UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026
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: 001-37722

SPYRE THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-4312787**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

221 Crescent Street
Building 23, Suite 105
Waltham, MA 02453

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (617) 651-5940
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, $0.0001 Par Value Per Share	SYRE	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large

accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 27, 2026, the registrant had 94,969,184 shares of common stock, $0.0001 par value per share, outstanding.

SPYRE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2026
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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the quarter ended September 30, 2026 (this "Quarterly Report") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 27A of the Securities Act of 1933, as amended (the "Securities Act"). All statements contained in this Quarterly Report, other than statements of historical fact, including, without limitation, statements regarding any future payouts under our contingent value rights ("CVRs") issued in connection with the acquisition of the assets of Spyre Therapeutics, Inc. (the "Asset Acquisition"); our future results of operations and financial position; our business strategy, including our ability to elevate the standard in immunology by delivering more complete disease control, greater durability, and a simpler treatment experience for patients and to develop potential first-in-class and best-in-class therapeutics for inflammatory bowel disease ("IBD"), psoriatic arthritis ("PsA"), axial spondyloarthritis ("axSpA"), hidradenitis suppurativa ("HS") and other immune-mediated diseases and rheumatic diseases ("RD") that meaningfully improve both efficacy and convenience compared to today's standard of care; our plans to expand the development of our product candidates to indications beyond IBD, RD and HS; our plans to develop a new program to advance SPY072 into late-stage development for HS, including timing thereof; our plans to develop a SPY072 monotherapy for the treatment of HS; our ability to achieve the expected benefits or opportunities with respect to our product candidates, including their potential commercialization; the potential consistency of the SPY001, SPY002, SPY072 and SPY003 Phase 1 trial and Phase 2 trial final data readouts with previously disclosed data for our programs; expectations regarding the drug delivery of our product candidates, including in the form of a subcutaneous injection; the planned dosing regimen for SPY001, SPY002, SPY072 and SPY003, as well as rational combination programs, including the potential for a Q3M-Q6M dosing profile and the potential for such dosing profile to be the leading product profile in IBD, RD and HS; our current and planned non-clinical and clinical development activities, including our plans for and timing of cohort initiation and data readouts for the ongoing SKYWAY Phase 2 basket trial, SKYLINE Phase 2 platform trial and SKYLIGHT Phase 2 trial, and the inclusion of each rational combination in Part B of the SKYLINE Phase 2 platform trial; estimated market sizes and potential growth opportunities; statements regarding the Company's cash guidance; the potential efficacy, tolerability, convenience, commercial viability and safety profile of our product candidates, including rational combination programs; the potential therapeutic benefits and economic value of our product candidates as monotherapies or our rational combination programs and their extended half-life; the expected impact of macroeconomic conditions, including inflation, increasing interest rates and volatile market conditions, and current or potential bank failures, as well as global events, including the ongoing military conflicts between the United States and Iran and Ukraine and Russia, the conflicts in the Middle East, instability in Venezuela and geopolitical tensions between the United States and other countries, including China, on our operations, and the implementation of changes in law, tariffs, sanctions, export or import controls, and other government measures that could impact our business operations, including restricting international trade by the United States, China or other countries; are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: uncertainties and risks arising from regulatory feedback, including potential disagreement by regulatory authorities with our interpretation of data and our ongoing or planned clinical trials for our product candidates, including our plans for and timing of cohort initiation for combination arms for the ongoing SKYLINE Phase 2 platform trial across different jurisdictions; the unpredictable relationship between preclinical study results and clinical study results; the potential for interim data not being delivered within expected time frames or final clinical data not being consistent with or different than the previously disclosed data for our programs; the impacts of adverse events or disappointing results in clinical trials of third parties, including our competitors developing product candidates that target similar mechanisms of action and/or indications as our product candidates; the expected or potential impact of macroeconomic conditions, including inflationary pressures, rising interest rates, general economic slowdown or a recession, changes in tariff/trade and monetary policy, volatile market conditions and financial institution instability, as well as geopolitical instability, including the ongoing conflicts between the United States and Iran and Ukraine and Russia, conflicts in the Middle East, instability in Venezuela and geopolitical tensions between the United States and other countries, including China, on our operations; the implementation of changes in law, tariffs, sanctions, export or import controls, and other government measures that could impact our business operations, including restricting international trade by the United States, China or other countries and the BIOSECURE Act; and those

uncertainties and factors described in Item 1A, “Risk Factors” included in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Quarterly Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless the context indicates otherwise, as used in this Quarterly Report, the terms “Spyre,” the “Company,” “we,” “us,” and “our” refer to Spyre Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries taken as a whole. “Spyre” and all product candidate names are our common law trademarks. This Quarterly Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

All references to “our product candidates,” “our programs” and “our pipeline” in this Quarterly Report refer to the research programs with respect to which we have signed a license agreement for or have the option to acquire intellectual property license rights to pursuant to that certain antibody discovery and option agreement, dated May 25, 2023, and subsequently amended and restated on September 29, 2023 and May 14, 2024, by and among us, Paragon Therapeutics, Inc. (“Paragon”) and Parapyre Holding LLC (“Parapyre”) (as amended, the “Paragon Agreement”).

PART I. – Financial Information.

Item 1. Financial Statements (Unaudited).

Spyre Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 82,727	$ 85,721
Marketable securities	989,180	670,812
Prepaid expenses and other current assets	27,821	21,248
Total current assets	1,099,728	777,781
TOTAL ASSETS	$ 1,099,728	$ 777,781
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 9,466	$ 8,904
CVR liability	—	22,820
Accrued and other current liabilities	30,595	26,947
Related party accounts payable	82	14
Total current liabilities	40,143	58,685
Non-current CVR liability	6,760	3,860
Other non-current liabilities	1,290	—
TOTAL LIABILITIES	48,193	62,545
Commitments and Contingencies (Notes 6 and 7)		
CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Series A non-voting convertible preferred stock, $0.0001 par value; 1,086,341 shares authorized as of September 30, 2026 and December 31, 2025; 346,045 shares issued and outstanding as of September 30, 2026 and December 31, 2025.	146,425	146,425
Series B non-voting convertible preferred stock, $0.0001 par value; 271,625 shares authorized as of September 30, 2026 and December 31, 2025; nil and 16,667 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.	—	9,395
Preferred stock, $0.0001 par value; 8,642,034 shares authorized as of September 30, 2026 and December 31, 2025; no shares issued and outstanding as of September 30, 2026 and December 31, 2025.	—	—
Common stock, $0.0001 par value; 400,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 89,953,997 shares and 78,189,811 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.	16	15
Additional paid-in capital	2,239,437	1,686,167
Accumulated other comprehensive (loss) income	(5,382)	869
Accumulated deficit	(1,328,961)	(1,127,635)
TOTAL STOCKHOLDERS' EQUITY	1,051,535	715,236
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 1,099,728	$ 777,781

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

Spyre Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development [1]	$ 89,169	$ 45,247	$ 215,083	$ 127,015
General and administrative [2]	16,550	11,641	47,916	35,375
Gain on sale of in-process research and development asset	—	—	(70,000)	(10,000)
Total operating expenses	105,719	56,888	192,999	152,390
Loss from operations	(105,719)	(56,888)	(192,999)	(152,390)
Other income (expense):				
Interest income	10,625	5,379	27,673	17,746
Other (expense) income, net	(1,027)	40,326	(36,000)	41,956
Total other income (expense)	9,598	45,705	(8,327)	59,702
Loss before income tax benefit	(96,121)	(11,183)	(201,326)	(92,688)
Income tax benefit	—	—	—	15
Net loss	$ (96,121)	$ (11,183)	$ (201,326)	$ (92,673)
Net loss per share, basic and diluted, Series A Preferred Stock	$ (37.60)	$ (5.97)	$ (81.74)	$ (49.53)
Weighted-average Series A non-voting convertible preferred stock outstanding, basic and diluted	346,045	346,045	346,045	346,045
Net loss per share, basic and diluted, Series B Preferred Stock	—	$ (5.97)	$ (81.74)	$ (49.53)
Weighted-average Series B non-voting convertible preferred stock outstanding, basic and diluted	—	16,667	10,623	16,667
Net loss per share, basic and diluted, common	$ (0.94)	$ (0.15)	$ (2.04)	$ (1.24)
Weighted-average common stock outstanding, basic and diluted	88,410,821	60,414,223	84,255,008	60,338,541

(1) Includes related party expenses of $0.1 million and $7.0 million for the three months ended September 30, 2026 and 2025, respectively. Includes related party expenses of $3.2 million and $9.6 million for the nine months ended September 30, 2026 and 2025, respectively.

(2) Includes related party expenses of $0.3 million for the three months ended September 30, 2026 and 2025, and $0.8 million for the nine months ended September 30, 2026 and 2025.

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

Spyre Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited, in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (96,121)	$ (11,183)	$ (201,326)	$ (92,673)
Other comprehensive income (loss):				
Foreign currency translation adjustment	—	—	—	(22)
Unrealized (loss) gain on marketable securities	(2,986)	337	(6,251)	633
Total comprehensive loss	$ (99,107)	$ (10,846)	$ (207,577)	$ (92,062)

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

Spyre Therapeutics, Inc.
Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity
(Unaudited, in thousands)

	Three and Nine Months Ended September 30, 2026									
	Series A Non-Voting Convertible Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances - December 31, 2025	346	$ 146,425	17	$ 9,395	78,190	$ 15	$ 1,686,167	$ 869	$ (1,127,635)	$ 715,236
Issuance of common stock in connection with at-the-market offering program, net of financing costs	—	—	—	—	296	—	9,747	—	—	9,747
Issuance of common stock in connection with exercise of stock options	—	—	—	—	354	—	3,663	—	—	3,663
Stock-based compensation expense	—	—	—	—	—	—	12,806	—	—	12,806
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(1,636)	—	(1,636)
Net loss	—	—	—	—	—	—	—	—	(69,005)	(69,005)
Balances - March 31, 2026	346	$ 146,425	17	$ 9,395	78,840	$ 15	$ 1,712,383	$ (767)	$ (1,196,640)	$ 670,811
Conversion of Series B Non-Voting Convertible Preferred Stock to common stock	—	—	(17)	(9,395)	667	—	9,395	—	—	—
Issuance of common stock in connection with follow-on offering, net of offering costs	—	—	—	—	7,475	1	434,897	—	—	434,898
Issuance of common stock in connection with exercise of stock options and employee stock purchase plan	—	—	—	—	1,083	—	19,749	—	—	19,749
Stock-based compensation expense	—	—	—	—	—	—	13,512	—	—	13,512
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(1,629)	—	(1,629)
Net loss	—	—	—	—	—	—	—	—	(36,200)	(36,200)
Balances - June 30, 2026	346	$ 146,425	—	$ —	88,064	$ 16	$ 2,189,936	$ (2,396)	$ (1,232,840)	$ 1,101,141
Issuance of common stock in connection with at-the-market offering programs, net of financing costs	—	—	—	—	327	—	29,520	—	—	29,520
Issuance of common stock in connection with exercise of warrants	—	—	—	—	1,161	—	—	—	—	—
Issuance of common stock in connection with exercise of stock options	—	—	—	—	368	—	5,814	—	—	5,814
Vesting of restricted stock units	—	—	—	—	34	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	14,167	—	—	14,167
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(2,986)	—	(2,986)
Net loss	—	—	—	—	—	—	—	—	(96,121)	(96,121)
Balances - September 30, 2026	346	$ 146,425	—	$ —	89,954	$ 16	$ 2,239,437	$ (5,382)	$ (1,328,961)	$ 1,051,535

	Three and Nine Months Ended September 30, 2025									
	Series A Non-Voting Convertible Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances - December 31, 2024	346	$ 146,425	17	$ 9,395	60,257	$ 13	$ 1,334,223	$ 180	$ (972,432)	$ 517,804
Issuance of common stock in connection with exercise of stock options and employee stock purchase plan	—	—	—	—	19	—	218	—	—	218
Stock-based compensation expense	—	—	—	—	—	—	8,859	—	—	8,859
Foreign currency translation adjustment	—	—	—	—	—	—	—	14	—	14
Unrealized gain on marketable securities	—	—	—	—	—	—	—	488	—	488
Net loss	—	—	—	—	—	—	—	—	(44,773)	(44,773)
Balances - March 31, 2025	346	$ 146,425	17	$ 9,395	60,276	$ 13	$ 1,343,300	$ 682	$ (1,017,205)	$ 482,610
Issuance of common stock in connection with exercise of stock options and employee stock purchase plan	—	—	—	—	97	—	730	—	—	730
Stock-based compensation expense	—	—	—	—	—	—	9,378	—	—	9,378
Foreign currency translation adjustment	—	—	—	—	—	—	—	(36)	—	(36)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(192)	—	(192)
Net loss	—	—	—	—	—	—	—	—	(36,717)	(36,717)
Balances - June 30, 2025	346	$ 146,425	17	$ 9,395	60,373	$ 13	$ 1,353,408	$ 454	$ (1,053,922)	$ 455,773
Vesting of restricted stock units	—	—	—	—	34	—	—	—	—	—
Issuance of common stock in connection with exercise of stock options and employee stock purchase plan	—	—	—	—	65	—	607	—	—	607
Stock-based compensation expense	—	—	—	—	—	—	9,566	—	—	9,566
Unrealized gain on marketable securities	—	—	—	—	—	—	—	337	—	337
Net loss	—	—	—	—	—	—	—	—	(11,183)	(11,183)
Balances - September 30, 2025	346	$ 146,425	17	$ 9,395	60,472	$ 13	$ 1,363,581	$ 791	$ (1,065,105)	$ 455,100

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

Spyre Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (201,326)	$ (92,673)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	40,485	27,803
Change in fair value of CVR liability	35,813	(42,199)
Gain on sale of in-process research and development asset	(70,000)	(10,000)
Net accretion of discount on marketable securities	(9,493)	(6,005)
Interest proceeds from maturities of zero coupon U.S. Treasury Bills	—	2,069
Changes in operating assets and liabilities:		
Accounts payable	562	6,791
Accrued and other liabilities	4,937	(3,888)
Related party accounts payable	68	3,367
Prepaid expenses and other assets	(5,790)	(9,939)
Net cash used in operating activities	(204,744)	(124,674)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from maturities and sales of marketable securities	351,664	277,440
Purchases of marketable securities	(666,790)	(180,505)
Proceeds from sale of in-process research and development asset	70,000	7,000
Net cash (used in) provided by investing activities	(245,126)	103,935
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock in connection with follow-on offering, net of issuance costs	435,240	—
Proceeds from issuance of common stock in connection with at-the-market offering program, net of issuance costs	39,275	—
Payment of deferred offering costs in connection with shelf registration	(754)	(93)
Payments related to contingent value rights liability	(55,733)	(5,251)
Proceeds from employee stock option exercises and employee stock plan purchases	28,848	1,557
Net cash provided by (used in) financing activities	446,876	(3,787)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,994)	(24,526)
CASH AND CASH EQUIVALENTS		
Beginning of period	85,721	89,423
End of period	$ 82,727	$ 64,897
Supplemental Disclosure of Non-Cash Financing Information:		
Proceeds from stock option exercises received in subsequent period	$ 380	$ —
Allocation of deferred offering costs against proceeds of issuance of common stock	$ 351	$ —
Conversion of Series B non-voting convertible preferred stock into common stock	$ 9,395	$ —

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

1. The Company and Basis of Presentation

Spyre Therapeutics, Inc., formerly Aeglea BioTherapeutics, Inc. ("Spyre" or the "Company"), is a clinical stage biotechnology company committed to developing next-generation therapies that elevate the standard in immunology by delivering more complete disease control, greater durability, and a simpler treatment experience for patients. The Company was formed as a Limited Liability Company in Delaware on December 16, 2013 under the name Aeglea BioTherapeutics Holdings, LLC and was converted from a Delaware LLC to a Delaware corporation on March 10, 2015. On June 22, 2023, the Company acquired the assets of Spyre Therapeutics, Inc., a privately held biotechnology company (the "Asset Acquisition"), and on November 27, 2023, the Company completed its corporate rebranding, changing the name of the Company to Spyre Therapeutics, Inc. The Company operates in one segment and has its principal offices in Waltham, Massachusetts.

In connection with the Asset Acquisition, a non-transferable contingent value right ("CVR") was distributed to stockholders of record of the Company as of the close of business on July 3, 2023 (the "Legacy Stockholders"). Holders of the CVRs are entitled to receive certain cash payments from proceeds received by the Company prior to July 3, 2026, the third anniversary of the contingent value rights agreement (the "CVR Agreement") we entered into with Equiniti Trust Company LLC (f/k/a American Stock Transfer & Trust Company LLC) as rights agent in connection with the Asset Acquisition, if any, related to the disposition or monetization of its legacy assets during the one-year period following the closing of the Asset Acquisition.

On September 6, 2024, the Company entered into a sales agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC as its agent, pursuant to which the Company may issue and sell up to $200.0 million of shares of common stock under an at-the-market ("ATM") offering program. During the three and nine months ended September 30, 2026, the Company sold an aggregate of nil and 296,396 shares of common stock, respectively, under the ATM offering program pursuant to the 2024 Sales Agreement resulting in net proceeds of nil and $9.7 million, respectively. The 2024 Sales Agreement was terminated on June 26, 2026 and the Company concurrently entered into a new sales agreement (the "2026 Sales Agreement") with TD Securities (USA) LLC as its agent, pursuant to which the Company may issue and sell up to $500.0 million of shares of common stock under an ATM offering program. During the three and nine months ended September 30, 2026, the Company sold 327,391 shares under the ATM offering program pursuant to the 2026 Sales Agreement, resulting in net proceeds of $29.5 million. As of September 30, 2026, $469.9 million remained available for sale under the 2026 Sales Agreement. Subsequent to September 30, 2026, and through November 3, 2026, the Company sold 200,111 shares under the ATM offering program pursuant to the 2026 Sales Agreement, resulting in net proceeds of $18.0 million and $451.6 million remaining available for sale under the 2026 Sales Agreement as of November 3, 2026.

On October 13, 2025, the Company entered into an underwriting agreement (the "October 2025 Underwriting Agreement"), pursuant to which the Company sold an aggregate of 17,094,594 shares of its common stock, inclusive of 2,229,729 shares pursuant to the full exercise of the underwriters' over-allotment option, at a public offering price per share of $18.50, resulting in net proceeds of approximately $296.4 million after deducting approximately $19.9 million of underwriting discounts and other offering costs. The over-allotment option was exercised in full on October 14, 2025 and the transaction closed on October 15, 2025.

On April 13, 2026, the Company entered into an underwriting agreement (the "April 2026 Underwriting Agreement"), pursuant to which the Company sold an aggregate of 7,475,000 shares of its common stock, inclusive of 975,000 shares pursuant to the full exercise of the underwriters' over-allotment option, at a public offering price per share of $62.00, resulting in net proceeds of approximately $435.2 million after deducting approximately $28.2 million of underwriting discounts and other offering costs (the "April 2026 Offering"). The over-allotment option was exercised in full on April 15, 2026 and the transaction closed on April 16, 2026.

On October 5, 2026, the Company entered into an underwriting agreement (the "October 2026 Underwriting Agreement") for the sale of 4,117,648 shares of its common stock (the "Firm Shares") at a public offering price of $85.00 per share. The Company also granted the underwriters an option to purchase up to 617,647 additional shares (the "Option Shares") at the same price. The sale of the Firm Shares closed on

October 7, 2026. The underwriters exercised their option in full on October 12, 2026, and the sale of the Option Shares closed on October 13, 2026. In total, the Company sold an aggregate of 4,735,295 shares of its common stock in the offering, resulting in net proceeds of approximately $378.0 million after deducting approximately $24.5 million of underwriting discounts and other offering costs (the "October 2026 Offering").

Liquidity

The Company is a clinical stage biotechnology company with a limited operating history, and due to its significant research and development expenditures, the Company has generated operating losses since its inception and has not generated any revenue from the commercial sale of any products. There can be no assurance that profitable operations will ever be achieved, and, if achieved, whether profitability can be sustained on a continuing basis.

Since its inception and through September 30, 2026, the Company has funded its operations by raising an aggregate of approximately $2.2 billion of gross proceeds from the sale and issuance of convertible preferred stock and common stock, pre-funded warrants, the collection of grant proceeds, and the licensing of its product rights for commercialization of pegzilarginase in Europe and certain countries in the Middle East. As of September 30, 2026, Spyre had an accumulated deficit of $1.3 billion, and cash, cash equivalents, and marketable securities of $1.1 billion.

Based on its current operating plans, the Company has sufficient resources to fund operations for at least one year from the issuance date of these financial statements with existing cash, cash equivalents, and marketable securities. The Company will need to secure additional financing in the future to fund additional research and development, and before a commercial drug can be produced, marketed and sold. If the Company is unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on the Company.

Basis of Presentation

The condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") as defined by the Financial Accounting Standards Board ("FASB") and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this Quarterly Report on Form 10-Q are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of September 30, 2026, and its results of operations for the three and nine months ended September 30, 2026 and 2025, changes in convertible preferred stock and stockholders' equity for the three and nine months ended September 30, 2026 and 2025, and cash flows for the nine months ended September 30, 2026 and 2025. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other future annual or interim period. The December 31, 2025 balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP for complete financial statements. These financial statements should be read in conjunction with the audited financial statements included in the Company's Form 10-K for the year ended December 31, 2025 (the "Annual Report") as filed with the U.S. Securities and Exchange Commission ("SEC") on February 19, 2026.

2. Summary of Significant Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and SEC instructions for interim financial information, and should be read in conjunction with the Annual Report. Significant accounting policies and other disclosures normally provided have been omitted since

such items are disclosed in the Annual Report. The Company uses the same accounting policies in preparing quarterly and annual financial statements.

There have been no significant changes from the significant accounting policies and estimates disclosed in the Notes titled “1. The Company and Basis of Presentation” and “2. Summary of Significant Accounting Policies” of the Annual Report, except as disclosed below:

Contingent Value Rights

As of June 30, 2026, CVRs are no longer a significant accounting policy. The Company determined that remaining significant contingencies regarding its future payment obligations under the CVR Agreement have been resolved. Accordingly, the Company has measured the fair value of its CVR liability by discounting the estimated future payments to be made under the CVR Agreement using the Company’s weighted average cost of capital. This fair value measurement is based on inputs observable in the market and thus represents a Level 2 measurement as defined in ASC 820, Fair Value Measurement. The estimated value of the CVR consideration is based upon available information and certain assumptions which the Company's management believes are reasonable under the circumstances. The ultimate payout under the CVRs may differ materially from the assumptions used in determining the fair value of the CVR consideration.

Recently Adopted Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements adopted during the three months ended September 30, 2026 that are of significance or potential significance to the Company.

Not Yet Adopted Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update 2024-03 (“ASU 2024-03”) Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses to require more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact ASU 2024-03 will have on its disclosures.

3. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The following tables set forth the fair value of the Company's financial assets and liabilities at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 71,847	$ —	$ —	$ 71,847
U.S. government treasury securities	305,536	—	—	305,536
U.S. government agency securities	—	173,901	—	173,901
Commercial paper	—	375,428	—	375,428
Corporate bonds	—	134,315	—	134,315
Total financial assets	$ 377,383	$ 683,644	$ —	$ 1,061,027
Liabilities:				
CVR liability	$ —	$ 6,760	$ —	$ 6,760
Total liabilities	$ —	$ 6,760	$ —	$ 6,760

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 74,004	$ —	$ —	$ 74,004
U.S. government treasury securities	266,064	—	—	266,064
U.S. government agency securities	—	119,590	—	119,590
Commercial paper	—	194,355	—	194,355
Corporate bonds	—	100,790	—	100,790
Total financial assets	$ 340,068	$ 414,735	$ —	$ 754,803
Liabilities:				
CVR liability	$ —	$ —	$ 26,680	$ 26,680
Total liabilities	$ —	$ —	$ 26,680	$ 26,680

The Company measures the fair value of money market funds and U.S. government treasury securities on quoted prices in active markets for identical assets or liabilities. The Level 2 assets include U.S. government agency securities, commercial paper and corporate bonds, and are valued based on quoted prices for similar assets in active markets and inputs other than quoted prices that are derived from observable market data. The Company evaluates transfers between levels at the end of each reporting period. There were no financial asset transfers between Level 1, Level 2, or Level 3 during the periods presented.

CVR Liability

In connection with the Asset Acquisition, a non-transferable CVR was distributed to the Legacy Stockholders. Holders of the CVR are entitled to receive certain cash payments from proceeds received by the Company for a three-year period ending July 3, 2026, related to the disposition or monetization of the Company's legacy assets for a period of one year following the closing of the Asset Acquisition.

As of December 31, 2025, the fair value of the CVR liability was determined using the probability weighted discounted cash flow method to estimate future cash flows associated with the sale of the legacy assets. Analogous to a dividend being declared/approved in one period and paid out in another, the liability was recorded at the date of approval, June 22, 2023, as a common stock dividend, returning capital to the Legacy

Stockholders. Changes in fair value of the liability were recognized as a component of Other income (expense), net in the consolidated statement of operations and comprehensive loss in each reporting period. The liability value was based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of regulatory success, and discount rates, which represent a Level 3 measurement within the fair value hierarchy.

As of June 30, 2026, all contingencies related to the disposition or monetization of the Company's legacy assets are resolved and the fair value of the CVR liability was determined by discounting future payments to holders of the CVR. Changes in fair value of the liability will be recognized as a component of Other income (expense), net in the consolidated statement of operations and comprehensive loss in each reporting period. The liability is based on inputs observable in the market such as estimated discount rates which represent a Level 2 measurement within the fair value hierarchy.

The significant inputs used to estimate the fair value of the CVR liability were as follows:

	September 30, 2026
Risk-adjusted discount rate	12.10%

The CVR liability decreased by $19.9 million between December 31, 2025 and September 30, 2026, reflecting payments totaling $55.7 million to CVR holders, partially offset by a $35.8 million increase in fair value. The fair value increase was primarily driven by the achievement status of certain milestones, the receipt of certain cash consideration within the CVR term and time value of money adjustments.

The following table presents changes in the CVR liability for the periods presented (in thousands):

	CVR Liability
Beginning balance as of December 31, 2025	$ 26,680
Changes in the fair value of the CVR liability	35,813
Payments	(55,733)
Ending balance as of September 30, 2026	$ 6,760

4. Cash Equivalents and Marketable Securities

The following tables summarize the estimated fair value of the Company's cash equivalents and marketable securities and the gross unrealized gains and losses (in thousands):

	September 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 71,847	$ —	$ —	$ 71,847
Total cash equivalents	$ 71,847	$ —	$ —	$ 71,847
Marketable securities:				
Commercial paper	$ 376,082	$ 1	$ (655)	$ 375,428
Corporate bonds	135,058	—	(743)	134,315
U.S. government treasury securities	307,521	11	(1,996)	305,536
U.S. government agency securities	175,901	—	(2,000)	173,901
Total marketable securities	$ 994,562	$ 12	$ (5,394)	$ 989,180

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 74,004	$ —	$ —	$ 74,004
Commercial paper	9,987	—	—	9,987
Total cash equivalents	$ 83,991	$ —	$ —	$ 83,991
Marketable securities:				
Commercial paper	$ 184,423	$ 25	$ (80)	$ 184,368
Corporate bonds	100,753	60	(23)	100,790
U.S. government treasury securities	265,316	748	—	266,064
U.S. government agency securities	119,450	153	(13)	119,590
Total marketable securities	$ 669,942	$ 986	$ (116)	$ 670,812

The following table summarizes the available-for-sale securities in an unrealized loss position for which an allowance for credit losses has not been recorded as of September 30, 2026 and December 31, 2025, aggregated by major security type and length of time in a continuous unrealized loss position (in thousands):

	September 30, 2026					
	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 370,652	$ (655)	$ —	$ —	$ 370,652	$ (655)
Corporate bonds	134,315	(743)	—	—	134,315	(743)
U.S. government treasury securities	253,898	(1,996)	—	—	253,898	(1,996)
U.S. government agency securities	173,901	(2,000)	—	—	173,901	(2,000)
Total marketable securities	$ 932,766	$ (5,394)	$ —	$ —	$ 932,766	$ (5,394)

	December 31, 2025					
	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 99,837	$ (80)	$ —	$ —	$ 99,837	$ (80)
Corporate bonds	58,296	(23)	—	—	58,296	(23)
U.S. government agency securities	22,828	(13)	—	—	22,828	(13)
Total marketable securities	$ 180,961	$ (116)	$ —	$ —	$ 180,961	$ (116)

The Company evaluated its securities for credit losses and considered the decline in market value to be primarily attributable to current economic and market conditions and not to a credit loss or other factors. Additionally, the Company does not intend to sell the securities in an unrealized loss position and does not expect it will be required to sell the securities before recovery of the unamortized cost basis. As of September 30, 2026 and December 31, 2025, an allowance for credit losses had not been recognized. Given the Company's intent and ability to hold such securities until recovery, and the lack of significant change in credit risk of these investments, the Company does not consider these marketable securities to be impaired as of September 30, 2026 and December 31, 2025.

The financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash deposits. Accounts at each of the Company's two U.S. banking institutions are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 per depositor. As of September 30, 2026 and December 31, 2025, cash deposits at the Company's U.S. banking institutions exceeded the FDIC limits.

There were no realized gains or losses on marketable securities for both the three and nine months ended September 30, 2026 and 2025. Interest on marketable securities is included in interest income. Accrued interest receivable on available-for-sale debt securities as of September 30, 2026 and December 31, 2025, was $5.8 million and $4.5 million, respectively, and is reflected in Prepaid expenses and other current assets.

The following table summarizes the contractual maturities of the Company's marketable securities at estimated fair value (in thousands):

	September 30, 2026	December 31, 2025
Due in one year or less	$ 688,095	$ 440,895
Due in 1-2 years	301,085	229,917
Total marketable securities	$ 989,180	$ 670,812

The Company may sell investments at any time for use in current operations even if they have not yet reached maturity. As a result, the Company classifies marketable securities, including securities with maturities beyond twelve months as current assets.

5. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued compensation	$ 7,345	$ 7,940
Accrued contracted research and development costs	20,769	17,424
Accrued professional and consulting fees	2,337	1,404
Accrued other	144	179
Total accrued and other current liabilities	$ 30,595	$ 26,947

6. Licensing Agreements

On July 12, 2023, December 14, 2023, and June 5, 2024, the Company exercised the Option (as defined below) available under the antibody discovery and option agreement, dated May 25, 2023, and subsequently amended and restated on September 29, 2023 and May 14, 2024, by and among the Company, Paragon Therapeutics, Inc. ("Paragon") and Parapyre Holding LLC ("Parapyre") (as amended, the "Paragon Agreement") with respect to the SPY001, SPY002 and SPY072, and SPY003 research programs, respectively.

On May 14, 2024, the Company and Paragon entered into (i) a license agreement (the "SPY001 License Agreement"), pursuant to which Paragon granted the Company a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting α4β7 integrin and (ii) a license agreement (the "SPY002 and SPY072 License Agreement"), pursuant to which Paragon granted the Company a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting TL1A, respectively, which includes the Company's SPY002 and SPY072 product candidates.

On October 11, 2024, the Company and Paragon entered into a license agreement (as amended, the "SPY003 License Agreement", and together with the SPY001 License Agreement and the SPY002 and SPY072 License Agreement, the "License Agreements"), pursuant to which Paragon granted the Company a royalty-

bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 in the field of IBD.

On February 24, 2025, the SPY003 License Agreement was amended and restated to, among other things, clarify each party's rights and obligations with respect to license exclusivity and patent prosecution. On May 29, 2026, the SPY003 License Agreement was further amended to expand the definition of “Field” to encompass all therapeutic, prophylactic, palliative and diagnostic uses of SPY003, subject to certain restrictions (as summarized below).

Under the terms of each License Agreement, the Company is obligated to pay Paragon up to $22.0 million based on specific development, regulatory and clinical milestones for the first product under each agreement, respectively, that achieves such specified milestones, including a milestone payment of $5.0 million upon the first dosing of a human patient in a Phase 3 trial. In addition, the following summarizes other key terms of each License Agreement:

- Paragon will provide the Company with an exclusive license to its patents covering the related antibody, the method of use and its method of manufacture.
- Paragon will not conduct any new campaigns that generate anti-α4β7 or anti-TL1A monospecific antibodies in any field or anti-IL-23 monospecific antibodies in the field of IBD, in each case for at least 5 years.
- The Company will pay Paragon a low single-digit percentage royalty for single antibody products and a mid single-digit percentage royalty for products containing more than one antibody from Paragon.
- There is a royalty step-down of 1/3rd if there is no Paragon patent in effect during the royalty term.
- The royalty term ends on the later of (i) the last-to-expire licensed patent or Company patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of a Company product.
- Each License Agreement may be terminated on 60 days’ notice by the Company; on material breach without cure; and to the extent permitted by law, on a party’s insolvency or bankruptcy.
- With respect to the SPY002 and SPY072 License Agreement only, on a product by product basis, the Company will pay sublicensing fees of up to approximately $20 million upon the achievement of mostly commercial milestones.
- With respect to the SPY003 License Agreement only, the Company will not dose a human patient in a clinical trial of SPY003 for an indication outside of inflammatory bowel disease as part of a combination until June 1, 2028 or as a monotherapy until June 1, 2030 (the “Monotherapy Dosing Restriction”). In the event the Company or a licensee of Paragon's retained rights under the SPY003 License Agreement consummates a material transaction, including a change of control of the Company or such licensee, then any remaining restrictions outside of the initial definition of “Field” set forth in the Monotherapy Dosing Restriction shall remain in effect only until June 1, 2028 and thereafter terminate and be of no further force or effect.

The Company recognizes the expense associated with each milestone when the achievement of the milestone is deemed probable.

The Company recognized expense related to Paragon license milestone payments, recorded within Research and development expenses in the accompanying condensed statement of operations, of nil and $6.0 million for the three months ended September 30, 2026 and 2025, respectively. The Company recognized expense related to Paragon license milestone payments, recorded within Research and development expenses in the accompanying condensed statement of operations, of $3.0 million and $8.5 million for the nine months ended September 30, 2026 and 2025, respectively.

The Company paid milestone payments to Paragon totaling nil and $3.0 million for the three months ended September 30, 2026 and 2025, respectively. The Company paid milestone payments to Paragon totaling $3.0 million and $5.5 million for the nine months ended September 30, 2026 and 2025, respectively. As of

September 30, 2026 and December 31, 2025, there were no milestone payments outstanding and payable to Paragon.

Additionally, the Company recognized $0.1 million in sublicensing fees expense for the three and nine months ended September 30, 2026, and $1.0 million in sublicensing fees expense for the three and nine months ended September 30, 2025, which were recorded as Research and development expenses in the accompanying condensed statement of operations.

There were no payments related to sublicensing fees for the three and nine months ended September 30, 2026. The Company paid sublicensing fees to Paragon totaling nil and $0.5 million for the three and nine months ended September 30, 2025, respectively.

As of September 30, 2026 and December 31, 2025, there were $0.1 million and nil sublicensing fees outstanding and payable to Paragon, respectively.

7. Related Party Transactions

Paragon and Parapyre each beneficially own less than 5% of a class of the Company's voting securities through their respective holdings of the Company's common stock. Fairmount Funds Management LLC (“Fairmount”) beneficially owns more than 5% of a class of the Company's voting securities, has one seat on the Board (held by Tomas Kiselak) and beneficially owns more than 5% of Paragon. Fairmount appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers of Paragon.

The following is the summary of expenses related to the License Agreements and other Paragon reimbursable expenses, which are ultimately settled in cash (in millions) and recorded within Research and development in the consolidated statement of operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
License Agreements milestone and sublicensing fees	$ 0.1	$ 7.0	$ 3.1	$ 9.5
Other Paragon reimbursable expenses	—	—	0.1	0.1
Total related party expense	$ 0.1	$ 7.0	$ 3.2	$ 9.6

For the three months ended September 30, 2026 and 2025, the Company recognized de minimis expenses related to services provided by Paragon, which were recorded as Research and development expenses in the consolidated statements of operations. For the nine months ended September 30, 2026 and 2025, the Company recognized $0.1 million of Paragon reimbursable expenses.

Related party accounts payable were $0.1 million and de minimis as of September 30, 2026 and December 31, 2025.

For the three months ended September 30, 2026 and 2025, the Company made de minimis payments in connection with Paragon reimbursable expenses. For the nine months ended September 30, 2026 and 2025, the Company made payments totaling $0.1 million and $0.2 million, respectively, in connection with Paragon reimbursable expenses.

Paragon License Agreements

See Note 6 for disclosures related to the License Agreements entered into with Paragon.

Mark McKenna Option Grant

On February 1, 2024, the Board appointed Mark McKenna as a Class I director. Mr. McKenna and the Company are parties to a consulting agreement, pursuant to which Mr. McKenna agreed to continue to provide

consulting services as an independent contractor to the Company, with an effective date of August 1, 2023 (the "Vesting Commencement Date"). As compensation for Mr. McKenna's consulting services, on November 22, 2023, he was granted non-qualified stock options to purchase 477,000 shares of the Company's common stock under the 2016 Plan (as defined in Note 9) with an exercise price of $10.39 per share, which vest as to 25% on the one year anniversary of the Vesting Commencement Date and thereafter vest and become exercisable in 36 equal monthly installments, subject to Mr. McKenna's continued service to the Company through each applicable vesting date. The Company recognized stock-based compensation expense related to Mr. McKenna's consulting agreement of $0.3 million for the three months ended September 30, 2026 and 2025, and $0.8 million for the nine months ended September 30, 2026 and 2025.

8. Convertible Preferred Stock and Stockholders' Equity

Warrants

As of September 30, 2026, all 1,532,591 warrants previously issued to Parapyre pursuant to the Paragon Agreement, with a weighted-average exercise price of $22.49, have been exercised, and no warrants remain outstanding.

Series A Non-Voting Convertible Preferred Stock

Pursuant to the Company's Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock (the "Series A Preferred Stock") (the "Series A Certificate of Designation"), holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal to, on an as-if-converted-to-common stock basis, and in the same form as, dividends actually paid on shares of common stock. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock: (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, or alter or amend the Series A Certificate of Designation, amend or repeal any provision of, or add any provision to, the Company's Certificate of Incorporation or its Bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock, regardless of whether any of the foregoing actions will be by means of amendment to the Certificate of Incorporation or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (b) issue further shares of Series A Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock, (c) prior to the stockholder approval of the conversion of the Series A Preferred Stock into shares of common stock in accordance with Nasdaq Stock Market Rules or at any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, consummate (x) any Fundamental Transaction (as defined in the Series A Certificate of Designation) or (y) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the Company's stockholders immediately before such transaction do not hold at least a majority of the Company's capital stock immediately after such transaction or (d) enter into any agreement with respect to any of the foregoing. The Series A Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

As of September 30, 2026, 346,045 shares of Series A Preferred Stock remained outstanding and are convertible into 13,841,800 common shares.

Series B Non-Voting Convertible Preferred Stock

Prior to the retirement of the Company's Series B Non-Voting Convertible Preferred Stock (the "Series B Preferred Stock") described below, pursuant to the Company's Certificate of Designation of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock (as amended, the "Series B Certificate of Designation"), holders of Series B Preferred Stock were entitled to receive dividends on shares of Series B Preferred Stock equal to, on an as-if-converted-to-common stock basis, and in the same form as, dividends actually paid on shares of common stock. Except as provided in the Series B Certificate of

Designation or as otherwise required by law, the Series B Preferred Stock did not have voting rights. However, as long as any shares of Series B Preferred Stock were outstanding, the Company would not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, or alter or amend the Series B Certificate of Designation, amend or repeal any provision of, or add any provision to, the Company's Certificate of Incorporation or its Bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series B Preferred Stock, regardless of whether any of the foregoing actions were by means of amendment to the Certificate of Incorporation or by merger, consolidation, recapitalization, reclassification, conversion or otherwise. The Series B Preferred Stock did not have a preference upon any liquidation, dissolution or winding-up of the Company.

On June 23, 2026, all 16,667 shares of Series B Preferred Stock outstanding were converted at the option of the holder into 666,680 shares of common stock. As of September 30, 2026, no shares of Series B Preferred Stock remained outstanding.

On October 29, 2026, the Company filed with the Secretary of State of the State of Delaware (i) a Corrected Second Amended and Restated Certificate of Incorporation to correct the inadvertent omission from its Second Amended and Restated Certificate of Incorporation of the Series A Certificate of Designation and the Series B Certificate of Designation and (ii) a Certificate of Elimination of Series B Non-Voting Convertible Preferred Stock to effect the retirement of its Series B Preferred Stock, which resulted in the previously authorized shares of the retired Series B Preferred Stock being returned to authorized, unissued and undesignated preferred stock.

ATM Facility

On September 6, 2024, the Company entered into the 2024 Sales Agreement, pursuant to which the Company may issue and sell up to $200.0 million of shares of common stock under an ATM offering program.

During the year ended December 31, 2025, the Company sold an aggregate of 445,668 shares of common stock under its ATM offering program pursuant to the 2024 Sales Agreement resulting in net proceeds of $14.8 million.

During the nine months ended September 30, 2026, the Company sold an aggregate of 296,396 shares of common stock under the ATM offering program pursuant to the 2024 Sales Agreement resulting in net proceeds of $9.7 million.

The 2024 Sales Agreement was terminated on June 26, 2026 and the Company concurrently entered into a new sales agreement (the "2026 Sales Agreement") with TD Securities (USA) LLC as its agent, pursuant to which the Company may issue and sell up to $500.0 million of shares of common stock under an ATM offering program.

During the three and nine months ended September 30, 2026, the Company sold 327,391 shares under the ATM offering program pursuant to the 2026 Sales Agreement, resulting in net proceeds of $29.5 million. As of September 30, 2026, $469.9 million remained available for sale under the 2026 Sales Agreement.

Subsequent to September 30, 2026, and through November 3, 2026, the Company sold 200,111 shares under the ATM offering program pursuant to the 2026 Sales Agreement, resulting in net proceeds of $18.0 million and $451.6 million remaining available for sale under the 2026 Sales Agreement as of November 3, 2026.

October 2025 Underwritten Offering

On October 13, 2025, the Company entered into the October 2025 Underwriting Agreement, pursuant to which the Company sold an aggregate of 17,094,594 shares of common stock, inclusive of 2,229,729 shares pursuant to the full exercise of the underwriters' over-allotment option, at a public offering price per share of $18.50, resulting in net proceeds of approximately $296.4 million after deducting approximately $19.9 million of

underwriting discounts and other offering costs. The over-allotment option was exercised in full on October 14, 2025 and the transaction closed on October 15, 2025.

April 2026 Underwritten Offering

On April 13, 2026, the Company entered into the April 2026 Underwriting Agreement, pursuant to which the Company sold an aggregate of 7,475,000 shares of its common stock, inclusive of 975,000 shares pursuant to the full exercise of the underwriters' over-allotment option, at a public offering price per share of $62.00, resulting in net proceeds of approximately $435.2 million after deducting approximately $28.2 million of underwriting discounts and other offering costs. The over-allotment option was exercised in full on April 15, 2026 and the transaction closed on April 16, 2026.

October 2026 Underwritten Offering

On October 5, 2026, the Company entered into the October 2026 Underwriting Agreement for the sale of 4,117,648 Firm Shares at a public offering price of $85.00 per share. The Company also granted the underwriters an option to purchase up to 617,647 Option Shares at the same price. The sale of the Firm Shares closed on October 7, 2026. The underwriters exercised their option in full on October 12, 2026, and the sale of the Option Shares closed on October 13, 2026. In total, the Company sold an aggregate of 4,735,295 shares of its common stock in the offering, resulting in net proceeds of approximately $378.0 million after deducting approximately $24.5 million of underwriting discounts and other offering costs.

9. Stock-based Compensation

2016 Equity Incentive Plan

The Company's 2016 Equity Incentive Plan (the “2016 Plan”) became effective in April 2016 and serves as the successor to the Company’s 2015 Equity Incentive Plan. Under the 2016 Plan, the Company may grant stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance awards, and stock bonuses. The 2016 Plan, as amended, provides for an automatic increase in the number of shares reserved for issuance thereunder on January 1 of each year for the remaining term of the plan equal to (a) 5.0% of the number of issued and outstanding shares of common stock (including such shares issuable pursuant to the exercise or conversion, as applicable, of any outstanding pre-funded warrants and nonvoting convertible preferred stock) on December 31 of the immediately preceding year, or (b) a lesser amount as approved by the board each year (the “Evergreen Provision”). As a result of the Evergreen Provision, on January 1, 2026 and 2025, an additional 4,711,544 and 3,814,905 shares, respectively, became available for issuance under the 2016 Plan.

As of September 30, 2026, the 2016 Plan had 14,999,732 shares available for future issuance, of which 6,822,482 shares were subject to outstanding option awards and restricted unit awards.

2018 Equity Inducement Plan

The 2018 Equity Inducement Plan (“2018 Plan”) became effective in February 2018.

During the second quarter of 2025, the Company amended the 2018 Plan to increase the number of shares of common stock reserved for issuance by 750,000. After this amendment and as of September 30, 2026, the 2018 Plan had 6,164,834 shares available for future issuance, of which 5,735,274 shares were subject to outstanding option awards and restricted unit awards.

Service-based awards granted under the 2018 Plan and 2016 Plan generally vest over four years and expire after ten years, although awards have been granted with vesting terms less than four years. Under the

2016 Plan and 2018 Plan, the Company may grant stock-based awards with service conditions, performance conditions, and market conditions.

The following table summarizes the Company's stock awards granted under all equity incentive and inducement plans for each of the periods indicated:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2026		2025		2026		2025	
	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value
Stock options	80,385	$ 90.34	213,900	$ 15.88	2,849,446	$ 34.81	2,539,617	$ 19.94
Restricted stock units	49,976	$ 89.63	—	—	175,376	$ 47.43	—	—

2016 Employee Stock Purchase Plan

Under the Company's Amended and Restated 2016 Employee Stock Purchase Plan ("2016 ESPP"), the Company issued and sold 19,967 shares of the Company's common stock during the nine months ended September 30, 2026, resulting in aggregate cash proceeds of $0.5 million. There were no shares issued or sold under the ESPP during the three months ended September 30, 2026.

The Company issued and sold 17,298 and 34,175 shares during the three and nine months ended September 30, 2025, respectively, resulting in aggregate cash proceeds of $0.2 million and $0.6 million, respectively.

Stock-based Compensation Expense

Total stock-based compensation expense recognized from the Company's equity incentive plans, 2018 Plan and 2016 ESPP during the periods presented was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 6,683	$ 4,248	$ 18,692	$ 11,860
General and administrative	7,484	5,318	21,793	15,943
Total stock-based compensation expense	$ 14,167	$ 9,566	$ 40,485	$ 27,803

The following table summarizes the weighted-average Black-Scholes option pricing model assumptions used to estimate the fair value of stock options granted under the Company's equity incentive plans, and the shares purchased under the 2016 ESPP during the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock Options Granted				
Expected term (in years)	6.08	6.08	6.02	5.98
Expected volatility	66%	75%	73%	76%
Risk-free interest rate	4.35%	3.92%	3.89%	4.34%
Dividend yield	—	—	—	—
2016 ESPP				
Expected term (in years)	0.50	0.38	0.50	0.44
Expected volatility	59%	72%	63%	70%
Risk-free interest rate	4.00%	4.21%	3.69%	4.22%
Dividend yield	—	—	—	—

10. Sale of Pegzilarginase to Immedica

On July 27, 2023, the Company announced that it had entered into an agreement to sell the global rights to pegzilarginase to Immedica Pharma AB (“Immedica”) for $15.0 million in upfront cash proceeds and up to $100.0 million in contingent milestone payments.

The milestone payments are contingent on formal reimbursement decisions by national authorities in key European markets and pegzilarginase approval by the U.S. Food and Drug Administration (“FDA”), among other events. In the three and nine months ended September 30, 2026, the Company recognized a gain of nil and $70.0 million, respectively, within Gain on Sale of in-process research and development, for achieving certain milestones. As of September 30, 2026 and December 31, 2025, $3.0 million remains outstanding and due to the Company from a previously achieved milestone, which is reflected in Prepaid expenses and other current assets.

Milestone payments received by the Company by July 3, 2026, net of allowable expenses and adjustments, will be distributed to CVR holders pursuant to the CVR agreement resulting from the Asset Acquisition and will reduce the CVR liability.

11. Segment Reporting

The Company operates under a single operating and reportable segment, which is the development of biopharmaceutical products for the treatment of patients with immune-mediated diseases. The Company's Chief Operating Decision Maker (“CODM”) is the Company's Chief Executive Officer. The CODM uses consolidated Net loss as the measure of segment profit or loss and uses consolidated Total Assets as reported on the balance sheet as the measure of segment assets. The CODM compares Net loss against budgeted and/or forecasted amounts to track the Company's financial performance against expectations and to inform, along with development timelines and scientific and commercial considerations, their decisions regarding resource allocations to fund the Company's development of its pipeline.

The following table sets forth the significant expenses provided to the CODM on a regular basis (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Compensation	$ 12,550	$ 9,397	$ 36,855	$ 24,507
Stock-based compensation [1]	14,167	9,566	40,485	27,803
Research and development, excluding compensation and stock-based compensation [2] [3]	73,790	34,769	171,129	99,069
Other segment items [4] [5] [6]	(4,386)	(42,549)	(47,143)	(58,706)
Segment net loss	$ 96,121	$ 11,183	$ 201,326	$ 92,673

[1] Includes related party expenses of $0.3 million for the three months ended September 30, 2026 and 2025, and $0.8 million for the nine months ended September 30, 2026 and 2025.

[2] Includes non-clinical study, clinical trial, and manufacturing expenses.

[3] Includes related party expenses of $0.1 million and $7.0 million for the three months ended September 30, 2026 and 2025, respectively. Includes related party expenses of $3.2 million and $9.6 million for the nine months ended September 30, 2026 and 2025, respectively.

[4] Includes general and administrative expenses — such as audit, legal, and other professional fees — interest income, and other expense, net.

[5] Includes gains of $70.0 million and $10.0 million for the nine months ended September 30, 2026 and 2025, respectively, related to milestone payments earned in connection with the 2023 sale of the global rights to the legacy assets, pegzilarginase, to Immedica. There were no related gains for the three months ended September 30, 2026 and 2025.

[6] Includes a $0.9 million increase and a $40.4 million decrease in the fair value of the CVR liability for the three months ended September 30, 2026 and 2025, respectively. Includes a $35.8 million increase and a $42.2 million decrease in the fair value of the CVR liability for the nine months ended September 30, 2026 and 2025, respectively.

12. Net Loss Per Share

The Company computes net loss per share of common stock, Series A Preferred Stock, and Series B Preferred Stock using the two-class method required for multiple classes of common stock and other participating securities.

The two-class method is an earnings (loss) allocation method under which earnings (loss) per share is calculated for each class of common stock. The Company has determined that the Series A Preferred Stock and Series B Preferred Stock do not have preferential rights when compared to the Company's common stock and therefore it must allocate losses to these other classes of common stock, as illustrated in the table below.

Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares outstanding during the period, without consideration of potential dilutive securities. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potential shares of common stock would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share of common stock, Series A Preferred Stock, and Series B Preferred Stock (in thousands, except share and per share amounts):

	Three Months Ended September 30,					
	2026			2025		
	Series A Preferred Stock	Series B Preferred Stock	Common Stock	Series A Preferred Stock	Series B Preferred Stock	Common Stock
Net loss per share, basic and diluted:						
Numerator						
Allocation of losses	$ (13,012)	$ —	$ (83,109)	$ (2,066)	$ (100)	$ (9,017)
Denominator						
Weighted-average shares outstanding	346,045	—	88,410,821	346,045	16,667	60,414,223
Net loss per share, basic and diluted	$ (37.60)	—	$ (0.94)	$ (5.97)	$ (5.97)	$ (0.15)

	Nine Months Ended September 30,					
	2026			2025		
	Series A Preferred Stock	Series B Preferred Stock	Common Stock	Series A Preferred Stock	Series B Preferred Stock	Common Stock
Net loss per share, basic and diluted:						
Numerator						
Allocation of losses	$ (28,285)	$ (868)	$ (172,173)	$ (17,138)	$ (825)	$ (74,710)
Denominator						
Weighted-average shares outstanding	346,045	10,623	84,255,008	346,045	16,667	60,338,541
Net loss per share, basic and diluted	$ (81.74)	$ (81.74)	$ (2.04)	$ (49.53)	$ (49.53)	$ (1.24)

The following weighted-average equity instruments were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Options to purchase common stock	8,760,161	1,170,956	7,795,560	1,267,158
Unvested restricted stock units	149,950	18,068	129,671	13,978
Outstanding Parapyre warrants	1,316,029	—	1,459,610	—

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report for the quarterly period ended September 30, 2026 (this "Quarterly Report") as well as the audited consolidated financial statements and notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2025 (the "Annual Report"), filed with the U.S. Securities and Exchange Commission (the "SEC") on February 19, 2026. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements regarding our expected results, outcomes, and the timing of these results and outcomes, plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. As used in this report, unless the context suggests otherwise, "we", "us", "our", the "Company," or "Spyre" refers to Spyre Therapeutics, Inc. and its consolidated subsidiaries taken as a whole.

Overview

We are a clinical stage biotechnology company committed to developing next-generation therapies that elevate the standard in immunology by delivering more complete disease control, greater durability, and a simpler treatment experience for patients. Our pipeline includes extended half-life antibodies targeting α4β7, TL1A, IL-23, IL-17A/F (each as defined below) as well as rational combination programs.

Our Strategy

Our goal is to develop next-generation therapeutics to elevate the standard of care for the treatment of immune-mediated diseases in the following therapeutic areas:

- **Gastroenterology**: Advancing three potential first- and best-in-class combination programs in inflammatory bowel disease ("IBD"), a market forecasted to exceed $40 billion by 2030 (includes ulcerative colitis ("UC") and Crohn's disease ("CD"))

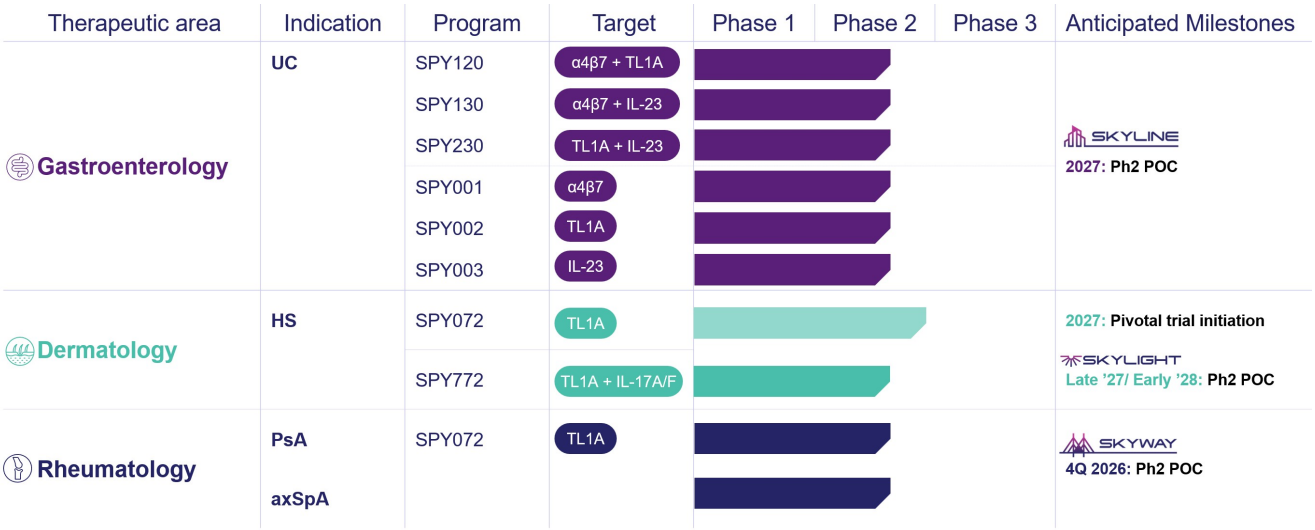
- **Dermatology**: Advancing a potential first- and best-in-class anti-TL1A + IL-17A/F combination program, as well as a potential best-in-class anti-TL1A agent, in hidradenitis suppurativa ("HS"), a market forecasted to exceed $10 billion by 2035

- **Rheumatology**: Advancing a potential first- and best-in-class anti-TL1A agent in psoriatic arthritis ("PsA") and axial spondyloarthritis ("axSpA"), markets forecasted to exceed $10 billion by 2030, with potential for combination therapy following anti-TL1A proof-of-concept

Our Portfolio and Development Plan Updates

We are advancing a pipeline of monoclonal antibodies ("mAbs") for the treatment of immune-mediated diseases. The following table (Figure 1) summarizes our pipeline and development strategy, including our SKYLINE Phase 2 platform trial evaluating SPY120, SPY130, SPY230, and monotherapy components thereof in subjects with moderately to severely active UC, our SKYLIGHT trial evaluating SPY072 as an add-on to bimekizumab as a proof-of-concept trial for the dual inhibition of anti-TL1A and IL-17A/F, as well as our SPY772 combination program in HS, and our SKYWAY basket trial evaluating SPY072 in three rheumatic diseases ("RD"): rheumatoid arthritis ("RA"), PsA, and axSpA. Additionally, we plan to advance SPY072 monotherapy into pivotal studies for HS in 2027.

Figure 1. Spyre portfolio



**SKYLIGHT proof-of-concept study with SPY072 + bimekizumab, serving as a surrogate for internal SPY007 long-acting IL-17A/F antibody.*

SKYLINE Phase 2 Platform Trial in UC

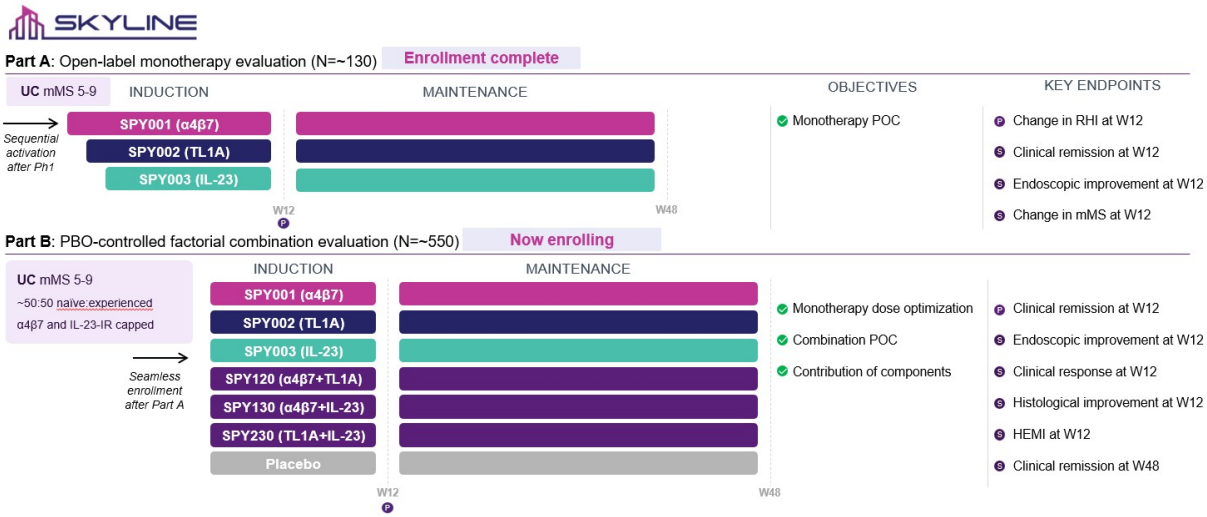
In May 2025, we initiated our SKYLINE Phase 2 platform trial evaluating SPY001, SPY002 and SPY003, as well as pairwise combinations thereof (six investigational agents in total), in subjects with moderately to severely active UC (Figure 2). The trial consists of two parts:

- **Part A:** Open-label assessment of the safety and preliminary efficacy of a single dose level of each investigational monotherapy. Enrollment for Part A has completed, with initial SPY001, SPY002 and SPY003 Part A topline induction data announced in April 2026, June 2026, and September 2026, respectively.

- **Part B:** Randomized and placebo-controlled assessment of the safety and efficacy of monotherapies and combinations, designed to provide dose-ranging data on monotherapies, proof-of-concept and contribution of components for combinations, with induction data expected in 2027.

SKYLINE is currently enrolling subjects into Part B of the trial.

Figure 2. SKYLINE trial design



mMS=modified mayo score; RHI=Robarts Histopathology Index; HEMI=Histo-Endoscopic Mucosal Improvement; P=primary endpoint; S=secondary endpoint. Initiation of each cohort subject to regulatory clearance.

Topline induction data from Part A of the SKYLINE trial in UC subjects were presented in 2026. Baseline characteristics were consistent with expectations (Figure 3). SPY001, SPY002, and SPY003 were well-tolerated with a safety profile consistent with in-class comparators (Figure 4). SPY001, SPY002, and SPY003 achieved their respective primary endpoints, demonstrating a statistically significant reduction in the RHI score of 9.2 points, 10.7 points, and 10.0 points, respectively. Rates of key secondary endpoints of clinical remission and endoscopic improvement were clinically meaningful at 40% and 51%, respectively, for SPY001, 33% and 42%, respectively, for SPY002, and 20% and 30%, respectively, for SPY003 (Figure 5). The change in the modified Mayo Score from baseline at Week 12 for both SPY001 and SPY002 was -3.7, and for SPY003 was -3.5, reflecting consistency across secondary endpoints.

Figure 3. Baseline demographics from SKYLINE Part A Induction Topline

	SPY001 (α4β7), N = 43	SPY002 (TL1A), N = 48	SPY003 (IL-23), N = 44
Age (years, mean)	44	45	42
Sex (% female)	28	42	39
Weight (kg, mean)	76	74	74
Geographic region Europe North America APAC Middle East	 88% 12% - -	 71% 23% 6% -	 41% 30% 25% 4%
Duration of UC (years, mean)	4.5	7.0	7.1
RHI (mean ± SD)	15.6 ± 8.6	16.9 ± 8.5	17.2 ± 8.3
Baseline mMS (mean ± SD)	6.8 ± 1.1	6.9 ± 1.0	6.9 ± 1.2
Mayo Endoscopy Score (MES) (n, %) 2 3	 19 (44%) 24 (56%)	 21 (44%) 27 (56%)	 18 (41%) 26 (59%)
Concomitant immunomodulator use (n, %)	0	0	0
Concomitant corticosteroid use (n, %)	18 (42%)	19 (40%)	19 (43%)
Number of prior advanced therapies (n, %) Naïve 1 ≥2	 35 (81%) 7 (16%) 1 (2%)	 31 (65%) 12 (25%) 5 (10%)	 26 (59%) 9 (20%) 9 (20%)

Figure 4. Safety summary from SKYLINE Part A Induction Topline

	SPY001 (α4β7), N=43	SPY002 (TL1A), N = 48	SPY003 (IL-23), N = 44
Subjects with any Treatment-Emergent Adverse Event (n, %)	**6 (14%)**	**20 (41.7%)**	**19 (43.2%)**
Severe (Grade ≥ 3) AE	1 (2%)	2 (4.2%)	5 (11.4%)[1]
Drug-Related AE	0	3 (6.3%)	1 (2.3%)[2]
AE Leading to Drug Discontinuation	0	2 (4.2%)	0
Serious Adverse Event (SAE)	1 (2%)	2 (4.2%)	3 (6.8%)[3]
Drug-Related SAE	0	0	0
AEs of Special Interest	0	0	0
Death	0	0	0
TEAEs in ≥2 patients (n, %)	Back pain (2, 4.7%)	Arthralgia (2, 4.2%), hypertension (3, 6.3%), nausea (2, 4.2%), ulcerative colitis (2, 4.2%), viral respiratory tract infection (2, 4.2%)	Arthralgia (2, 4.5%), nasopharyngitis (2, 4.5%), urinary tract infection (2, 4.5%)

[1]UC flare (serious), intervertebral disc protrusion, anaemia, urinary tract infection, and acute cholecystitis (serious), each in one subject; all deemed not drug-related.

[2]Pruritus (Grade 1) that resolved without intervention or treatment interruption.

[3]Hospitalization for UC flare, hemorrhoid thrombosis, and acute cholecystitis, each in one subject; all deemed not drug-related. Data pertain to the induction treatment period (through Week 12), with a data cutoff of July 27, 2026 and database lock on August 27, 2026.

Figure 5. Efficacy summary from SKYLINE Part A Induction Topline

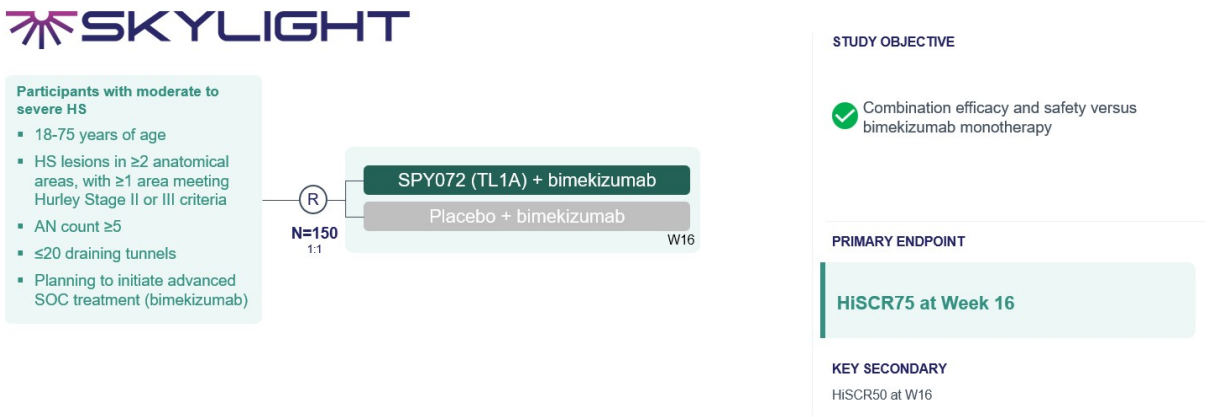
	SPY001	SPY002	SPY003
PART A PRIMARY			
ΔRHI from baseline	**-9.2**	**-10.7**	**-10.0**
PART A SECONDARY			
% Clinical remission	**40%**	**33%**	**20%**
% Endoscopic improvement	**51%**	**42%**	**30%**
ΔmMS from baseline	**-3.7**	**-3.7**	**-3.5**

SKYLIGHT Phase 2 Trial in HS

In September 2026, we initiated our SKYLIGHT Phase 2 trial of SPY072 in subjects with moderately to severely active HS who are initiating bimekizumab (Figure 6). The trial serves as a surrogate proof-of-concept

study for our internal SPY772 combination program combining SPY072 (long-acting anti-TL1A) and SPY007 (long-acting anti-IL-17A/F). Topline results are planned in late 2027 or early 2028.

Figure 6. SKYLIGHT trial design



SKYWAY Phase 2 Basket Trial in Rheumatic Diseases (RA, PsA, axSpA)

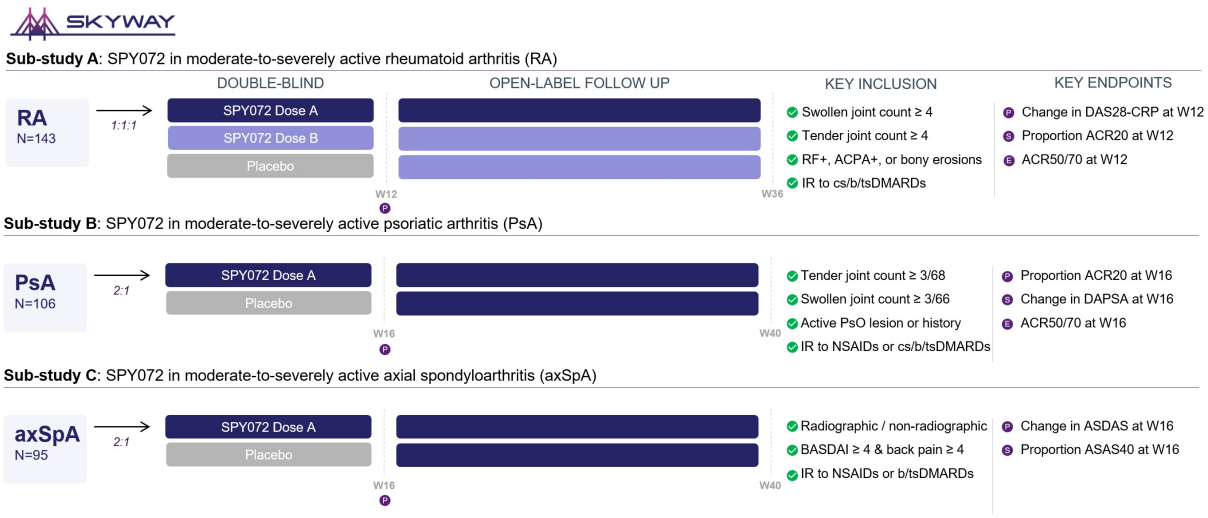
In September 2025, we initiated our SKYWAY Phase 2 randomized and placebo-controlled basket trial of SPY072 in subjects with moderately to severely active RA, PsA, or axSpA (Figure 7). The trial consists of three sub-studies, all of which completed enrollment on or ahead of schedule:

- **RA sub-study:** Double-blind, placebo-controlled safety and efficacy study of two dose levels of SPY072 at Week 12 with open-label follow-up through Week 36. Topline proof-of-concept data were released in August 2026. Both doses of SPY072 demonstrated statistically significant benefits compared to placebo on one or more of the primary (change from baseline in DAS28-CRP), key secondary (ACR20), and exploratory endpoints (ACR50). SPY072 was well tolerated, with a safety profile consistent with the TL1A class. The results provide proof-of-mechanism for TL1A in RA and support its potential in other autoimmune diseases and as a combination component, but did not meet the Company's internal bar to prioritize advancement of SPY072 in RA.

- **PsA sub-study:** Double-blind, placebo-controlled safety and efficacy study of a single dose level of SPY072 at Week 16 with open-label follow-up through Week 40. Topline proof-of-concept data are expected in the fourth quarter of 2026.

- **axSpA sub-study:** Double-blind, placebo-controlled safety and efficacy study of a single dose level of SPY072 at Week 16 with open-label follow-up through Week 40. Topline proof-of-concept data are expected in the fourth quarter of 2026.

Figure 7. SKYWAY trial design



RF=rheumatoid factor; ACPA= Anti-citrullinated protein antibodies; cs/b/tsDMARD=conventional synthetic, biologic, or targeted synthetic disease modifying antirheumatic drugs; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; P=primary endpoint; S=secondary endpoint; E=exploratory endpoint. IR=inadequate response.

Our Assets

SPY001 – anti-α4β7 mAb

SPY001 is a highly potent, highly selective, and humanized monoclonal immunoglobulin G1 investigational antibody designed to bind selectively to the α4β7 integrin ("α4β7") being developed for the treatment of IBD (UC and CD). The α4β7 integrin is a protein found on the surface of immune cells. This integrin regulates the migration of immune cells to the gut where they contribute to the inflammatory process in IBD. By selectively binding to the α4β7 integrin, SPY001 is designed to prevent the interaction of these immune cells with MAdCAM-1, a molecule expressed on endothelial cells lining the blood vessels in the gut. By blocking the interaction between α4β7 integrin and MAdCAM-1, SPY001 aims to reduce the recruitment of immune cells to the gut, leading to a decrease in inflammation. Since it specifically targets the gut immune system, SPY001 is designed to minimize systemic immunosuppressive effects unrelated to IBD pathology.

SPY002 and SPY072 – anti-TL1A mAbs

For our anti-TL1A program, we nominated two highly potent, highly selective, and fully human mAb candidates designed to bind to tumor necrosis factor-like ligand 1A ("TL1A"). SPY002 (formerly SPY002-091) is being developed for the treatment of IBD (UC and CD), SPY072 (formerly SPY002-072) is being developed for the treatment of RD, and we plan to initiate late-stage development of SPY072 as a monotherapy for the treatment of HS.

TL1A is a protein that plays a role in regulating the immune system and is elevated in tissue of individuals with immune-mediated diseases. TL1A interacts with its receptor, death receptor 3 ("DR3"), which is expressed in various immune cells, including T cells and fibroblast-like synoviocytes. This interaction triggers signaling pathways that contribute to inflammation and joint injury in RD, leading to symptomology, such as pain and swelling. SPY002 and SPY072 have been designed to block the interaction between TL1A and DR3, and thereby inhibit the downstream signaling events to dampen the inflammatory response. By neutralizing TL1A, we believe that SPY002 and SPY072 have the potential to modulate the immune response in patients with immune-mediated diseases, potentially reducing disease activity.

SPY003 – anti-IL-23 mAb

SPY003 is a clinical-stage program designed to bind to interleukin 23 ("IL-23") and incorporates half-life extending modifications. IL-23 is a cytokine that is produced by immune cells and is involved in immune response regulation. IL-23 promotes the survival, expansion, and activity of Th17 cells. Th17 cells produce inflammatory cytokines, such as IL-17, which contribute to the inflammation seen in IBD. IL-23 also helps in the

recruitment and activation of other immune cells, such as neutrophils, which further contribute to tissue damage in the gut.

SPY003 binds to the p19 subunit of IL-23 with subnanomolar potency in cellular assays. SPY003 also exhibited extended PK half-life of greater than three-fold relative to a synthesized risankizumab comparator that does not incorporate half-life extending modifications, based on head-to-head preclinical studies in non-human primates ("NHPs").

SPY007 – anti-IL-17A/F mAb

SPY007 is a preclinical-stage program designed to bind to interleukin 17A ("IL-17A") and interleukin 17F ("IL-17F") while incorporating half-life extending modifications. SPY007 is being developed for the treatment of HS in combination with our anti-TL1A mAb (SPY072). IL-17A and IL-17F are closely related cytokines produced by Th17 cells and other immune cells. Both are elevated in the skin lesions of individuals with HS. IL-17A and IL-17F act on keratinocytes and other cells in the skin, driving the production of pro-inflammatory cytokines, chemokines, and antimicrobial peptides. These signals recruit neutrophils and other immune cells to the skin, which contributes to the painful nodules, abscesses, and draining tunnels seen in HS.

SPY120 – combination, anti-α4β7 and anti-TL1A mAbs

SPY120 combines SPY001 (anti-α4β7) and SPY002 (anti-TL1A) antibodies, pairing two complementary mechanisms studied in third-party clinical trials targeting non-overlapping sites of action.

In February and May 2025, we presented preclinical data demonstrating that combinations resulted in additive or greater than additive in vivo biological activity relative to either monotherapy in mouse hapten reagent 2,4,6-trinitrobenzene sulfonic acid ("TNBS") and anti-CD40 colitis models. In October 2025, we presented preclinical data further demonstrating that combined inhibition resulted in superior efficacy relative to constituent monotherapies in a mouse TNBS-induced colitis model. In addition, combination toxicology studies have been completed with no drug-related adverse findings observed.

SPY130 – combination anti-α4β7 and anti-IL-23 mAbs

SPY130 combines SPY001 (anti-α4β7) and SPY003 (anti-IL-23) antibodies, pairing two commercially validated mechanisms targeting non-overlapping sites of action.

In October 2024, we presented preclinical data, demonstrating in a T-cell transfer model of IBD, that combinations with anti-IL-23 and anti-α4β7 improved body weight and reduced colonic CD4+ infiltration and IL-17 levels relative to monotherapy. In March and October 2025, we presented additional preclinical data, demonstrating that combinations resulted in superior in vivo biological activity relative to either monotherapy in mouse TNBS model. In addition, combination toxicology studies have been completed with no drug-related adverse findings observed.

SPY230 – combination anti-TL1A and anti-IL-23 mAbs

SPY230 combines SPY002 (anti-TL1A) and SPY003 (anti-IL-23) antibodies, pairing two complementary mechanisms of action with potential to address overlapping and non-overlapping triggers of inflammation.

In October 2024, we presented preclinical data, demonstrating that anti-IL-23 and anti-TL1A have a synergistic effect on promoting IL-17 secretion from human and mouse cells, and that the combination of anti-IL-23 and anti-TL1A suppressed IL-17 secretion more effectively than either agent alone. In March and October 2025, we presented additional preclinical data, demonstrating that combinations resulted in superior in vivo biological activity relative to either monotherapy in mouse TNBS model. In addition, combination toxicology studies have been completed with no drug-related adverse findings observed.

SPY772 – combination anti-TL1A and anti-IL-17A/F mAbs

SPY772 combines SPY072 (anti-TL1A) and SPY007 (anti-IL-17A/F) antibodies, pairing two complementary mechanisms of action with potential to address overlapping and non-overlapping triggers of inflammation. By combining an IL-17A/F mAb with an anti-TL1A mAb, we aim to target multiple inflammatory pathways involved in HS, with the potential to improve efficacy over single-mechanism therapies, neutralize both IL-17A and IL-17F, and thereby inhibit the downstream signaling events to dampen the inflammatory response.

Paragon Agreement

Pursuant to the Paragon Agreement, we received the option to license the intellectual property rights related to four research programs (collectively, the "Option") from Paragon in accordance with a license agreement to be entered into following each exercise of the Option.

On July 12, 2023, December 14, 2023 and June 5, 2024, we exercised our Option available under the Paragon Agreement with respect to the SPY001, SPY002 and SPY072, and SPY003 research programs, respectively. In May 2024, we signed license agreements with Paragon for rights to royalty-bearing, world-wide, exclusive licenses to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting α4β7 integrin (SPY001 program) (the "SPY001 License Agreement") and TL1A (SPY002 and SPY072 programs) (the "SPY002 and SPY072 License Agreement") and, in October 2024, we signed a license agreement for rights to a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 (SPY003 program) (the "SPY003 License Agreement" and, together with the SPY001 License Agreement and the SPY002 and SPY072 License Agreement, the "License Agreements") in the field of IBD. The SPY003 License Agreement was subsequently amended and restated in February 2025 and further amended in May 2026 to expand the definition of "Field" to encompass all therapeutic, prophylactic, palliative and diagnostic uses for SPY003, subject to certain restrictions. The Option with respect to one additional program remains unexercised under the Paragon Agreement.

Under the terms of each License Agreement, we are obligated to pay Paragon up to $22.0 million upon the achievement of specific development, regulatory and clinical milestones for the first product under each agreement, respectively, that achieves such specified milestones, including a milestone payment of $5 million upon the first dosing of a human patient in a Phase 3 trial. With respect to the SPY002 and SPY072 License Agreement only, on a product-by-product basis, we are obligated to pay sublicensing fees of up to approximately $20 million upon the achievement of mostly commercial milestones. Subject to the execution of the Option with respect to the remaining research program, we expect to be obligated to make similar payments upon and following the execution of a license agreement with respect to such research program.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. These estimates form the basis for judgments we make about the carrying values of our assets, liabilities and equity and the amount of revenues and expenses, which are not readily apparent from other sources. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. On an ongoing basis, we evaluate our estimates and assumptions. Our actual results may differ materially from these estimates under different assumptions or conditions.

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. The most significant estimates and assumptions that management considers in the preparation of our financial statements relate to accrued research and development costs and inputs used in the Black-Scholes model for stock-based compensation expense.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. There have been no significant changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report, except as disclosed below:

Contingent Value Rights

As of June 30, 2026, Contingent Value Rights ("CVRs") are no longer a critical accounting policy or estimate. We determined that remaining significant contingencies regarding our future payment obligations under the contingent value rights agreement (the "CVR Agreement") we entered into with Equiniti Trust Company LLC (f/k/a American Stock Transfer & Trust Company LLC) as rights agent in connection with the Asset Acquisition have been resolved. Accordingly, we have measured the fair value of our CVR liability by discounting the estimated future payments to be made under the CVR Agreement using our weighted average cost of capital. The estimated value of the CVR consideration is based upon available information and certain assumptions which our management believes are reasonable under the circumstances. The ultimate payout under the CVRs may differ materially from the assumptions used in determining the fair value of the CVR consideration.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025, together with the changes in those items in dollars and as a percentage:

	Three Months Ended September 30,		Increase/ (Decrease)	% Change
	2026	2025		
	(in thousands)			
Operating expenses:				
Research and development	$ 89,169	$ 45,247	$ 43,922	97 %
General and administrative	16,550	11,641	4,909	42 %
Total operating expenses	105,719	56,888	48,831	86 %
Loss from operations	(105,719)	(56,888)	48,831	86 %
Other income (expense):				
Interest income	10,625	5,379	5,246	98 %
Other (expense) income, net	(1,027)	40,326	(41,353)	*
Total other income	9,598	45,705	(36,107)	*
Loss before income tax benefit	(96,121)	(11,183)	84,938	*
Income tax benefit	—	—	—	*
Net loss	$ (96,121)	$ (11,183)	$ 84,938	*

* Percentage not meaningful

Research and Development Expenses. Research and development expenses increased by $43.9 million, or 97%, to $89.2 million for the three months ended September 30, 2026, from $45.2 million for the three months ended September 30, 2025. The increase was primarily driven by higher manufacturing expenses, clinical trial expenses, and compensation costs partially offset by a decrease in licensing fees.

	Three Months Ended September 30,		Increase/ (Decrease)	% Change
	2026	2025		
	(in thousands)			
External research and development expenses:				
Preclinical	$ 3,578	$ 2,522	$ 1,056	42 %
Gastroenterology	38,328	24,949	13,379	54 %
Rheumatology	19,360	6,826	12,534	184 %
Dermatology	11,935	—	11,935	—
Other	—	5	(5)	(100)%
Total external research and development expenses	73,201	34,302	38,899	113 %
Internal research and development expenses:				
Compensation	8,696	6,229	2,467	40 %
Stock-based compensation	6,683	4,248	2,435	57 %
Other	589	468	121	26 %
Total internal research and development expenses	15,968	10,945	5,023	46 %
Total research and development expense	$ 89,169	$ 45,247	$ 43,922	97 %

External research and development expenses include costs associated with third parties contracted to conduct research and development activities on our behalf including through contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), and third-party laboratories. For the three months ended September 30, 2026 and 2025, external research and development costs accounted for $73.2 million and $34.3 million, respectively. Preclinical expenses increased primarily due to SPY007 pre-clinical development costs. Gastroenterology and Rheumatology program expenses increased primarily due to an increase in manufacturing costs and clinical development activities related to ongoing or planned clinical trials. Dermatology program expenses increased primarily due to the initiation of clinical development activities.

Internal research and development expenses include compensation and related costs associated with our research and development employees. For the three months ended September 30, 2026 and 2025, internal research and development costs accounted for $16.0 million and $10.9 million, respectively. The increase was primarily driven by an increase in research and development headcount.

General and Administrative Expenses. General and administrative expenses increased by $4.9 million, or 42%, to $16.6 million for the three months ended September 30, 2026, from $11.6 million for the three months ended September 30, 2025. The increase was primarily attributable to an increase in general and administrative headcount as well as professional services costs.

Interest Income. Interest income was $10.6 million and $5.4 million for the three months ended September 30, 2026 and 2025, respectively. The increase was primarily due to higher investment balances.

Other (Expense) Income, Net. Other (expense), net was $1.0 million for the three months ended September 30, 2026, compared to Other income, net of $40.3 million for the three months ended September 30, 2025. The decrease was primarily due to differences in recognized CVR liability fair value revaluations in the respective periods.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30,		Increase/ (Decrease)	% Change
	2026	2025		
	(in thousands)			
Operating expenses (income):				
Research and development	$ 215,083	$ 127,015	$ 88,068	69 %
General and administrative	47,916	35,375	12,541	35 %
Gain on sale of in-process research and development asset	(70,000)	(10,000)	(60,000)	*
Total operating expenses	192,999	152,390	40,609	27 %
Loss from operations	(192,999)	(152,390)	40,609	27 %
Other income (expense):				
Interest income	27,673	17,746	9,927	56 %
Other (expense) income, net	(36,000)	41,956	(77,956)	*
Total other (expense) income	(8,327)	59,702	(68,029)	*
Loss before income tax benefit	(201,326)	(92,688)	108,638	*
Income tax benefit	—	15	(15)	*
Net loss	$ (201,326)	$ (92,673)	$ 108,653	*

* Percentage not meaningful

Research and Development Expenses. Research and development expenses increased by $88.1 million, or 69%, to $215.1 million for the nine months ended September 30, 2026, from $127.0 million for the nine months ended September 30, 2025. The increase was primarily driven by higher manufacturing expenses, clinical trial expenses, and compensation costs, partially offset by lower early-stage research and development.

	Nine Months Ended September 30,		Increase/ (Decrease)	% Change
	2026	2025		
	(in thousands)			
External research and development expenses:				
Preclinical	$ 7,280	$ 15,078	$ (7,798)	(52)%
Gastroenterology	106,361	70,958	35,403	50 %
Rheumatology	39,998	11,975	28,023	234 %
Dermatology	15,720	—	15,720	—
Other	(15)	184	(199)	(108)%
Total external research and development expenses	169,344	98,195	71,149	72 %
Internal research and development expenses:				
Compensation	25,262	16,085	9,177	57 %
Stock-based compensation	18,692	11,860	6,832	58 %
Other	1,785	875	910	104 %
Total internal research and development expenses	45,739	28,820	16,919	59 %
Total research and development expense	$ 215,083	$ 127,015	$ 88,068	69 %

External research and development expenses include costs associated with third parties contracted to conduct research and development activities on our behalf including through CROs, CMOs, and third-party laboratories. For the nine months ended September 30, 2026 and 2025, external research and development costs accounted for $169.3 million and $98.2 million, respectively. Preclinical expenses decreased primarily due to a reduction in early-stage research and development activities given our pipeline's advancement, partially offset by an increase in SPY007 preclinical development costs. Gastroenterology and Rheumatology program expenses increased primarily due to an increase in manufacturing costs and clinical development activities related to ongoing or planned clinical trials. Dermatology program expenses increased primarily due to the initiation of clinical development activities.

Internal research and development expenses include compensation and related costs associated with our research and development employees. For the nine months ended September 30, 2026 and 2025, internal research and development costs accounted for $45.7 million and $28.8 million, respectively. The increase was primarily driven by an increase in research and development headcount.

General and Administrative Expenses. General and administrative expenses increased by $12.5 million, or 35%, to $47.9 million for the nine months ended September 30, 2026, from $35.4 million for the nine months ended September 30, 2025. The increase was primarily attributable to an increase in general and administrative headcount as well as professional services costs.

Gain on Sale of In-Process Research and Development Asset. During the nine months ended September 30, 2026 and 2025, the Company recognized gains of $70.0 million and $10.0 million, respectively, related to milestone payments earned in connection with the 2023 sale of the global rights to the legacy Aeglea Biotherapeutics, Inc. asset pegzilarginase to Immedica.

Interest Income. Interest income was $27.7 million and $17.7 million for the nine months ended September 30, 2026 and 2025, respectively. The increase was primarily due to higher investment balances.

Other (Expense) Income, Net. Other (expense), net was $36.0 million for the nine months ended September 30, 2026, compared to Other income, net of $42.0 million for the nine months ended September 30, 2025. The decrease was primarily due to differences in recognized CVR liability fair value revaluations in the respective periods.

Liquidity and Capital Resources

We are a clinical stage biotechnology company with a limited operating history, and due to our significant research and development expenditures, we have generated operating losses since our inception and have not generated any revenue from the commercial sale of any products. There can be no assurance that profitable operations will ever be achieved, and, if achieved, whether profitability can be sustained on a continuing basis.

Since our inception and through September 30, 2026, we have funded our operations by raising an aggregate of approximately $2.2 billion of gross proceeds from the sale and issuance of convertible preferred stock and common stock, pre-funded warrants, the collection of grant proceeds, and the licensing of our product rights for commercialization of pegzilarginase in Europe and certain countries in the Middle East. As of September 30, 2026, we had an accumulated deficit of $1.3 billion.

Our primary use of cash is to fund the development of our product candidates and advance our pipeline. This includes both the research and development costs and the general and administrative expenses required to support those operations. Since we are a clinical stage biotechnology company, we have incurred significant operating losses since our inception and we anticipate such losses, in absolute dollar terms, to increase as we continue to pursue clinical development of our product candidates, prepare for the potential commercialization of our product candidates, and expand our development efforts in our pipeline of nonclinical candidates. Based on current operating plans, we have sufficient resources to fund operations for at least one year from the issuance date of the financial statements included in this Quarterly Report with existing cash, cash equivalents, and marketable securities. We will need to secure additional financing in the future to fund additional research and development, and before a commercial drug can be produced, marketed and sold. If we

are unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on us.

We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026, together with the net proceeds from the October 2026 Offering and sales under the 2026 Sales Agreement subsequent to September 30, 2026, will be sufficient to fund our planned operating expenses and capital expenditure requirements into the second half of 2029. 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.

Sources of Liquidity

On September 6, 2024, the Company entered into a sales agreement (the "2024 Sales Agreement") with TD Securities (USA) LLC as its agent, pursuant to which the Company may issue and sell up to $200.0 million of shares of common stock under an at-the-market ("ATM") offering program. During the year ended December 31, 2025, we sold an aggregate of 445,668 shares of common stock under the ATM offering program pursuant to the 2024 Sales Agreement resulting in net proceeds of $14.8 million. During the three and nine months ended September 30, 2026, the Company sold an aggregate of nil and 296,396 shares of common stock, respectively, under the ATM offering program pursuant to the 2024 Sales Agreement resulting in net proceeds of nil and $9.7 million, respectively. The 2024 Sales Agreement was terminated on June 26, 2026 and the Company concurrently entered into a new sales agreement (the "2026 Sales Agreement") with TD Securities (USA) LLC as its agent, pursuant to which the Company may issue and sell up to $500.0 million of shares of common stock under an ATM offering program. During the three and nine months ended September 30, 2026, the Company sold 327,391 shares under the ATM offering program pursuant to the 2026 Sales Agreement, resulting in net proceeds of $29.5 million. Subsequent to September 30, 2026, and through November 3, 2026, the Company sold 200,111 shares under the ATM offering program pursuant to the 2026 Sales Agreement, resulting in net proceeds of $18.0 million.

As of September 30, 2026 and November 3, 2026, $469.9 million and $451.6 million, respectively, remained available for sale under the 2026 Sales Agreement.

In October 2025, we sold 17,094,594 shares of our common stock in an underwritten public offering, inclusive of 2,229,729 shares pursuant to the full exercise of the underwriters' over-allotment option, under our shelf registration statement on Form S-3 at a price per share of $18.50, resulting in net proceeds of $296.4 million after deducting approximately $19.9 million of underwriting discounts and other offering costs.

In April 2026, we sold an aggregate of 7,475,000 shares of our common stock in an underwritten public offering, inclusive of 975,000 shares pursuant to the full exercise of the underwriters' over-allotment option, at a public offering price per share of $62.00, resulting in net proceeds of approximately $435.2 million after deducting approximately $28.2 million of underwriting discounts and other offering costs.

In October 2026, we sold 4,735,295 shares of our common stock in an underwritten public offering, inclusive of 617,647 shares pursuant to the full exercise of the underwriters' over-allotment option, at a public offering price per share of $85.00, resulting in net proceeds of approximately $378.0 million after deducting approximately $24.5 million of underwriting discounts and other offering costs.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash and cash equivalents (used in) provided by:		
Operating activities	$ (204,744)	$ (124,674)
Investing activities	(245,126)	103,935
Financing activities	446,876	(3,787)
Net increase (decrease) in cash and cash equivalents	$ (2,994)	$ (24,526)

Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2026 was $204.7 million and primarily reflected a net loss of $201.3 million, adjusted for a $70.0 million gain on sale of in-process research and development and $9.5 million of adjustments related to our marketable securities, partially offset by non-cash expenses of $40.5 million for share-based compensation and $35.8 million from an increase in the fair value of the CVR liability.

Cash used in operating activities for the nine months ended September 30, 2025 was $124.7 million and primarily reflected a net loss of $92.7 million, adjusted for a $10.0 million gain on sale of in-process research and development, a $42.2 million decrease in the fair value of the CVR liability, $3.9 million of net adjustments related to our marketable securities, and a $3.7 million net cash outflow from changes in operating assets and liabilities, partially offset by non-cash share-based compensation expense of $27.8 million.

Cash (Used in) Provided by Investing Activities

Cash used in investing activities for the nine months ended September 30, 2026 was $245.1 million and primarily consisted of $666.8 million in purchases of marketable securities, partially offset by $351.7 million in maturities and sales of marketable securities and $70.0 million in proceeds from the sale of a legacy in-process research and development asset.

Cash provided by investing activities for the nine months ended September 30, 2025 was $103.9 million and primarily consisted of $277.4 million in maturities and sales of marketable securities and $7.0 million in proceeds from the sale of an in-process research and development asset, partially offset by $180.5 million in purchases of marketable securities.

Cash Provided by (Used in) Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2026 was $446.9 million, which primarily consisted of $435.2 million and $39.3 million net proceeds from the issuance of common stock in connection with the April 2026 Offering and under our at-the-market offering programs, respectively, and $28.8 million proceeds from stock option exercises and sales of common stock under our ESPP, partially offset by a $55.7 million payment to CVR holders.

Cash used in financing activities for the nine months ended September 30, 2025 was $3.8 million, which primarily consisted of a $5.3 million payment to CVR holders partially offset by $1.6 million proceeds from stock option exercises and sales of common stock under our Employee Stock Purchase Plan.

Contingent Contractual Obligations

Through the Asset Acquisition, we received the Option to license certain intellectual property rights related to certain research programs. The exercise of the Option allows for us to enter into an exclusive license agreement with Paragon for the respective research program. Thus far we have exercised the Option and entered into license agreements with respect to SPY001, SPY002 and SPY072, and SPY003. Under the terms

of each License Agreement, we are obligated to pay Paragon up to $22.0 million based on specific development, regulatory and clinical milestones for the first product under each agreement. As of September 30, 2026, we have incurred a total of $21.0 million of milestone fees out of a total maximum of $66.0 million in potential milestone fees across all License Agreements. As of September 30, 2026, no achieved milestone fees are outstanding and payable. With respect to the SPY002 and SPY072 License Agreement only, on a product-by-product basis, we are obligated to pay sublicensing fees of up to approximately $20.0 million upon the achievement of mostly commercial milestones. As of September 30, 2026, we have incurred $2.7 million of sublicensing fees of which $0.1 million is outstanding and payable.

Recently Adopted Accounting Pronouncements

There were no recently adopted accounting pronouncements that have had a material effect on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities related to our interest-earning investments, foreign currency exchange rates and inflation risk affecting labor costs and clinical trial costs.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in marketable securities. As of September 30, 2026, we held $1.1 billion in cash, cash equivalents, and marketable securities, all of which were denominated in U.S. dollars, and consisted primarily of investments in money market funds, commercial paper, U.S. government obligations, and corporate bonds. Our marketable securities are subject to interest rate risk and could fall in value if market interest rates increase. However, we believe that our exposure to interest rate risk is not significant as the majority of our investments are short-term in duration and have a low risk profile. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material effect on the total market value of our cash equivalents and marketable securities as of September 30, 2026. To date, we have not experienced a loss of principal on any of our investments and as of September 30, 2026, we did not record any allowance for credit loss from our investments.

Foreign Currency Risk

We are also exposed to market risk related to changes in foreign currency exchange rates as a result of our entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. Volatile market conditions arising from the macroeconomic environment (including financial conditions affecting the banking system and financial institutions), inflation, tariff/trade policy, or global political instability may result in significant changes in exchange rates, and in particular, a weakening of the U.S. dollar relative to foreign currencies may negatively affect our expenses and net income as expressed in U.S. dollars. An adverse movement in foreign exchange rates could have a material effect on payments made to foreign suppliers. For the nine months ended September 30, 2026, a majority of our expenditures were denominated in U.S. dollars. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Inflation Fluctuation Risk

Inflation generally affects us by increasing our costs, such as the cost of labor and research and development contract costs. We do not believe inflation has had a material adverse effect on the results of our operations during the three and nine months ended September 30, 2026.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and 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 the foregoing evaluation of our disclosure controls and procedures, as of September 30, 2026, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures 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 Securities Exchange Act of 1934, as amended (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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2026, 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

The following summarizes the principal factors that make an investment in the Company speculative or risky, all of which are more fully described in the Risk Factors section below. This summary should be read in conjunction with the Risk Factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future. The occurrence of any of these risks, could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

Risk Factor Summary

Risks Related to Our Financial Condition and Capital Requirements

- We will need to raise additional capital to fund our operations and if we are unable to raise such capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts and raising additional capital may cause dilution to our stockholders and restrict our operations.
- We have never generated any revenue from product sales and may never be profitable.
- We anticipate that we will continue to incur significant losses for the foreseeable future.

Risks Related to Discovery, Development and Commercialization

- Our programs are in clinical and preclinical stages of development and may fail or suffer delays or may be more costly than anticipated for various reasons, including but not limited to delays or failures in achieving alignment with regulatory authorities on interpretation of data and its sufficiency to support approval of our product candidates, participant recruitment or other clinical trial or supply challenges.
- We are substantially dependent on the success of the SPY001, SPY002, SPY072 and SPY003 programs, as well as our rational combination programs, and may fail to achieve our development goals and timelines.
- Any drug delivery device used may have its own regulatory development, supply, and other risks.
- We may not be successful in building a pipeline of product candidates with commercial value.
- Our studies and trials may be insufficient to support regulatory approval of any product candidates.
- We may not be successful in discovering, developing and commercializing our intra-portfolio investigational drug combinations to achieve superior outcomes relative to the use of other therapies.
- Preliminary or “topline” data from our clinical trials may change as more data becomes available.
- Our current or future clinical trials may reveal significant adverse events or undesirable side effects.
- We may fail to capitalize on more profitable or potentially successful product candidates.
- Our products may not achieve regulatory approval, market acceptance or commercial success.
- Our programs may compete with each other and may face third-party program competition.
- Regulatory authorities may not accept data from clinical trials we conduct at sites outside the United States or other jurisdiction.

Risks Related to Government Regulation

- We may not be able to achieve our timelines or obtain timely regulatory approvals of product candidates.
- We may not be able to meet requirements for chemistry, manufacturing and control of our programs.
- Our product candidates may face competition sooner than anticipated based on rules and regulations that may apply or government decisions with respect to our intellectual property.
- Even if we receive regulatory approval, we will be subject to extensive ongoing regulatory obligations.
- We may be negatively impacted by healthcare legislative reform measures and other changes in law.
- Our potential revenue may be adversely affected due to unfavorable regulations, laws and/or policies.
- We may face criminal liability or other consequences if we violate U.S. and foreign trade regulations.
- Any accelerated review designations we may pursue may not hasten development or regulatory review.
- We may be negatively impacted by disruptions at the FDA and other government agencies, including as a result of a government shutdown.

Risks Related to Our Intellectual Property

- We may fail in obtaining, maintaining and protecting our patents and other proprietary rights.
- We may be subject to patent infringement claims or may need to file such claims.
- We may be subject to claims of wrongful hiring of employees or wrongful use of confidential information.
- Our patents and our ability to protect our products may be impaired by changes to patent laws.
- Our patent protection could be reduced or eliminated for non-compliance with legal requirements.
- We may fail to identify or interpret relevant patents that may have priority over our patents.
- We may become subject to claims challenging the inventorship or ownership of our intellectual property.
- Patent terms may be inadequate to protect the competitive position of our programs.
- Our technology licensed from various third parties may be subject to retained rights or may be affected by failure to comply with obligations in license agreements or other disruptions to business relationships with licensors resulting in loss of license rights that are important to our business.
- We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world.
- The intellectual property landscape around engineered antibodies is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

Risks Related to Our Reliance on Third Parties

- We may fail to maintain collaborations and licensing arrangements with third parties that we rely on.
- Third parties we rely on for nonclinical studies and clinical trials may fail to satisfy contractual duties.
- We may be unable to use third-party manufacturing sites, our third-party manufacturers may encounter difficulties in production or we may need to switch or create third-party manufacturer redundancies.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

- We may experience difficulties in managing the growth of our organization.
- We may fail to attract or retain highly qualified personnel.
- Our ability to operate in foreign markets is subject to regulatory burdens, risks and uncertainties.
- Our estimates of market opportunity may be inaccurate and our business may not grow at similar rates.
- Our employees or third parties may engage in misconduct or other improper activities.
- We may be impacted by information security incidents, cybersecurity or data breaches or other improper access to our data that could have a negative impact on our business or reputation.
- Our expanding use of AI exposes us to operational, regulatory, legal, and ethical risks that could adversely affect our business, reputation, financial condition, and results of operations.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- We may fail to comply with privacy, data security, safety and other regulations despite compliance efforts.

- We may be subject to adverse legislative or regulatory tax changes.
- We may fail to realize the benefits of our business or product acquisitions or our strategic alliances.

Risks Related to Our Common Stock

- The market price of our common stock has historically been volatile and may drop in the future.
- Our certificate of incorporation, Delaware law and certain contracts include anti-takeover provisions.
- We do not anticipate paying any dividends in the foreseeable future.
- Future sales and issuances of equity/debt may dilute stockholders and/or result in a drop in our stock price.
- Our principal stockholders own a significant percentage of our stock.

General Risk Factors

- Our product liability insurance may be insufficient to cover costly and damaging liability claims.
- Litigation costs and the outcome of litigation could have a material adverse effect on our business.
- We continue to incur significant costs for compliance with public company laws and regulations.
- Our failure to maintain proper and effective internal controls may adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner, decrease investor confidence in us, and reduce the value of our common stock. For example, in the fourth quarter of 2024, we identified a material weakness in our internal control over financial reporting which resulted in restatements of our previously-issued financial statements to amend certain net loss per share disclosures.
- Our business could be adversely affected by macroeconomic conditions, including geopolitical unrest.

Risks Related to Our Financial Condition and Capital Requirements

We will need substantial additional capital to fund our operations, and if we are unable to raise such capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of September 30, 2026, we had $1,071.9 million of cash, cash equivalents, and marketable securities. We will need to raise additional capital to continue to fund our operations in the future. If we are unable to raise additional capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and development programs or future commercialization efforts.

Developing our product candidates requires a substantial amount of capital. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we advance our product candidates through clinical trials. We will need to raise additional capital to fund our operations and such funding may not be available to us on acceptable terms, or at all, and such funding may become even more difficult to obtain due to macroeconomic conditions, including rising interest rates, tariffs and trade restrictions, global conflicts, and other conditions that could result in volatility in the U.S. capital markets and the biotechnology sector in general. Competition for additional capital among biotechnology companies may be particularly intense during economic uncertainty. We may be unable to raise capital through public offerings of our common stock and may need to turn to alternative financing arrangements. Such arrangements, if we pursue them, could involve sources of funding, such as issuances of secured debt and structured revenue-based financing, and/or issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt or debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make-whole has been paid. Interest on any newly-issued debt securities and/or newly-incurred borrowings would increase our operating costs and reduce our net income (or increase our net loss), and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be materially and adversely affected.

We do not currently have any products approved for sale and do not generate any revenue from product sales. Accordingly, we expect to rely primarily on equity and/or debt financings to fund our continued operations. Our ability to raise additional funds will depend, in part, on the success of our nonclinical studies

and clinical trials and other product development activities, regulatory events, our ability to identify and enter into licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to political, financial, economic and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back, or discontinue the development or commercialization of our product candidates;
- seek strategic partnerships, or amend existing partnerships, for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursue the sale of our company to a third party at a price that may result in a loss on investment for our stockholders; or
- file for bankruptcy or cease operations altogether (and face any related legal proceedings).

Any of these events could have a material adverse effect on our business, operating results and prospects. Even if successful in raising new capital, we could be limited in the amount of capital we raise due to investor demand restrictions placed on the amount of capital we raise or other reasons.

Additionally, any capital raising efforts are subject to significant risks and contingencies, as described in more detail under the risk factor titled “Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights.”

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates for which we complete clinical trials;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- qualify for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we obtain regulatory and marketing approval;
- marketing, launching, and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products and technological and market developments;
- implementing internal systems and infrastructure, as needed;
- protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;

- obtaining coverage and adequate reimbursement from third-party payors and maintaining pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by regulatory authorities to perform clinical and other studies in addition to those that we are currently conducting or anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Portions of our research programs may be in-licensed from third parties, which make the commercial sale of such in-licensed products potentially subject to additional royalty and milestone payments to such third parties. We will also have to develop or acquire manufacturing capabilities or continue to contract with contract manufacturers in order to continue development and potential commercialization of our product candidates. For instance, if the costs of manufacturing our biologic product are not commercially feasible, we will need to develop or procure our biologic product in a commercially feasible manner in order to successfully commercialize a future approved product, if any. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We have historically incurred losses, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a biopharmaceutical company with a limited operating history. Since inception, we have incurred significant operating losses. For the years ended December 31, 2025, 2024 and 2023, we reported a net loss of $155.2 million, $208.0 million and $338.8 million, respectively. As of September 30, 2026, we had an accumulated deficit of $1.3 billion. We will need to raise substantial additional capital to continue to fund our operations in the future.

Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. If we are unable to acquire additional capital or resources, we will be required to modify our operational plans to complete future milestones and we may be required to delay, limit, reduce or eliminate development or future commercialization efforts of product candidates and/or programs. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. We may be forced to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings or entering into strategic collaborations.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including conducting nonclinical and clinical development of the legacy rare disease clinical trials conducted by us prior to the Asset Acquisition and the nonclinical and clinical development of our current pipeline, and providing general and administrative support for our operations. To date, we have funded our operations primarily from the sale and issuance of convertible preferred and common equity securities, pre-funded warrants, the collection of grant proceeds, and the licensing of our product rights for commercialization of pegzilarginase in Europe and certain countries in the Middle East. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect our losses to increase as our product candidates enter more advanced clinical trials. It may be several years, if ever, before we complete pivotal clinical trials or have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to regulatory approval.

If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, coverage and adequate reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive

regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the nonclinical and clinical development of our product candidates;
- continue efforts to discover and develop new product candidates;
- continue the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our product candidates into larger, more expensive clinical trials;
- initiate additional nonclinical studies or clinical trials for our product candidates;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty, or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical and product candidates such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for ongoing or planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights.

Until such time, if ever, as we can generate substantial revenue from the sale of our product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and development agreements. To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of common stock. 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 additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our 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 or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity, including pursuant to any sales under convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our stockholders. For instance, in December 2023, we sold an aggregate of 6,000,000 shares of our common stock and 150,000 shares of our Series B Preferred Stock pursuant to a private

placement to certain investors for gross proceeds of approximately $180 million, in March 2024, we sold an aggregate of 121,625 shares of our Series B Preferred Stock pursuant to a private placement to certain investors for gross proceeds of approximately $180 million, in October 2025, we sold 17,094,594 shares of our common stock in an underwritten public offering for gross proceeds of approximately $316 million, in April 2026, we sold 7,475,000 shares of our common stock in an underwritten public offering for gross proceeds of approximately $463 million and in October 2026, we sold an aggregate of 4,735,295 shares of our common stock in an underwritten public offering for gross proceeds of approximately $403 million. Following stockholder approval of the Series B Conversion Proposal, an aggregate of 271,625 shares of Series B Preferred Stock were converted to 10,865,000 shares of common stock.

Debt financing, if available, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

Risks Related to Discovery, Development and Commercialization

We face competition from entities that have developed or may develop programs for the diseases and/or mechanisms of action targeted by our product candidates.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, clinical trial conduct, regulatory approvals, marketing and market access 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, recruiting participants for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

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 competitive safety, efficacy, dosing and/or presentation profiles. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance. See the section titled “Business – Competition” in our most recent Annual Report for more discussion about our competitors.

Furthermore, adverse events or disappointing results in clinical trials of third parties, including our competitors developing product candidates that target similar mechanisms of action and/or in the same indications as our product candidates, could reduce expectations regarding the potential success or perceived benefits of any of our programs, increase regulatory scrutiny of our product candidates, decrease confidence of current or potential trial participants and clinical trial collaborators in our investigational programs and/or have a negative impact on collaborations or demand for any product we may develop. These events also could result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is

influenced by claims that the use of therapies with shared or similar characteristics as ours is unsafe, ineffective or otherwise fails to meet expectations, our product candidates may not be accepted or favored by the general public, the medical community or the investment community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials or may discontinue their participation in our clinical trials. Negative developments could result in reduced probability of success of clinical trials involving our product candidates, challenges enrolling clinical trial participants, greater governmental regulation, stricter labeling requirements, decreased market potential and potential regulatory delays in the testing or approvals of our product candidates.

In addition, because of the competitive landscape for inflammatory and immunology ("I&I") indications, we may also face competition for clinical trial enrollment. Clinical trial enrollment will depend on many factors, including if potential clinical trial participants 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 participants could, among other things, delay our development timeline, which may further harm our competitive position.

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

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

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

- regulators, such as the U.S. Food and Drug Administration ("FDA"), or ethics committees ("ECs")/ institutional review boards ("IRBs") may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site or as otherwise planned;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites, and any CRO personnel changes could lead to operational delays or complications;
- clinical trial sites may deviate from trial protocol or drop out of a clinical trial;
- clinical trials of any product candidates may fail to demonstrate safety or efficacy, produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- the number of participants required for clinical trials of any product candidates may be larger than we anticipate and enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our CROs or other 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 fail to adhere to clinical trial protocols or fail to perform in accordance with the FDA's or any other regulatory authority's good clinical practice ("GCP") requirements or applicable regulatory guidelines in other countries or our clinical trial protocols may require changes;
- we may elect to, or regulators and/or ECs/IRBs may require that we or our investigators materially modify, 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;
- we may select clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- we may experience delays if we or our contract manufacturing organizations ("CMOs") are required to make changes to manufacturing processes;
- we may experience delays in identifying, recruiting and training suitable clinical investigators and their study teams;
- the cost of clinical trials of any of our programs may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- we may be unable to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our programs;
- the FDA or other regulatory authorities may not agree with our interpretation of the results of clinical trials or non-clinical studies or our clinical trial designs and plans;
- we may fail to establish an appropriate safety profile for a product candidate based on clinical or nonclinical data for such product candidates as well as data emerging from other therapies in the same class as our product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, additional clinical data or additional manufacturing data or impose other requirements before permitting us to initiate clinical trials or approving marketing/commercial sales.

Commencing clinical trials in the United States and in other countries is subject to acceptance by the FDA and other regulatory authorities of an investigational new drug ("IND") application or similar application and finalizing the trial design based on discussions with the FDA or other regulatory authority. In the event that the FDA or other regulatory authority requires us to complete additional nonclinical studies or clinical trials or we are required to satisfy other regulatory authority requests prior to commencing future planned clinical trials, the start of such planned clinical trials may be delayed or such planned clinical trials may be commenced in a modified manner. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any future clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional nonclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. Additionally, if the results of our nonclinical studies or clinical trials are not positive or are only modestly positive or if there are safety concerns, we may be required to repeat or conduct additional clinical trials or nonclinical studies for our product candidates beyond those that we currently expect. Even if we conduct such additional nonclinical studies or clinical trials or otherwise modify our planned clinical trials, the FDA or other regulatory authorities could determine that the data from our nonclinical studies or clinical trials are insufficient to support the approval of our product candidates. There are equivalent processes and risks applicable to clinical trial applications in other countries outside of the United States, which may require us to complete additional nonclinical studies or clinical trials, delay the enrollment of our clinical trials or otherwise modify our planned clinical trials or impose stricter approval conditions than we currently expect. Most product candidates that commence clinical trials are never approved as products, and

our current or future clinical trials ultimately may fail to support the approval of our current or any future product candidates.

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

We are substantially dependent on the success of our SPY001, SPY002, SPY072 and SPY003 programs, as well as our rational combination programs, and our current and planned 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 SPY001, SPY002, SPY072 and SPY003 programs, as well as our rational combination programs. We are investing a majority of our efforts and financial resources into the research and development of these programs. We initiated a Phase 2 platform trial of SPY001, SPY002 and SPY003, including their pairwise combinations, for IBD in the United States and certain other countries beginning with SPY001 in May 2025. Enrollment for Part A of the Phase 2 UC platform trial is now complete. Part B, which includes combination arms, with each arm subject to regulatory feedback and approval, was opened for enrollment in March 2026. We also initiated a Phase 2 basket trial of SPY072 for RD, including RA, PsA and axSpA, in the United States and Europe in Q3 2025 through Q2 2026 and a Phase 2 trial of SPY072 and anti-IL-17A/F for HS in Q3 2026. Enrollment for the Phase 2 basket trial is complete. Alignment with regulatory authorities on issues that arise before clinical trials commence, during clinical trials or after our clinical trials are completed could result in additional capital expenditures or delays in development that could have a material adverse impact on our business. The success of our programs is dependent on observing longer half-lives of our product candidates and/or their combinations in humans and comparable or better safety and efficacy profiles than other mAbs currently marketed or in development. We believe longer half-lives have the potential to result in more favorable dosing schedules for our product candidates, assuming they successfully complete clinical development and obtain marketing approval. To the extent we do not observe these extended half-lives with favorable safety and efficacy profiles when we dose patients with our product candidates in our clinical trials, it would significantly and adversely affect the clinical and commercial potential of our product candidates and our business.

Our programs will require additional clinical, nonclinical and manufacturing development and 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/or comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any current or future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in commercializing SPY001, SPY002, SPY072 or SPY003, alone or in combination, or are significantly delayed in doing so, our business will be materially harmed.

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

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of nonclinical studies and clinical trials, such as the expected timing of enrollment and readouts for topline data from our ongoing clinical trials, 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, including positions that may be taken by or requirements of regulatory authorities. If we do not meet these milestones as publicly announced, or at all, the commercialization of our product candidates 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.

Any drug delivery device that we potentially use to deliver our product candidates may have its own regulatory, development, supply and other risks.

We expect to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. If our product candidates are intended to be used with drug delivery devices, we expect to utilize drug delivery devices authorized for marketing under clearances or approvals held by third parties. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices that we choose to develop do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained for our products, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances, if required, for their drug delivery devices once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

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 research programs leverages clinically validated mechanisms of action in IBD and HS, 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.

The long-term safety and efficacy of these technologies and the extended half-lives and exposure profiles of our programs compared to currently approved products are unknown.

We may ultimately discover that our investigational products developed with half-life extension technologies do not possess certain properties required for therapeutic effectiveness and could lead to adverse effects. We currently have only reported interim Phase 2 induction topline data for SPY001, SPY002 and SPY003 from Part A of our SKYLINE clinical trial, Phase 2 interim topline data for SPY072 from the RA sub-study of our SKYWAY clinical trial, Phase 1 clinical data in healthy volunteers for SPY001, SPY002, SPY072 and SPY003, and nonclinical data for these programs. We have limited available data on the increased half-life and drug clearance properties of our programs and the anticipated half-life extension and/or drug clearance properties of each of our product candidates may not be seen in participants in our future clinical trial results. In addition, programs using half-life extension technologies may demonstrate different chemical and pharmacological properties in participants 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 product candidate. 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 research 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 involve lengthy and expensive processes that are subject to delays and may result in 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 experience delays or are insufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate 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, shortages of NHPs could significantly increase costs or delay the preclinical studies required before we submit an IND or foreign equivalent and initiate clinical development. We may experience difficulty in conducting our clinical trials as planned if we are unable to enroll a sufficient number of participants in any such trial as a result of variables outside of our control. See the risk factor titled “If we encounter difficulties enrolling participants in our current and future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.”

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 stage clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. In addition, we expect to rely on participants to provide feedback on measures such as measures of disease activity and measures of 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 participant, from participant to participant, and from site to site within a clinical trial.

We cannot be sure that the FDA, or comparable foreign regulatory authority, as applicable, will agree with our clinical development plans. If the FDA and/or comparable foreign regulatory authority requires us to materially modify our proposed trial designs, conduct additional trials or enroll additional participants, our development timelines may be delayed. We cannot be sure that submission of an IND, clinical trial application 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 them.

We could also encounter delays if an ongoing or planned clinical trial is required to be materially modified or suspended or terminated by us, by the ECs/IRBs of the institutions in which such clinical trials are being conducted, by the external Data Monitoring Committee or equivalent body, if any, for such clinical trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend, put on clinical hold or terminate a clinical trial due to a number of factors, including not aligning with or supporting our clinical trial designs or our 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 product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or the safety and efficacy results do not support regulatory approval of or commercial viability of our product candidates, our business and results of operations may be materially and adversely affected and we may incur significant additional costs.

A key element of our strategy is the development of intra-portfolio investigational drug combinations. If we are not successful in discovering, developing and commercializing investigational products that take advantage of different mechanisms of action to achieve superior outcomes relative to the use of monotherapies or other combinations, our ability to achieve our strategic objectives would likely be impaired.

A key element of our strategy is to build a broad portfolio of investigational products that will allow for the development of intra-portfolio combinations. We believe that by developing or licensing these investigational products, we can control the combinations we pursue and, if and when approved, maximize the commercial potential of these combinations. However, these combinations have not been tested before and may fail to achieve superior outcomes relative to the use of single agents or other combinations, may exacerbate adverse events associated with one of the investigational products when used as monotherapy, may yield new adverse events not observed with either of the monotherapies, or may fail to demonstrate sufficient safety or efficacy in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combinations. In addition, demonstrating that our combinations are superior to our single agents is likely necessary for marketing authorization of the combinations. However, comparing active treatments may be difficult to do in a controlled manner in our clinical trials, and we may be unable to interpret the results of comparisons between our combinations and single agents in a manner that satisfies regulatory requirements.

Even if we are successful in developing combinations, competition from other investigational products in the same class which are either already approved or further along in development than ours may prevent us from realizing the commercial potential of our combinations and prevent us from achieving our strategic objectives, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Development of combination therapies may present more or different challenges than development of monotherapies.

We plan to pursue development of our investigational products in combination with one or more additional products or investigational products. The development of combination therapies may be more complex than the development of monotherapies and generally requires that sponsors demonstrate the contribution of each investigational product to the claimed effect and the safety and efficacy of the combination as a whole. Regulatory authority requirements for the development of combination therapies may make the design and conduct of clinical trials more complex and/or burdensome, requiring more clinical trial participants and additional time and cost to complete than we plan or anticipate. We also may not be able to meet the FDA's or comparable foreign regulatory authority's current or future approval standards required for combination therapies or combination products, including if we decided to administer or package combinations as a single drug product. For example, under the "combination rule", the FDA may not file or approve a fixed-dose combination product unless each component of a proposed drug product is shown to make a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is safe and effective for the intended population. To satisfy these requirements, the FDA typically requires a clinical factorial trial, designed to assess the effects attributable to each drug in the combination product. This is particularly true when the ingredients are directed at the same sign or symptom of the disease or condition. Aside from factorial trials, the FDA has accepted a variety of approaches to satisfy the combination rule and has made statements that it may be possible to use other types of clinical and nonclinical data and mechanistic information available to demonstrate the contributions of the individual active ingredients to the effect of the combination. In addition, combination products may require dose selection for each agent in the combination, which may require more and/or larger groups of participants than single agents. Our clinical trial and research efforts may not satisfy regulators' expectations of adequate exploration of dose ranging required for drug approval. Moreover, the applicable requirements for approval of combinations may differ from country to country. See the section titled "Business – Government Regulation – Combination Therapy" in our most recent Annual Report for a more detailed description of regulation of combination therapies in the United States.

In the event that one of our investigational products were to fail to demonstrate sufficient safety and efficacy data or establish its contribution to the claimed effects of combinations or if we are unable to meet the FDA's or comparable foreign regulatory authority's current or future approval standards required for combination therapies or combination products in a timely manner, we would need to identify and research alternative monotherapy or combination treatments, run additional trials to produce supportive data or modify existing clinical trial plans. In the event we are unable to do so or are unable to do so on commercially reasonable terms or we are unable to continue development of one or more of investigational products, our business and prospects would be materially harmed.

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

We may experience difficulties in participant enrollment in our current and future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trial until its conclusion. The enrollment of participants will depend on many factors, including:

- the prevalence and severity of the disease under investigation;
- the participant eligibility and the inclusion and exclusion criteria defined in the protocol;
- the incidence and prevalence of target trial populations under clinical investigation;
- the proximity of participants to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and participants' perceptions as to the potential advantages of the drug candidate(s) being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant consents;
- our ability to monitor participants adequately during and after treatment;
- the risk that participants enrolled in clinical trials will drop out of the trials before completion or fail to attend scheduled trial visits; and
- factors we may not be able to control, including the impacts of geopolitical unrest or public health crises, which may limit the availability of participants, investigators or their staff, or clinical sites.

In addition, our clinical trials will compete with other clinical trials with product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of participants who are available for our clinical trials at such clinical trial sites. Additionally, the number of participants required for clinical trials of our programs may be larger than we anticipate. Even if we are able to enroll a sufficient number of participants for our current or future clinical trials, we may have difficulty maintaining participants in our clinical trials. Our inability to enroll or maintain a sufficient number of participants would result in significant delays in completing clinical trials or receipt of marketing approvals, increased development costs or our cessation of one or more clinical trials altogether.

Additionally, our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including, without limitation: difficulty in establishing or managing relationships with CROs and physicians; different standards for the conduct of clinical trials; different standard-of-care for patients with a particular disease; difficulty in locating qualified local consultants, physicians and partners; and potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

Preliminary, "topline" or interim data from our clinical trials that we announce or publish from time to time may change as more participant 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 nonclinical studies and clinical trials, which are based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a more comprehensive review or taking into account additional data that become available. In reviewing preliminary or topline data, we also make assumptions, estimations, calculations and conclusions as part of our analyses that may change once a complete data set is available. 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.

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 product candidate, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular nonclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

Results of our nonclinical studies or clinical trials could reveal a high and unacceptable severity and/or prevalence of side effects, adverse events or unexpected characteristics at any point in time during the development process for our product candidates. We cannot assure you that the future results of our nonclinical studies or clinical trials will not reveal such characteristics. If significant adverse events or undesirable side effects are observed in any of our current or future nonclinical studies or clinical trials, we may have difficulty recruiting participants to such trials, participants may drop out of our trials, or we may be required to cease or materially modify our development efforts of one or more programs. We, the FDA or other applicable regulatory authorities, or an EC/IRB, may suspend or require the material modification of any clinical trials of any program at any time for various reasons, including a belief that participants 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 nonclinical studies, which side effects do not present themselves in clinical trials in humans. Even if the side effects do not preclude the product candidate 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 participant recruitment or the ability of enrolled participants to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel. In addition, safety findings associated with competing products or product candidates that target similar pathways could result in the FDA or comparable foreign regulatory authorities imposing restrictions on our clinical trials or product labeling or denying approval of our products. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

Our product candidates have mechanisms of action in common with other approved drugs that have been associated with certain adverse reactions and/or events in patients. For example, nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities are the most common adverse reactions noted with ENTYVIO®, which is in the same drug class as SPY001 and is approved for the treatment of moderately to severely active UC in adults and of moderately to severely active CD in adults. In addition, mAbs targeting TL1A such as our product candidates SPY002 and SPY072 in clinical trials are associated with patient adverse events that most commonly include headache, nausea, nasopharyngitis, urinary tract infection, SARS-CoV-2 infection, fever, fatigue, arthralgia, and back pain. Finally, for SKYRIZI®, which is in the same drug class as SPY003 and is approved for the treatment of moderately to severely active UC in adults and of moderately to severely active CD in adults, the most common adverse reactions are upper respiratory

infections, headache, arthralgia, injection site reactions, abdominal pain, anemia, pyrexia, back pain, arthropathy, and urinary tract infection in patients with CD and arthralgia, pyrexia, injection site reactions, and rash in patients with UC. In addition, for patients treated with BIMZELX®, which is approved for moderate-to-severe HS in adults and is being used as a surrogate IL-17A/F in our Phase 2 trial in HS, the most common adverse reactions are upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue. Participants in our clinical trials for SPY001, SPY002, SPY072 and SPY003 as well as our rational combination programs, may experience similar or additional adverse reactions and/or events such as infections (including rare infections such as tuberculosis or JC virus reactivation, which could lead to multifocal leukoencephalopathy, which is a theoretical risk for the drug class), infusion-related reactions, other hypersensitivity reactions (including injection site reactions and delayed hypersensitivity reactions), hepatotoxicity, increased risk of suicidal ideation and behavior, liver biochemical abnormalities, and inflammatory bowel disease, as has been observed with other biologics, including those with similar mechanisms of action. Although our product candidates have observed to be well tolerated to date, we have observed adverse events, including serious adverse events, in our clinical trials consistent with known safety profiles of drugs with the same mechanisms of action. It is possible we may observe additional safety events that may or may not be consistent with such third-party product safety profiles.

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

If any of the foregoing events occurs or has a negative impact on the safety profile of one or more of our product candidates, or if one or more of our research 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 SPY001, SPY002, SPY003, SPY072, SPY007 and rational combination programs. As a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate 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 product candidate.

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/or product candidates in later stages of development for the treatment of each of IBD, PsA, axSpA and HS. However, our programs incorporate advanced antibody engineering to optimize the half-life and formulation of antibodies; to date, no such antibody has been approved by the FDA for the treatment of IBD, PsA, axSpA or HS. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates half-life

extension for our targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. An extended half-life may make it more difficult for patients to change treatments and there is a perception that half-life extension could exacerbate side effects or experience waning efficacy, each of which may adversely affect our ability to gain market acceptance. Market acceptance of our product candidates 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 product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

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

We have multiple product candidates, alone and in combination, in development for the same indication, IBD, and are developing one product candidate (SPY072) as a monotherapy for RD and HS and one combination (SPY072 and IL-17A/F) for HS. We may in the future develop our programs for other I&I indications. Each such program targets a single or multiple mechanisms of action that could provide differentiation from standard of care or each other. 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 participants. In addition, if multiple product candidates 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 in the United States and various other jurisdictions, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are conducting and may conduct future clinical trials in the United States and various other countries. The acceptance of trial data from clinical trials conducted outside the United States or other jurisdiction by the FDA or comparable foreign regulatory authority may be subject to conditions imposed by such regulatory authority or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the applicable clinical trial data on the basis of foreign data alone unless, among other conditions, (i) the clinical trial is well-designed and conducted and performed by qualified investigators in accordance with ethical principles, (ii) the trial population adequately represents the U.S. population, and (iii) the data is applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Many foreign regulatory authorities have similar approval requirements. In addition, clinical trials are subject to the applicable local laws of the jurisdictions where the trials are conducted and acceptance of the data by the FDA or any comparable foreign regulatory authority may depend on its determination that the trials also complied with all applicable local laws and regulations. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, 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 or any comparable foreign regulatory authority accepted such data, it could require us to modify our ongoing or planned clinical trials to receive clearance to initiate such trials in the applicable jurisdiction 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 participants in foreign countries to adhere to the 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, as well as political and economic risks relevant to foreign countries. For additional disclosures regarding political and economic risks involved with international clinical trials, see the risk factor titled "Our business could be adversely affected by economic downturns, inflation, increases in

interest rates, natural disasters, public health crises, political crises, U.S. elections, international or geopolitical events, such as the ongoing conflicts between the United States and Iran and Russia and Ukraine, instability in Venezuela, conflicts between the U.S. and other countries, and conflicts in the Middle East, the implementation of measures that restrict international trade or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition."

Risks Related to Government Regulation

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

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including SPY001, SPY002, SPY072 and SPY003, alone or in combination, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and potential inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective or more effective than the standard of care or competing products or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or successfully commercializing them. 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 nonclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. In addition, the FDA and comparable foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations or revise existing regulations, or take other actions, which may impact our clinical development plans or prevent or delay approval of our programs under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance.

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

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

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 manufacture, characterize, and control our drug products and drug delivery devices safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation and drug delivery device, manufacturing the drug product and drug delivery device, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, meeting facility, process, testing, validation and commercialization requirements, and demonstrating that our drug products meet standards for parenteral administration as well as stability and quality 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. In addition, we must show, or show through data from a third-party, that the drug delivery device is of adequate quality to deliver the drug product in a commercial setting.

Manufacturing biologics is highly susceptible to losses due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. The impact to drug supply may be compounded by the long lead times needed to manufacture additional drug product due to plant capacity limitations or other potential restrictions at our CMOs. In some cases, even minor deviations from normal manufacturing processes may result in reduced production yields, lot failures, product defects, product liability claims, or other supply disruptions. If issues arise at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the issues, which could delay clinical trials and adversely affect our business. Problems in third-party manufacturing processes or facilities could restrict our ability to ensure sufficient clinical material for our clinical trials or delay or prevent us from obtaining marketing approval.

Scaling up a biologic manufacturing process can be a difficult task and is associated with additional risks, including cost overruns, process scale-up, process reproducibility, stability issues, compliance with current good manufacturing practices ("cGMPs"), lot consistency and timely availability of sufficient quantity of raw materials. Even if we obtain regulatory approval for any of our product candidates, manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our third-party manufacturers are unable, or decide not, to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If our manufacturers are unable to produce sufficient quantities of drug substance and/or drug product for clinical trials or for commercialization we will need to identify and negotiate with other CMOs an agreement for clinical and/or commercial supply and it is not certain we will be able to come to agreement timely or on terms acceptable to us, which would likely jeopardize our ability to provide any product candidates to trial subjects in clinical trials and products to patients, if approved.

Our product candidates 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 that sponsor's own nonclinical data and data from that sponsor's own adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates 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 accord our product candidates reference product exclusivity relative to biosimilar 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 will depend on a number of marketplace and regulatory factors that are still developing.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing post marketing 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 post marketing regulatory requirements or experience unanticipated problems with our products.

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

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 post-approval trials, including full or partial holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may be negatively impacted by changes in law or other policy, including healthcare reform initiatives.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay development of or regulatory approval of our product candidates and/or increase

our manufacturing costs, including raw materials, general operating costs or other costs. 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 fail to adequately prepare for the impacts of or 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, our product candidates may be delayed in obtaining regulatory approval or may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. In addition, the impact of legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current presidential administration on us and the pharmaceutical industry as a whole is unclear. These government actions could cause delays in our business plans, increase the cost of execution of our business plans or otherwise have a material adverse effect on our business. For example, the U.S. government has recently taken actions and made statements, including in relation to the imposition or threatened imposition of tariffs (including tariffs on patented pharmaceutical products), affecting (among others) certain products manufactured in China and other non-U.S. countries. These measures could impact the cost of manufacturing our product candidates for our ongoing and planned clinical trials and may increase other costs such as import and export costs across different jurisdictions, costs of drug product and clinical trial supplies, and other costs of running our trials and executing on our business plans, which could negatively impact our financial position. We may seek alternative or additional sources for our drug substance or drug product for our clinical trials, clinical trial sites, or service providers, which could negatively impact our expected costs, timelines and business plan. Additionally, the BIOSECURE Act enacted as part of the FY 2026 National Defense Authorization Act has the potential to severely restrict our ability to purchase services or products from, or otherwise collaborate with, certain Chinese "biotechnology companies of concern" ("BCOC") without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We currently rely on foreign CMOs, including WuXi Biologics, which is based in China. Although none of our CMOs have yet been named as a BCOC, if any of our CMOs are identified as a BCOC, we could be required to switch or move development of our product candidates from one CMO to another, and as a result we may incur additional development costs or delays in manufacturing product for clinical trials or commercialization. We are in the process of creating manufacturing capabilities with third parties outside of China, including within the United States, and have taken several measures to strengthen our supply chain in the event that our manufacturers are impacted. In the U.S., in recent years, the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by major legislative, administrative and executive initiatives addressing drug pricing and payment, access to healthcare or funding of healthcare as well as more general actions affecting federal budgets and tariffs. See the section titled "Business – Government Regulation – Healthcare Reform" in our most recent Annual Report for a more detailed description of healthcare reform measures that may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, patients and others 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 product candidates, if approved. In the U.S., these laws include, but are not limited to the following, some of which are likely to apply only if or when we obtain marketing approval for a product candidate:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to calculate, report and certify certain complex product prices and other data to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, which data may be used in the calculation of reimbursement and/or discounts on approved products;
- the federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including state anti-kickback and false claims laws, consumer protection and unfair competition laws and laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with health care providers, or marketing expenditures and/or require the registration of pharmaceutical sales representatives.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

See the section titled "Business – Government Regulation – Other Healthcare Laws and Compliance Requirements" in our most recent Annual Report for a more detailed description of certain laws that may affect our ability to operate.

Ensuring compliance is time-consuming and costly. If and when one of our product candidates is approved, our compliance efforts will need to expand and evolve to address newly applicable laws. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

Even if we are able to commercialize any product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such product candidates at competitive prices, which would seriously harm our business.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in significant part on the extent to which reimbursement or coverage for these product candidates and related treatments will be available from government health

administration authorities, government health benefit programs, private health insurers, such as managed care plans, and other organizations. Government authorities and other third-party payors decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by restricting coverage, controlling utilization and limiting the amount of reimbursement for particular medications. Third party payors may take action to encourage use of other products perceived to be clinically superior or more cost effective which may limit demand for our products. Our ability to commercialize our product candidates successfully may also be adversely affected by discounts or rebates that we are required to provide in order to ensure coverage of our products and compete in the marketplace. Additionally, if any of our product candidates is approved and we are found to have improperly promoted off-label uses of those product candidates, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See the sections titled "Business – Government Regulation – Coverage and Reimbursement" and "Business – Government Regulation – Regulation in the European Union" in our most recent Annual Report for a more detailed description of the government regulations and third-party payor practices that may affect our ability to commercialize our product candidates.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly member states of the EU and other markets that use health technology assessment ("HTA") processes, 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 HTA markets, and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. If the UK, certain EU member states or other HTA markets were to

significantly alter their regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

A breakthrough therapy, fast track, or other expedited designation for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those product candidates will receive marketing approval.

We may seek a breakthrough therapy, fast track, or other designation for appropriate product candidates. Designations such as these are within the discretion of the FDA, or other comparable foreign regulatory authorities. The receipt of a designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify under one of FDA's designation programs, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Additionally, changes in the leadership of the FDA and other actions taken by the presidential administration, including mass layoffs within the federal government, may impose constraints on the FDA's ability to engage in activities in the normal course and may result in reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to take advantage of the benefits for the Fast Track Designation and progress development of our programs or obtain regulatory approval for our programs. See the section titled "Business – Government Regulation – United States Biologics Regulation – Expedited Development and Review Programs" in our most recent Annual Report for a more detailed description of the process for seeking expedited designations such as fast track or breakthrough therapy designations.

Disruptions at the FDA and other government agencies, including as a result of a government shutdown, could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including government shutdowns as well as statutory, regulatory and policy changes, inadequate government budget funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel, and disruptions caused by public health crises. There have been mass layoffs of federal employees since the start of the current presidential administration in January 2025, the full impact of which is unclear at this time. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, the presidential administration has made and is expected to continue to make significant changes in the leadership of the FDA and other U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA. In addition, certain senior employees of FDA have not maintained long tenure in their positions, marking a period of high leadership turnover.

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

Additionally, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including FDA and the Center for

Medicare & Medicaid Services, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, 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, our business could be materially harmed.

Risks Related to Our Intellectual Property

Our ability to obtain and 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, confidentiality agreements, license agreements, including the License Agreements, and the Paragon Agreement to protect the intellectual property related to our programs and technologies and to prevent third parties from competing unfairly 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 expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States; the reverse may also occur. 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 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 product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford us any meaningful competitive advantage.

In addition to seeking patents for some of our technology and programs, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or state actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to

assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the U.S. may be less willing to protect trade secrets.

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 current and future licensors or collaboration partners. If any of our current and 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 product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates 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 current and future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our current and future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our current and future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our current and 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 product candidates, 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 current and 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 current and 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 product candidates 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 product candidates 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 product candidate and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g. patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of our common stock.

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some

of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

As is common in the biotechnology industry, in addition to our employees, we engage the services of consultants to assist us in the development of our programs. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. Despite our training and compliance efforts, we could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

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

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

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

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in *Amgen, Inc. v. Sanofi (Amgen)* recently held that *Amgen*'s patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement

where the patent specification provided twenty-six exemplary antibodies, but the claimed class of antibodies covered a "vast number" of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in *Amgen* or other recent precedential court decisions. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. 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, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in ways that could have a material adverse effect on our patent rights and weaken our ability to protect, defend and enforce our patent rights in the future.

Geopolitical instability 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 that hears patent infringement and revocation proceedings effective for member states of the EU. This could enable 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. Given that we own or license certain European patents or applications for our current pipeline, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC, or that we will have the ability to opt out of the UPC in the future.

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

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

formal documents. If we fail to maintain the patents and patent applications covering our programs, our competitive position would be adversely affected.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates 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 priority 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 and 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. The U.S. government has certain rights in such inventions under the applicable funding agreements and under applicable law. 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 the competitive position of our product candidates 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 United States 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 product candidates 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 product candidates, patents protecting such product candidates might expire before or shortly after such product candidates 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 or may be affected by our failure to comply with obligations under license agreements or other disruptions to business relationships with licensors resulting in loss of license rights that are important to our business.

Our current or 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. In addition, under our license agreements, we may be generally responsible for bringing any actions against third parties for infringing on the patents we have licensed. Certain of our license agreements may also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may seek regulatory approval of, and to market, products identical to ours or we may be required to cease our development and commercialization of one or more product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and growth prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights to third parties under our collaborative development relationships;
- our diligence obligations under the license agreement with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or broaden what we believe to be the scope of the licensor's rights to our intellectual property and technology, or increase what we believe to be our financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. It is also possible that a third party could be granted limited licenses to some of the same technology, in certain circumstances. Any such events could result in the loss of our ability to develop and commercialize one or more product candidates or we could lose other significant rights, any of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world.

We have limited intellectual property rights outside of the United States. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of foreign countries do not protect intellectual property rights to the same extent as the federal and state laws of the United States. In addition, intellectual property license agreements we enter into may not always include worldwide rights. Consequently, we may not be able to prevent third parties from using our intellectual property in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is difficult or impractical. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our patents and intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Moreover, the initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have invoked compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

The intellectual property landscape around engineered antibodies is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

Due to the intense research and development that is taking place in the field of engineered antibodies, including by us and our competitors, the intellectual property landscape is evolving and in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends upon our ability and the ability of our collaborators and licensors to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings

before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates we may develop, including interference proceedings, post-grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the EPO. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and they may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. We are aware of certain third-party patent applications that, if issued, may be construed to cover some of our product candidates. There may also be third-party patents of which we are currently unaware with claims to technologies, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement claims or lawsuit against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology, or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates. Even if we believe third-party intellectual property claims are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there can be no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing impacted product candidates we may develop and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize certain product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Defense of third-party claims of infringement of misappropriation, or violation of intellectual property rights involves substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent 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 the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Reliance on Third Parties

We rely on collaborations and licensing arrangements with third parties, including our arrangement 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.

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 research programs and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our programs and 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 upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

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

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs and strategic partners, to conduct and support our nonclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our nonclinical 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 nonclinical studies and clinical trials and the management of data developed through nonclinical 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 good laboratory practice ("GLP"), GCP and GVP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our programs in clinical development. If we or any of these third parties fail to comply with applicable GLP, GCP and GVP regulations, the nonclinical and clinical data generated in our nonclinical studies and clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical and 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 nonclinical studies and clinical trials comply with GLP, GCP and GVP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat nonclinical studies and 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 nonclinical studies and 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 nonclinical studies, clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our current or future product candidates. If any of our relationships with these third parties, including CMOs and CROs, are terminated, we may not be able to enter into arrangements with alternative CMOs, CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CMOs or CROs involves additional cost and requires company resources. In addition, there is a natural transition period when a new CMO or CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CMOs and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If these CMOs, CROs or other 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 (including by clinical sites or investigators) to adhere to our nonclinical and clinical protocols or regulatory requirements or for other reasons, our nonclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

In addition, we currently rely on foreign CROs and CMOs, including WuXi Biologics, and will likely continue to rely on foreign CROs and CMOs in the future. We or the foreign CROs or CMOs we work with may be subject to U.S. legislation, including the BIOSECURE Act included as part of the FY 2026 National Defense Authorization Act, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or

have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies or disrupt our supply chain. For example, in April 2025, the United States government imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or impose other restrictions on companies' ability to work with Chinese biotechnology companies. In April 2026, the U.S. announced the imposition of tariffs on patented pharmaceutical products, which may further increase costs or restrictions. We are in the process of creating manufacturing capabilities with third parties outside of China, including within the United States, and have taken several measures to strengthen our supply chain in the event that our manufacturers are impacted; however, to the extent the aforementioned restrictions or future tariffs are applicable to the material we import from China and other countries or if we are not able to secure supply of our product candidates as a result of applicable legislation, our business and financial condition could be adversely affected despite our mitigation efforts.

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

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

We do not currently own any facility that may be used as our clinical or commercial manufacturing and processing facility and must currently rely on CMOs to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our programs, if approved. Historically, we have generally had a sole source relationship for our supply of the SPY001, SPY002, SPY072 and SPY003 Phase 2 programs and are working to build dual sourcing for our potential Phase 3 clinical trials. If there should be any disruption in our product supply arrangements, including any adverse events affecting our suppliers, it could have a negative effect on the clinical development of our programs and other operations while we work to identify and qualify alternate supply sources. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and other qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and delays, and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties, including delays, due to resource constraints, supply chain issues, government activity under the Defense Production Act, proposed or actual legislative changes or requirements, or as a result of labor disputes or unstable political environments, including tariffs and restrictions imposed by the United States or other foreign governments on goods required for the operation of their business. If any CMOs on which we will rely are significantly delayed in delivering or fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our

business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs and other third parties 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 or increased costs as a result of tariffs on imports imposed by the United States or other foreign governments. 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 nonclinical studies and clinical trials or the approval of any of our product candidates by the FDA, resulting in higher costs or adversely impact commercialization of our product candidates. See the section titled "Business – Manufacturing and Supply" in our most recent Annual Report for a more detailed description of our manufacturing plans and assumptions and the factors that may affect the success of our programs.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

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

We expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, commercial operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the experience of our management team, who have only worked together for a limited time in managing a public company with such anticipated growth, 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.

We are a clinical stage biotechnology company with a limited operating history, and, as of September 30, 2026, we had 130 employees. We have been and will continue to be highly dependent on the research and development, clinical and business development expertise of our executive officers, as well as the other principal members of our management, scientific and clinical team. Any such officers and other principal members may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Attracting and retaining qualified personnel will also be critical to our success, including with respect to any strategic transaction that we may pursue. 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 because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, facilitate regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and nonclinical and clinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and retaliatory measures by foreign governments may disrupt the global supply chain for biopharmaceutical products. Any direct tariffs imposed on pharmaceutical products may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical CMOs, and a delay in our development timelines.

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

Our 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.

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.

Despite our employee training and compliance programs, 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 and ethics, policies, standard operating procedures and other compliance efforts 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 information technology systems, as well as those of any of our CROs, manufacturers, other contractors or consultants, third-party service providers, and potential future collaborators, are subject to the risk of failure, security breaches, data privacy incidents, or other unauthorized or improper

access to, use of, or destruction of proprietary, confidential, employee, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand, and material disruption to our business.

To achieve our business objectives, we depend on our own internal IT systems and networks, as well as those of third parties and their vendors. These systems are used to process and store sensitive data—including confidential research, business plans, financial information, intellectual property, trade secrets and various personal data that may be legally protected. They also play a critical role in maintaining the continuity of our supply chain and operations, and are integral to many of the products provided to customers.

Although we have implemented security measures designed to protect our information systems and the data they store, the size and complexity of these systems—and the increasing volume of information maintained on our internal IT systems and those of our third-party CROs, other contractors (including clinical trial sites), service providers, supply chain partners, and consultants—make them potentially vulnerable to a range of risks. These risks include breakdowns 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. Such incidents could compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. The evolving use of new and emerging technologies, such as AI, machine learning and quantum computing, by malicious actors is expected to further intensify cybersecurity threats. For example, AI can be leveraged to develop adaptive malware, generate highly convincing phishing or impersonation attacks (such as deepfakes), or automate the discovery and exploitation of software vulnerabilities, thereby increasing the likelihood and sophistication of future attacks. Furthermore, quantum computing could render encryption methods obsolete, exposing us to increased risks of data breaches, authentication bypasses and new types of cybersecurity threats. The increasing velocity of such disruptive innovations may outpace our ability to manage the risk appropriately.

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

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Even prompt detection and response may not fully mitigate impacts, and remediation efforts could divert management attention and increase costs. The use of AI by attackers may also contribute to faster, more coordinated attacks that evade traditional detection methods, placing additional pressure on our security infrastructure and incident response capabilities. 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. Remote work may increase exposure to insecure networks, device loss, and compromised credentials. 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. For further discussion of our evolving privacy and data security compliance obligations, see the sections titled "Business - Government Regulation - Data Privacy and Cybersecurity Requirements (U.S.)" and "Regulation in the European Union - European Data and Security Laws" in our most recent Annual Report.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Certain third-party platforms or vendors may incorporate AI-driven automation or analytics into their offerings, which may expose us to new categories of risk, such as data being repurposed for AI training, unexplainable outputs generated by machine learning models, or unintended reliance on automated decision-making systems that lack transparency or auditability. 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.

Internally, we are also evaluating and, in some cases, implementing AI-enabled technologies to support business operations, data analysis, and other workflow efficiencies. Although these tools offer potential benefits, they also present new and evolving risks, including exposure to biased outputs, regulatory uncertainty around AI governance, and the possibility that sensitive data could inadvertently be incorporated into AI model training datasets or disclosed through model inference. As global laws and guidance surrounding AI systems continue to evolve, noncompliance could result in restrictions on our use of AI, reputational consequences, or enforcement activity.

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 always include limitations of liability, and even when such provisions are present, there can be no assurance that they will be adequate to protect us from liabilities, damages, or claims arising from our data privacy and security obligations. We can also not guarantee that our cybersecurity insurance coverage will be sufficient to protect us from or mitigate liabilities arising out of our privacy and security practices or that such coverage will continue to be available on commercially reasonable terms or at all. Moreover, even robust cybersecurity and privacy controls under frameworks such as the National Institute of Standards and Technology ("NIST") cannot eliminate all risk, and we have identified cybersecurity risks that, if realized, are reasonably likely to materially affect us.

Our expanding use of AI exposes us to operational, regulatory, legal, and ethical risks that could adversely affect our business, reputation, financial condition, and results of operations.

We increasingly develop, procure, and deploy AI and machine learning ("ML") tools across our operations. While these tools may create efficiencies, they also introduce material risks related to data quality and bias, transparency and explainability, validation and lifecycle management, cybersecurity, intellectual property, privacy, discrimination, liability, and third-party dependencies. Errors or bias in AI outputs, inadequate

monitoring, or insufficient documentation could impair clinical development, pharmacovigilance, manufacturing quality, or commercial activities, resulting in delays, higher costs, product or batch actions, or reputational harm.

The emergence of AI and other technologies may exacerbate other risks, including those related to regulation, litigation, compliance issues, ethical concerns, confidentiality, and data privacy or security. For example, regulatory uncertainty related to AI or other emerging technologies may require significant resources to adjust business practices to comply with developing laws. Several governmental authorities have already proposed or enacted laws and other guidance governing AI.

For example, in the United States, the FDA has outlined a risk based credibility framework for AI used to support drug and biologics development, signaling expectations for context of use validation, lifecycle maintenance, traceability, and explainability, and continues to oversee AI/ML enabled medical devices; these expectations could increase development costs and elongate review. These and other developing obligations may prevent or make it harder for us to conduct or enhance our business using AI, or lead to regulatory fines, penalties, or other liability. Further, use of AI technologies could lead to unintended consequences, such as data leakage, healthcare fraud and abuse, cybersecurity incidents, intellectual property infringement, or unintended biases. Our AI use must also comply with privacy regimes, including the UK GDPR and EU GDPR (e.g., restrictions on automated decision making and profiling, and stringent transparency and data subject rights). Divergent and evolving requirements across jurisdictions may require region specific controls, duplicated validation, or delayed deployments; failure to comply could lead to investigations, fines, injunctions, adverse regulatory outcomes, litigation, loss of market access, or reputational damage.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage over a 3-year period. Upon certain events since our conversion from a Delaware limited liability company to a Delaware corporation in 2015, it is possible that we may have triggered an "ownership change" limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which are outside of our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs and other pre-change tax attributes to offset U.S. federal taxable income or taxes may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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 the third parties upon whom we rely, are or may become subject to numerous domestic and foreign laws, regulations, and standards governing privacy, data protection, and information security, as well as contractual and ethical obligations, many of which overlap or conflict and are subject to changing interpretations. As noted, these include the HIPAA/HITECH framework for protected health information in certain contexts; the amended CCPA and other comprehensive state privacy laws and their implementing regulations; state health data laws; federal and state consumer protection laws; data breach notification statutes; and the DOJ Bulk Data Rule. Outside the United States, we are subject to the GDPR, the DPA 2018, DUAA, the ePrivacy Directive, among others. These regimes impose obligations such as purpose limitation, data minimization, security safeguards, vendor contracting, impact/risk assessments, transparency and individual rights, breach notification, and restrictions on automated decision-making and profiling. New and proposed laws increasingly emphasize data localization and restrictions on cross-border transfers, and regulators have signaled heightened enforcement. Failure or perceived failure by us or our third parties to comply with any of these requirements could result in investigations, enforcement actions, litigation (including class claims), fines

and penalties, remedial orders, restrictions on processing, reputational harm, increased compliance and operational costs, and other adverse consequences that could materially and negatively affect our business, financial condition and results of operations. See the section titled “Business – Government Regulation – Data Privacy and Cybersecurity Requirements (U.S.)” and related international data protection disclosures in our most recent Annual Report for a more detailed description of the laws that may affect our ability to operate.

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

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

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. On July 4, 2025, the U.S. Congress enacted the One Big Beautiful Bill Act, which includes a provision restoring the immediate deductibility of domestic research and development expenditures. The impact of this newly enacted law on our tax position will depend on how the provision is implemented and interpreted by the Internal Revenue Service and other regulatory authorities. In addition, we have no assurance as to whether, when and how this provision may be subject to further amendment or repeal. 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 product candidates 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. 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 Our Common Stock

The market price of our common stock has historically been volatile, and the market price of our common stock may decline in the future.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Market prices for securities of clinical-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to maintain our existing third-party license and supply agreements;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public and the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions, including global inflationary pressures, rising interest rates, general economic slowdown or a recession, changes in tariff/trade and monetary policies, instability in financial institutions and the prospect of a shutdown of the U.S. federal government;
- geopolitical instability and government actions, including the ongoing military conflicts in Ukraine and Iran, conflicts in the Middle East, instability in Venezuela, geopolitical tensions between the United States and other countries, including China and Iran, and the implementation of measures that restrict international trade by the United States, China or other governments;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and

- period-to-period fluctuations in our financial results.

Moreover, the capital markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. For example, escalating trade tensions, elevated interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries. If the market price of our common stock does not exceed the price at which a stockholder purchases its shares, such stockholder may not realize any return on its investment in us and may lose some or all of its investment.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Anti-takeover provisions in our charter documents and under Delaware law and the terms of some of our contracts could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our Certificate of Incorporation and Bylaws may delay or prevent an acquisition or a change in management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

In addition, the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Series A Certificate of Designation") relating to our Series A Preferred Stock may delay or prevent a change in control of our company. At any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Series A Certificate of Designation) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which our stockholders immediately before such transaction do not hold at least a majority of our capital stock immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock. This provision of the Series A Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions as it would require the separate consent of a majority of the holders of the Series A Preferred Stock.

Our Certificate of Incorporation and Bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, and our Bylaws designate the federal courts of the United States as the exclusive forum for actions arising under the Securities Act, each of which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Certificate of Incorporation and Bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or our Bylaws or any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction. Any person purchasing or otherwise acquiring any

interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our Certificate of Incorporation and Bylaws.

Our Bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (a "Federal Forum Provision"). Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These choice of forum provisions will not apply to claims brought to enforce a duty or liability created by the Exchange Act. These choice of forum provisions may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the specified courts could face additional litigation costs in pursuing any such claim. The specified courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our governance documents inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

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

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. In addition, shares of our common stock that are subject to our outstanding options and restricted stock units will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act.

Future sales and issuances of equity and debt could result in additional dilution to our stockholders.

We expect that we will need significant additional capital to fund our current and future operations, including to complete ongoing and potential preclinical and clinical trials for our product candidates. 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. As a result, our stockholders may experience additional dilution, which could cause our stock price to fall.

Pursuant to our equity incentive plans, we may grant equity awards and issue additional shares of our common stock to our employees, directors and consultants, and the number of shares of our common stock reserved for future issuance under certain of these plans will be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options or other stock-based equity awards are granted and, if applicable, exercised, or we issue additional shares of common stock in the future, our stockholders may experience additional dilution, which could cause our stock price to fall.

Our principal stockholders own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our directors, officers, 5% stockholders, and their affiliates currently beneficially own a substantial portion of our outstanding voting stock. Therefore, these stockholders have the ability and may continue to have the ability to influence us through this ownership position. These stockholders may be able to determine some or all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of 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 believe are in your best interest as one of our stockholders.

General Risk Factors

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the use of our product candidates in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by participants or patients that use the product candidate or 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 product candidates, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

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

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

We continue to incur significant costs and demands upon management as a result of complying with the laws and regulations regulating public companies.

As a public company, and particularly after December 31, 2024, when we ceased to be a “smaller reporting company” and “non-accelerated filer,” and became a “large accelerated filer,” we have and will continue to incur significant legal, accounting and other expenses associated with public company reporting requirements, including costs associated with corporate governance requirements, such as requirements under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules implemented by the SEC and Nasdaq. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. 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. These rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations may also make it difficult and expensive for us to obtain directors’ and officers’ liability insurance. 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. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers, which may adversely affect investor confidence and

could cause our business or stock price to suffer. In addition, the increased costs may require us to reduce costs in other areas of our business or increase the prices of our product candidates, once commercialized. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are no longer a "smaller reporting company" within the meaning of the Securities Act and as a result we are or will be subject to certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources.

We are no longer a "smaller reporting company," as of January 1, 2025 and, as a result, we are required to comply with various disclosure and compliance requirements that did not previously apply, such as the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, the requirement that we hold a nonbinding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved, the requirement to provide full and more detailed executive compensation disclosure and the reduction in the amount of time for filing our periodic and annual reports. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the stock exchange on which our common shares are listed, or sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected. For example, in the fourth quarter of 2024, we identified a material weakness in our internal control over financial reporting which resulted in restatements of our previously-issued financial statements to amend certain net loss per share disclosures.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In addition to our management's report on the effectiveness of our internal controls over financial reporting, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. 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. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our annual report filing for that year, as required by Section 404 of the Sarbanes-Oxley Act.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, it could result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis, which could require a restatement, cause us to be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, cause investors to lose confidence in our financial information, or cause our stock price to decline.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. As described in our Annual Report for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting in connection with our net earnings (loss) per share disclosures, which resulted in the restatement of our consolidated financial statements as of and for the year ended December 31, 2023, as well as the quarterly condensed consolidated financial information for the interim periods ended March 31, 2024, June 30, 2024, and September 30, 2024. We have implemented measures designed to improve our disclosure controls and procedures and internal control over financial reporting to address the underlying causes of this material weakness, including enhancing the design of controls relevant to the preparation and presentation of financial reporting matters related to net earnings (loss) per share calculations and disclosures to ensure that economic substance beyond the legal form of our capital structure is considered when preparing disclosures related to net earnings (loss) per share.

In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm.

As a public company, we incur significant legal, accounting, insurance, and other expenses, and our management and other personnel have and will need to continue to devote a substantial amount of time to compliance initiatives resulting from operating as a public company. We may experience difficulty in meeting these reporting requirements in a timely manner for each period.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, U.S. elections, international or geopolitical events, such as the ongoing conflicts between the U.S. and Iran and Russia and Ukraine, instability in Venezuela, conflicts between the U.S. and other countries, and conflicts in the Middle East, the implementation of measures that restrict international trade or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, especially in light of recent comments and executive orders made by the Trump administration, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotechnology areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations, public health crises and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers. The United States has previously announced tariffs on imports from most countries, including significant tariffs on imports from Canada, Mexico and China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. In April 2026, the U.S. announced the imposition of tariffs on patented pharmaceutical products, and there can be no guarantee that further retaliatory tariffs will not be forthcoming. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. There is substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed,

modified or suspended. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, geopolitical uncertainties, international conflicts and government actions, including the ongoing military conflicts between the United States and Iran and Russia and Ukraine, instability in Venezuela, conflicts between U.S. and other countries, and ongoing conflicts in the Middle East involving Israel and various other parties, including Iran, Hamas and Hezbollah, as well as other conflicts in the region, rising tensions with China and the implementation of tariffs, sanctions, export or import controls, and other measures that restrict international trade by the United States, China or other governments, 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 or shipping 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. For example, our business may be generally exposed to the impact of political or civil unrest or military action. While we do not have any employees or offices in Ukraine, Venezuela, Russia or countries in the Middle East, including Israel and Jordan, we do have third-party partners and clinical trial sites with locations in Europe, South America and the Middle East, which may be affected by the ongoing conflicts affecting such countries. These third parties or clinical trial sites may be materially impacted by the increasing military conflicts in Europe and the Middle East, which could result in difficulties enrolling and retaining participants and/or delivering drug samples in such areas on schedule and cause delay in our clinical trials and/or increase trial costs. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic or political climate and financial market conditions could adversely impact our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On September 22, 2026, the Company issued 635,131 shares of common stock in connection with the cashless net exercise of 848,184 warrants to purchase common stock by Parapyre Holding LLC. The shares were issued free of any restrictive securities legend pursuant to Rule 144 of the Securities Act. The issuance was made in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act, as an exchange by the Company with an existing security holder where no commission or other remuneration was paid or given, directly or indirectly, for soliciting such exchange.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Trading Plans

During the three months ended September 30, 2026, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (in each case, as defined in Item 408(a) of Regulation S-K).

Amendment to Certificate of Incorporation

The information set forth below is included herewith for the purpose of providing the disclosures required under "Item 5.03 - Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year" of Form 8-K.

On October 29, 2026, the Company filed with the Secretary of State of the State of Delaware (i) a Corrected Second Amended and Restated Certificate of Incorporation (the "Corrected COI") to correct the inadvertent omission from its Second Amended and Restated Certificate of Incorporation of the Series A Certificate of Designation and the Series B Certificate of Designation and (ii) and Certificate of Elimination of Series B Non-Voting Convertible Preferred Stock (the "Series B Preferred Stock") (the "Series B Certificate of Elimination" and, together with the Corrected COI, the "COI Amendment") to effect the retirement of its Series B Preferred Stock, which resulted in the previously authorized shares of the retired Series B Preferred Stock being returned to authorized, unissued and undesignated preferred stock.

The foregoing description of the COI Amendment does not purport to be complete and is subject to and qualified in its entirety by reference to the full text of the Corrected COI and Series B Certificate of Elimination, copies of which are attached hereto as Exhibits 3.1 and 3.3 and incorporated herein by reference.

Amendments to Executive Offer Letters

The information set forth below is included herewith for the purpose of providing the disclosures required under "Item 5.02 - Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers" of Form 8-K.

On November 2, 2026, the Company and each of Dr. Cameron Turtle, Mr. Scott Burrows, Ms. Heidy King-Jones and Dr. Sheldon Sloan amended and restated their respective employment letter agreement (the "Amendments"). The Amendments provide for, among other ministerial changes, (i) an increase to Dr. Turtle's CIC Severance Amount (as defined therein) from 18 months of base salary plus 1.5x his target bonus to 24 months of base salary plus 2.0x his target bonus and an increase to his benefits continuation on a qualifying termination during the Change in Control Period (as defined therein) from 18 months to 24 months, (ii) an increase to each of Mr. Burrows' and Ms. King-Jones' CIC Severance Amount (as defined therein) by 0.5x of their respective target bonuses; and (iii) an increase to Dr. Sloan's Severance Amount (as defined therein) from 9 months to 12 months of base salary, an increase to his benefits continuation on a qualifying termination outside of the Change in Control Period (as defined therein) from 9 months to 12 months, an increase in his CIC Severance Amount (as defined therein) from 12 months of base salary plus 1.0x his target bonus to 18 months of base salary plus 1.5x his target bonus, and an increase to his benefits continuation on a qualifying termination during the Change in Control Period from 12 months to 18 months.

The foregoing description of the Amendments does not purport to be complete and is subject to and qualified in its entirety by reference to the full text of the Amendments, copies of which are attached hereto as Exhibits 10.1, 10.2, 10.3 and 10.4 and incorporated herein by reference.

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	Form	File No	Date of Filing	Exhibit No.	Filed Herewith
2.1	Agreement and Plan of Merger, dated June 22, 2023, by and among Aeglea BioTherapeutics, Inc. Aspen Merger Sub I, Inc., Sequoia Merger Sub II, LLC and Spyre Therapeutics, Inc.	S-1	333-276251	12/22/2023	2.1	
3.1	Corrected Second Amended and Restated Certificate of Incorporation of the Company, effective as of May 14, 2024					X
3.2	Amended and Restated Bylaws	S-1/A	333-276251	02/05/2024	3.2	
3.3	Certificate of Elimination of Series B Non-Voting Convertible Preferred Stock					X
10.1	Amended and Restated Offer Letter by and between the Company and Cameron Turtle, dated November 2, 2026					X
10.2	Amended and Restated Offer Letter by and between the Company and Scott Burrows, dated November 2, 2026					X
10.3	Amended and Restated Offer Letter by and between the Company and Heidy King-Jones, dated November 2, 2026					X
10.4	Amended and Restated Offer Letter by and between the Company and Sheldon Sloan, dated November 2, 2026					X
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934					X
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934					X
32.1(1)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X

Exhibit Number	Description	Form	File No	Date of Filing	Exhibit No.	Filed Herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	The cover page from this Quarterly Report formatted in Inline XBRL and contained in Exhibit 101					

(1) The certifications on Exhibit 32 hereto are deemed furnished and not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 3, 2026

Spyre Therapeutics, Inc.

By: /s/ Scott Burrows

Scott Burrows

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)