d) the appointment of a receiver for all or substantially all of a Party's assets, or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

**9.5 Disposal of Confidential Information.** In the event this Agreement expires or this Agreement or any Research Program is terminated and the Parties have not entered into a License Agreement with respect to an expired or terminated Research Program, each Party shall return to the other Party all Confidential Information of the other Party (including all copies thereof) in such Party's possession related to any expired or terminated Research Program; provided, however, that each Party may retain one copy of the other Party's Confidential Information in such Party's secure archives for the sole purpose of monitoring compliance with its obligations hereunder or Applicable Law.

**9.6** Accrued Rights; Survival. The expiration or termination of this Agreement for any reason shall not release either Party from any liability or obligation that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination, nor will expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement. In the event of expiration or any

termination of this Agreement, the following provisions of this Agreement shall survive such expiration or termination in accordance with their respective terms and conditions: <u>Article 5</u>, <u>Article 7</u>, <u>Article 10</u> and <u>Article 11</u>, as well as <u>Sections 2.3</u>, <u>6.1</u>, <u>6.2(a)</u>, <u>6.4</u>, <u>9.3</u>, <u>9.5</u> and this <u>Section 9.6</u>.

#### ARTICLE 10 INDEMNIFICATION; LIMITATION OF LIABILITY

**10.1 By Apogee.** Apogee hereby agrees to defend, indemnify, and hold harmless Paragon, its Affiliates and its or their Representatives (each, an "**Paragon Indemnitee**") from and against any and all losses, damages, liabilities, expenses, and costs, including reasonable legal expense and attorneys' fees (collectively, "**Losses**"), to which any Paragon Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party ("**Third Party Claim**") to the extent such Losses result from: (a) the negligence or willful misconduct of any Apogee Indemnitee in the performance of this Agreement; or (b) the material breach by any Apogee Indemnitee of this Agreement; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Paragon Indemnitee or the material breach by Paragon of this Agreement, or where such Losses are subject to indemnification pursuant to <u>Section 10.2</u> below.

**10.2 By Paragon**. Paragon hereby agrees to defend, indemnify, and hold harmless Apogee, its Affiliates and its or their Representatives (each, an "**Apogee Indemnitee**") from and against any and all Losses to which any Apogee Indemnitee may become subject as a result of any Third Party Claim to the extent such Losses result from: (a) the negligence or willful misconduct of any Paragon Indemnitee in the performance of this Agreement; or (b) the material breach by any Paragon Indemnitee of this Agreement; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Apogee Indemnitee, the material breach by Apogee of this Agreement, or where such Losses are subject to indemnification pursuant to <u>Section 10.1</u> above.

**10.3 Indemnification Procedure.** In connection with any Third Party Claim for which a Party (the "**Indemnified Party**") seeks indemnification from the other Party (the "**Indemnifying Party**") pursuant to this Agreement, the Indemnified Party will: (a) give the Indemnifying Party [\*\*\*] notice of the Third Party Claim; *provided*, *however*, that failure to provide such notice will not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, at the Indemnifying Party is expense, in connection with the defense and settlement of the Third Party Claim; *provided*, *however*, that the Indemnifying Party to control the defense and settlement of the Third Party Claim; *provided*, *however*, that the Indemnifying Party may not settle the Third Party Claim without the Indemnified Party's prior written consent, which will not be unreasonably withheld or delayed, in the event that such settlement materially adversely impacts the Indemnified Party's rights or obligations. Further, the Indemnified Party will have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

**10.4 Limitation of Liability.** EXCEPT FOR LIABILITY FOR BREACH OF <u>ARTICLE 7</u> OR FOR INDEMNIFICATION CLAIMS UNDER <u>ARTICLE 10</u>, IN NO EVENT SHALL EITHER PARTY BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, EVEN IF THE OTHER PARTY HAD NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

#### ARTICLE 11 MISCELLANEOUS

**11.1 Independent Contractor Relationship.** Paragon's relationship with Apogee is that of an independent contractor, and nothing in this Agreement should be construed to create a partnership, joint venture or employer-employee relationship. Neither Party is an agent of the other Party or authorized to make any representation, contract or commitment on behalf of the other Party.

**11.2 Force Majeure.** Neither Party will be charged with any liability for delay or failure in performance of an obligation under this Agreement (other than any obligation to pay monies when due) to the extent such delay or failure is due to a cause beyond the reasonable control of the affected Party, such as war, riots, labor disturbances, epidemic, pandemic, fire or explosion, and compliance in good faith with any Applicable Law. The Party affected will give prompt written notice to the other Party of the nature of the cause of any material delay or failure to perform, its anticipated duration and any action being taken to avoid or minimize the effect. The Party affected will use its diligent efforts to avoid or remove such causes of delay or failure to perform and to mitigate the effect of such occurrence, and will continue performance in accordance with the terms of this Agreement whenever such causes are removed. The Party affected will give prompt written notice to the other Party of such resumed performance. If any such failure or delay in a Party's performance hereunder continues for more than [\*\*\*\*] days, the other Party may terminate this Agreement upon written notice to the affected Party.

**11.3 Entire Agreement; Amendment.** This Agreement, together with all Exhibits attached hereto, constitutes the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements, relating to its subject matter. This Agreement (including its Exhibits) may not be changed, modified, amended or supplemented except by a written instrument signed by both Parties.

**11.4 Non-Waiver.** The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

**11.5 Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such

provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

**11.6 Assignment.** Neither this Agreement nor any rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that (a) Paragon may assign to an Affiliate or a Third Party its rights to receive some or all of the payments payable hereunder; and (b) either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent to its successor to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Except for an assignment pursuant to <u>clause (a)</u> above, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns to the extent necessary to carry out the intent of this <u>Section 11.6</u>. Any assignment not in accordance with this Agreement shall be void.

**11.7 Dispute Resolution.** The Parties recognize that a *bona fide* dispute as to certain matters may arise from time to time during the Term relating to either Party's rights or obligations hereunder or otherwise relating to the validity, enforceability or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any disputes relating to <u>Article 7</u> (Confidentiality) hereof or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights (hereinafter, a "**Dispute**"). In the event of the occurrence of any Dispute, the Parties will follow the following procedures in an attempt to resolve the dispute or disagreement:

(a) The Party claiming that such a Dispute exists will give notice in writing (a "**Notice of Dispute**") to the other Party of the nature of the Dispute.

(b) The Dispute will be referred to the then Chief Executive Officer of Paragon and the then Chief Executive Officer of Apogee who will meet no later than [\*\*\*] days following the initial receipt of the Notice of Dispute and use reasonable endeavors to resolve the Dispute.

(c) If, within [\*\*\*] days of initial receipt of the Notice of Dispute, the Dispute has not been resolved, or if, for any reason, the meeting described in <u>Section 11.7(b)</u> hereof has not been held within [\*\*\*] days of initial receipt of the Notice of Dispute, then the Parties agree that such Dispute will be finally resolved through binding arbitration to be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the Expedited Procedures in those Rules, as specifically modified by the provisions of this <u>Section 11.7(c)</u>. The arbitration will be conducted by a panel of three arbitrators. Within [\*\*\*] after the initiation of the arbitration, each Party will nominate one person to act as arbitrator, and the two arbitrators so named will then jointly appoint the third arbitrator within [\*\*\*] days of their appointment, who will serve as chairman of the panel. All three arbitrators must be independent

Third Parties having at least [\*\*\*] years of dispute resolution experience (which may include judicial experience) or legal or business experience in the biotech or pharmaceutical industry. If either Party fails to nominate its arbitrator, or if the arbitrators selected by the Parties cannot agree on a person to be named as chairman within such [\*\*\*]-day period, JAMS will make the necessary appointments for such arbitrator(s) or the chairman. Once appointed by a Party, such Party will have no *ex parte* communication with its appointed arbitrator. The place of arbitration will be in Boston, Massachusetts, or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrators have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 *et seq.*, and judgment upon the award rendered by the arbitrators may be entered in any court having competent jurisdiction thereof. The existence, content and results of any arbitration proceedings pursuant to this <u>Section 11.7</u> will be deemed the Confidential Information of both Parties.

(d) Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement.

(e) The Parties agree that any disputes relating to <u>Article 7</u> (Confidentiality) hereof or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights shall be subject to the exclusive jurisdiction of the state and federal courts in New York, New York and each Party hereby submits to such jurisdiction.

**11.8 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without reference to conflicts of laws principles.

**11.9 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, by internationally recognized express courier, by email, or by facsimile, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by express courier, the next Business Day the express courier regularly makes deliveries; or (c) if delivered by email, upon the date upon which the receipt of such email is confirmed by return email. Together with any notice provided by a Party to the other Party in accordance with this <u>Section 11.9</u>, the Party shall send a copy of such notice by email to the other Party.

If to Paragon:

Paragon Therapeutics, Inc. 221 Crescent Street Building 23, Suite 105 Waltham, MA 02453 Attn: President

If to Apogee:	Apogee Therapeutics, Inc. 221 Crescent Street Building 17, Suite 102B Waltham, MA 02453 Attn: President
With a Copy to:	Apogee Therapeutics, Inc. 221 Crescent Street Building 17, Suite 102B Waltham, MA 02453 Attn: Legal Department

**11.10 Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity shall be construed to include such person's or entity's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Articles or Exhibits shall be construed to refer to Sections, Articles or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "or". The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English

language. To the extent there is any inconsistency or conflict between the terms and conditions of this Agreement and any Research Plan, the terms and conditions of this Agreement will prevail.

**11.11 No Third-Party Rights.** The provisions of this Agreement are for the exclusive benefit of the Parties and their successors and permitted assigns, and no other person shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

**11.12 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

**11.13 Expenses.** Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

**11.14 Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

**11.15 Construction.** The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to both Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

**11.16 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

[Remainder of page left intentionally blank; signature page follows.]

**IN WITNESS WHEREOF,** the Parties hereto have executed this Antibody Discovery and Option Agreement on the Effective Date.

## PARAGON THERAPEUTICS, INC.

# APOGEE THERAPEUTICS, INC. By:

By: /s/ K. Evan Thompson Name: K. Evan Thompson Title: President Date: 09 Nov 2023 By: /s/ Michael Henderson Name: Michael Henderson Title: CEO Date: 08 Nov 2023

#### 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 13, 2023

By:

/s/ Michael Henderson

Michael Henderson Chief Executive Officer (principal executive officer)

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

I, Jane Pritchett Henderson, certify that:

- 1. I have reviewed this 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 13, 2023

By:

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

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

In connection with the Quarterly Report on Form 10-Q of Apogee Therapeutics, Inc. (the "Company") for the period ending September 30, 2023, 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By:

Date: November 13, 2023

Date: November 13, 2023

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

/s/ Michael Henderson

Michael Henderson Chief Executive Officer (principal executive 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, 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 Apogee Therapeutics, Inc. and will be retained by Apogee Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.