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 June 30, 2023

OR

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

For the transition period from to
Commission File Number: 001-37722

AEGLEA BIOTHERAPEUTICS, 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 17, Suite 102B
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:

805 Las Cimas Parkway
Suite 100
Austin, TX 78746

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	AGLE	The Nasdaq Stock Market LLC (Nasdaq Capital 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, 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 August 4, 2023, the registrant had 101,192,921 shares of common stock, $0.0001 par value per share, outstanding.

AEGLEA BIOTHERAPEUTICS, INC.

QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2023

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 statements regarding stockholder approval of the conversion rights of the Series A Preferred Stock (as defined herein), any future payouts under the CVR (as defined herein), our ability to achieve the expected benefits or opportunities and related timing with respect to our asset acquisition of Spyre Therapeutics, Inc. (“Spyre”) or to monetize any of our legacy assets, our future results of operations and financial position, business strategy, the length of time that we believe our existing cash resources will fund our operations, our market size, our potential growth opportunities, our preclinical and future clinical development activities, the efficacy and safety profile of our product candidates, the potential therapeutic benefits and economic value of our product candidates, the timing and results of preclinical studies and clinical trials, the expected impact of macroeconomic conditions, including inflation, increasing interest rates and volatile market conditions, current or potential bank failures, as well as global events, including the ongoing military conflict in Ukraine and geopolitical tensions in China on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, 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 those described in Item 1A, “Risk Factors” and elsewhere 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 “Aeglea,” “the Company,” “we,” “us,” and “our” refer to Aeglea BioTherapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries taken as a whole. “Aeglea” 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 exercised the Option (as defined herein in Note 7) to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Paragon Agreement (as defined herein in Note 1).

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

(In thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 235,358	$ 34,863
Marketable securities	—	20,848
Development receivables	1,646	375
Prepaid expenses and other current assets	2,882	6,172
Total current assets	239,886	62,258
Restricted cash	1,317	1,553
Property and equipment, net	—	3,220
Operating lease right-of-use assets	2,316	3,430
Other non-current assets	10	683
TOTAL ASSETS	$ 243,529	$ 71,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,854	$ 677
Forward contract liability	164,382	—
CVR liability	10,500	—
Operating lease liabilities	4,331	625
Deferred revenue	930	517
Accrued and other current liabilities	28,427	12,837
Related party accounts payable	20,810	—
Total current liabilities	232,234	14,656
Non-current CVR liability	19,000	—
Non-current operating lease liabilities	—	4,004
Deferred revenue, net of current portion	2,341	2,179
TOTAL LIABILITIES	253,575	20,839
Commitments and Contingencies (Note 11)		
Series A non-voting convertible preferred stock, $0.0001 par value; 1,086,341 and no shares authorized as of June 30, 2023 and December 31, 2022, respectively; 721,452 and no shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	197,323	—
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, $0.0001 par value; 8,913,659 shares and 10,000,000 authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 81,001,676 shares and 65,350,343 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	6	6
Additional paid-in capital	453,741	475,971
Accumulated other comprehensive income (loss)	11	(48)
Accumulated deficit	(661,127)	(425,624)
TOTAL STOCKHOLDERS' (DEFICIT) EQUITY	(207,369)	50,305
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 243,529	$ 71,144

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

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Development fee and royalty	$ 688	$ 625	$ 886	$ 1,987
Total revenue	688	625	886	1,987
Operating expenses:				
Research and development [1]	17,386	15,373	31,162	32,351
General and administrative	12,062	7,675	17,290	16,500
Acquired in-process research and development	130,486	—	130,486	—
Total operating expenses	159,934	23,048	178,938	48,851
Loss from operations	(159,246)	(22,423)	(178,052)	(46,864)
Other income (expense):				
Interest income	350	104	770	139
Change in fair value of forward contract liability	(58,170)	—	(58,170)	—
Other income (expense), net	(8)	5	(80)	1
Total other (expense) income	(57,828)	109	(57,480)	140
Loss before income tax expense	(217,074)	(22,314)	(235,532)	(46,724)
Income tax (expense) benefit	(7)	(9)	29	(35)
Net loss	$ (217,081)	$ (22,323)	$ (235,503)	$ (46,759)
Net loss per share, basic and diluted	$ (2.27)	$ (0.27)	$ (2.48)	$ (0.63)
Weighted-average common shares outstanding, basic and diluted	95,565,118	82,209,032	94,917,487	73,650,146

[1] Includes $1.4 million and no related party expense, for the three and six months ended June 30, 2023 and 2022, respectively.

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

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (217,081)	$ (22,323)	$ (235,503)	$ (46,759)
Other comprehensive income (loss):				
Foreign currency translation adjustment	18	(36)	28	(49)
Unrealized (loss) gain on marketable securities	(1)	(31)	31	(151)
Total comprehensive loss	$ (217,064)	$ (22,390)	$ (235,444)	$ (46,959)

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

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' (Deficit) Equity
(Unaudited)

(In thousands)

	Six Months Ended June 30, 2023							
	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances - December 31, 2022	—	$ -	65,350	$ 6	$ 475,971	$ (48)	$ (425,624)	$ 50,305
Issuance of common stock in connection with employee stock purchase plan	—	—	45	—	18	—	—	18
Stock-based compensation expense	—	—	—	—	1,709	—	—	1,709
Foreign currency translation adjustment	—	—	—	—	—	10	—	10
Unrealized gain on marketable securities	—	—	—	—	—	32	—	32
Net loss	—	—	—	—	—	—	(18,422)	(18,422)
Balances - March 31, 2023	—	$ -	65,395	$ 6	$ 477,698	$ (6)	$ (444,046)	$ 33,652
Issuance of Series A non-voting convertible preferred stock in connection with private placement, net of financing costs	721	197,323	—	—	—	—	—	—
Issuance of common stock forward in connection with the asset acquisition of Spyre	—	—	—	—	3,768	—	—	3,768
Issuance of common stock in connection with exercise of pre-funded warrants	—	—	15,607	—	—	—	—	—
CVR distribution to common stockholders	—	—	—	—	(29,500)	—	—	(29,500)
Stock-based compensation expense	—	—	—	—	1,775	—	—	1,775
Foreign currency translation adjustment	—	—	—	—	—	18	—	18
Unrealized loss on marketable securities	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(217,081)	(217,081)
Balances - June 30, 2023	721	$ 197,323	81,002	$ 6	$ 453,741	$ 11	$ (661,127)	$ (207,369)

	Six Months Ended June 30, 2022							
	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balances - December 31, 2021	—	$ -	49,355	$ 5	$ 425,765	$ (20)	$ (341,809)	$ 83,941
Issuance of common stock in connection with employee stock purchase plan	—	—	65	—	184	—	—	184
Stock-based compensation expense	—	—	—	—	2,101	—	—	2,101
Foreign currency translation adjustment	—	—	—	—	—	(13)	—	(13)
Unrealized loss on marketable securities	—	—	—	—	—	(120)	—	(120)
Net loss	—	—	—	—	—	—	(24,436)	(24,436)
Balances - March 31, 2022	—	$ -	49,420	$ 5	$ 428,050	$ (153)	$ (366,245)	$ 61,657
Issuance of common stock and pre-funded warrants in connection with registered direct offering, net of offering costs	—	—	10,753	1	42,872	—	—	42,873
Issuance of common stock in connection with exercise of pre-funded warrants	—	—	1,000	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,017	—	—	2,017
Foreign currency translation adjustment	—	—	—	—	—	(36)	—	(36)
Unrealized loss on marketable securities	—	—	—	—	—	(31)	—	(31)
Net loss	—	—	—	—	—	—	(22,323)	(22,323)
Balances - June 30, 2022	—	$ -	61,173	$ 6	$ 472,939	$ (220)	$ (388,568)	$ 84,157

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

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (235,503)	$ (46,759)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	744	781
Stock-based compensation	3,620	4,118
Acquired in-process research and development	130,486	—
Change in fair value of forward contract liability	58,170	—
Lease ROU asset and leasehold improvement impairment loss	2,580	—
Loss on disposal of long-lived assets	915	—
Amortization of operating lease assets	220	191
Purchase net premium on marketable securities	—	239
Net amortization of premium (accretion of discount) on marketable securities	(123)	(23)
Other	6	(7)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	3,368	(2,419)
Accounts payable	2,045	(1,352)
Deferred revenue	575	(914)
Development receivables	(1,271)	336
Operating lease liabilities	(298)	(250)
Accrued and other liabilities	189	(877)
Net cash used in operating activities	(34,277)	(46,936)
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash assumed from asset acquisition of Spyre	3,035	—
Purchases of property and equipment	—	(37)
Proceeds from sale of property and equipment	475	—
Purchases of marketable securities	—	(27,750)
Proceeds from maturities and sales of marketable securities	21,000	54,296
Net cash provided by investing activities	24,510	26,509
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of Series A non-voting convertible preferred stock, gross in connection with private placement	210,000	—
Proceeds from issuance of common stock and pre-funded warrants in registered direct offering, net of offering costs	—	42,979
Proceeds from employee stock plan purchases and stock option exercises	18	184
Principal payments on finance lease obligation	(16)	(347)
Net cash provided by financing activities	210,002	42,816
Effect of exchange rate on cash, cash equivalents, and restricted cash	24	(95)
NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	200,259	22,294
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH		
Beginning of period	36,416	16,980
End of period	$ 236,675	$ 39,274
Supplemental Disclosure of Non-Cash Investing and Financing Information:		
Unpaid direct transaction costs related to the asset acquisition of Spyre	$ 2,067	$ —
Unpaid amounts related to issuance of Series A non-voting convertible preferred stock in connection with private placement	$ 12,677	$ —

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

1. The Company and Basis of Presentation

Aeglea BioTherapeutics, Inc. (“Aeglea” or the “Company”) is a preclinical stage biotechnology company focused on developing next generation therapeutics for patients living with inflammatory bowel disease. The Company was formed as a Limited Liability Company ("LLC") 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. The Company operates in one segment and has its principal offices in Waltham, Massachusetts.

On April 12, 2023, based on the review of the inconclusive interim results from our Phase 1/2 clinical trial of pegtarviliase for the treatment of Classical Homocystinuria and other business considerations, the Company announced that it had initiated a process to explore strategic alternatives to maximize stockholder value and engaged an independent exclusive financial advisor to support this process. As a result, in April 2023, the Company implemented a restructuring plan resulting in an approximate 83% reduction of the Company’s existing headcount.

On June 22, 2023, the Company acquired, in accordance with the terms of the Agreement and Plan of Merger (the "Acquisition Agreement"), the assets of Spyre Therapeutics, Inc ("Spyre"), as disclosed in Note 7 and 8, a privately held biotechnology company advancing a pipeline of antibody therapeutics with the potential to transform the treatment of inflammatory bowel disease through a research and development option agreement ("Paragon Agreement") with Paragon Therapeutics ("Paragon"). The transaction was structured as a stock-for-stock transaction pursuant to which all of Spyre's outstanding equity interests were exchanged based on a fixed exchange ratio of 13.73622 to 1 for consideration from Aeglea of 12,945,385 shares of common stock and 364,887 shares of Series A non-voting convertible preferred stock, par value of $0.0001 per share ("Series A Preferred Stock") (convertible on a 1,000 to 1 basis) in addition to the assumption of outstanding and unexercised stock options to purchase 68,365 shares of common stock from the Amended and Restated Spyre 2023 Equity Incentive Plan (the "Asset Acquisition"). The Aeglea common stock and Aeglea Series A Preferred Stock related to the Asset Acquisition were issued to the Spyre stockholders on July 7, 2023. For additional information, see Note 7 and 8.

In connection with the Asset Acquisition, on June 26, 2023, the Company completed a private placement of shares of Series A Preferred Stock (the “PIPE”) to a group of investors (the “Investors”). The Company sold an aggregate of 721,452 shares of Series A Preferred Stock (the “PIPE Securities”) for an aggregate purchase price of approximately $210.0 million before deducting approximately $12.7 million placement agent and other offering expenses. For additional information, see Note 8.

In connection with the Asset Acquisition, a non-transferable contingent value right ("CVR") was distributed to Aeglea stockholders of record as of the close of business on July 3, 2023 (the "Legacy Stockholders"), but was not distributed to the holders of shares of common stock or Series A Preferred Stock issued to the former stockholders of Spyre or Investors in the Transactions. Holders of the CVRs will be entitled to receive cash payments from proceeds received by Aeglea for a three-year period, if any, related to the disposition or monetization of its legacy assets for a period of one-year following the closing of the Asset Acquisition. For additional information see Note 3.

Liquidity

As of June 30, 2023, the Company had accumulated deficit of $661.1 million, and cash and cash equivalents of $235.4 million, which includes proceeds from the PIPE. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of the Company’s product candidates will require significant additional financing before a commercial drug can be produced and marketed.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery, development, and commercialization of product candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company’s product candidates. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company’s future success.

In April 2023, the Board of Directors approved a restructuring of the Company’s workforce pursuant to which the Company’s workforce was reduced by approximately 83%, retaining approximately 10 employees. Additionally, the Company announced interim results from its ongoing Phase 1/2 clinical trial of pegtarviliase for the treatment of classical homocystinuria. Following a review of the interim results and other business considerations, the Company explored strategic

alternatives with the goal of maximizing stockholder value, including possible business combinations and/or a divestiture of the Company's clinical programs.

On June 22, 2023, the Company acquired, in accordance with the terms of the Acquisition Agreement, the net assets of Spyre, as disclosed in Note 7 and 8. Additionally, the Company completed the PIPE.

In accordance with ASC 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. If our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock, as described in our Certificate of Designation relating to the Series A Preferred Stock (see Note 9). The cash redemption is not in our control and raises substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements assume the Company will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this document 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 June 30, 2023, and its results of operations for the three and six months ended June 30, 2023 and 2022, changes in convertible preferred stock and stockholders' (deficit) equity for the three and six months ended June 30, 2023 and 2022, and cash flows for the six months ended June 30, 2023 and 2022. The results of operations for the three and six months ended June 30, 2023, are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The December 31, 2022 balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States ("U.S. GAAP"). 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, 2022 (the "Annual Report") as filed with the Securities and Exchange Commission ("SEC").

2. Summary of Significant Accounting Policies

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 Company's Annual Report. Significant accounting policies and other disclosures normally provided have been omitted since such items are disclosed in the Company's Annual Report. The Company uses the same accounting policies in preparing quarterly and annual financial statements.

Convertible Preferred Stock Issued through PIPE

The Company records shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company has applied the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities, and has therefore classified the Series A Preferred Stock outside of stockholders' (deficit) equity because, if conversion to common stock is not approved by the stockholders, the Series A Preferred Stock will be redeemable at the option of the holders for cash equal to the closing price of the common stock on the last trading day prior to the holder's redemption request. The Company determined that the conversion and redemption are outside of the Company's control. Additionally, the Company determined the conversion and redemption features did not require bifurcation as derivatives.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet

the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. When a transaction accounted for as an asset acquisition includes an in-process research and development ("IPR&D") asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. Otherwise, the cost allocated to acquire an IPR&D with no alternative future use is charged to expense at the acquisition date.

Contingent Value Rights

The Company evaluates its contracts to determine if those contracts qualify as derivatives under ASC 815, Derivatives and Hedging . For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date. Any changes in fair value are recorded as other income or expense for each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is probable within the next 12 months from the balance sheet date. The Company determined that certain contingent payments under the CVR Agreement qualified as derivatives under ASC 815, and as such, were recorded as a liability on the balance sheet as of June 30, 2023.

The Company applies a scenario-based method and weights them based on the possible achievement of certain milestones. The milestone payments are contingent on formal reimbursement decisions by national authorities in key European markets and pegzilarginase approval by the FDA, among other events. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820, Fair Value Measurement . The key assumptions used include the discount rate, probability of regulatory success, and reimbursement rates from certain government agencies. 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. This value is then remeasured for future expected payout as well as the increase in fair value due to the time value of money. These gains or losses, if any, are recognized in the consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities, and equity and the amount of revenues and expenses. Actual results could differ significantly from those estimates. The most significant estimates and assumptions that management considers in the preparation of the Company's financial statements relate to accrued research and development costs; the valuation of consideration transferred in acquiring IPR&D; the discount rate, probabilities of success, and timing of estimated cash flows in the valuation of the CVR liability; inputs used in the Black-Scholes model for stock-based compensation expense; estimated future cash flows used in calculating the impairment of right-of-use lease assets; and estimated cost to complete performance obligations related to revenue recognition.

Recently Adopted Accounting Pronouncement

We early adopted the Financial Accounting Standards Board's Accounting Standards Update 2020-06, "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), effective as of January 1, 2023 using the modified retrospective method. Among other amendments, ASU 2020-06 eliminates the cash conversion and beneficial conversion feature models in ASC 470-20 that require an issuer of certain convertible debt and preferred stock to separately account for embedded conversion features as a component of equity, as well as changed the accounting for diluted earnings-per-share for convertible instruments and contracts that may be settled in cash or stock. Additionally, ASU 2020-06 requires that the if-converted method, which is more dilutive than the treasury stock method, be used for all convertible

instruments. We applied ASU 2020-06 to all Series A Preferred Stock during 2023, accordingly the Company did not apply the cash conversion or beneficial conversion feature models in its analysis of the Series A Preferred Stock.

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):

	June 30, 2023			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 18,861	$ —	$ —	$ 18,861
Total financial assets	$ 18,861	$ —	$ —	$ 18,861
Liabilities:				
Forward contract liability	$ —	$ 164,382	$ —	$ 164,382
Parapyre Option Obligation	—	279	—	279
CVR liability	—	—	29,500	29,500
Total liabilities	$ —	$ 164,661	$ 29,500	$ 194,161

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial Assets:				
Money market funds	$ 15,250	$ —	$ —	$ 15,250
Commercial paper	—	23,641	—	23,641
U.S. government securities	—	4,230	—	4,230
Corporate bonds	—	3,732	—	3,732
Total financial assets	$ 15,250	$ 31,603	$ —	$ 46,853

The Company measures the fair value of money market funds on quoted prices in active markets for identical assets or liabilities. The Level 2 assets include commercial paper, U.S. government securities 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.

The forward contract liability and the Parapyre Option Obligation are considered Level 2 liabilities based on observable market data for substantially the full term of the liabilities. The forward contract liability was initially measured at its estimated fair value on the transaction date based on the underlying price per share on an as-converted basis of the Series A Preferred Stock issued in the PIPE. Subsequent remeasurement of the fair value of the forward contract liability as of June 30, 2023, was based on the market price of the Company's common stock, which represents the redemption value of the Series A Preferred Stock, with the change in value recorded as Change in fair value of forward contract liability within Other Income (Expense). The Parapyre Option Obligation is measured each period using a Black-Scholes model to estimate the fair value of the option grant. Changes in the pro-rated fair value of the Parapyre Option Obligation are recorded as stock-based compensation within Research and development expenses for non-employees who provided pre-clinical testing services within Research and development expenses.

The CVR liability value is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success, and risk-adjusted discount rates, which represent a Level 3 liability. As of December 31, 2022, the Company had no financial liabilities outstanding measured at fair value.

Forward Contract Liability

In connection with the Asset Acquisition, the Company entered into a contract for the issuance of 364,887 shares of Series A Preferred Stock as part of the consideration transferred. This forward contract was classified as a liability because the underlying preferred shares were contingently redeemable. The forward contract was carried at fair value on the balance sheet, with changes in fair value between the acquisition date and June 30, 2023 recorded in earnings. The liability was settled with the issuance of the Series A Preferred Stock on July 7, 2023 (see Note 7).

The fair value of the forward contract as of the acquisition date, June 22, 2023, was $106.2 million. The fair value of the forward contract on June 30, 2023 was $164.4 million. The $58.2 million change in fair value of the forward contract liability between the acquisition date and June 30, 2023, was recorded as Other Income (Expense) in the consolidated statements of operations for the three and six months ended June 30, 2023.

Parapyre Option Obligation

On June 22, 2023, in connection with the Asset Acquisition, the Company assumed the Parapyre Option Obligation which provided for an annual equity grant of options for Parapyre to purchase 1% of the then outstanding shares of Spyre's common stock, on a fully diluted basis, on the last business day of each calendar year during the term of the Paragon Agreement, at the fair market value determined by the board of directors of Spyre. As a result of the Asset Acquisition the Parapyre Option Obligation shall continue and Parapyre shall be entitled to receive the equivalent shares of the Company with the same terms. As of June 30, 2023, the pro-rated estimated fair value of the options to be granted on December 31, 2023, was approximately $0.3 million, of which $0.1 million was recognized as part of the liabilities assumed with the Asset Acquisition on June 22, 2023. For the three and six months ended June 30, 2023, $0.2 million was recognized as stock compensation expense related to the Parapyre Option Obligation.

CVR Liability

In connection with the Asset Acquisition, a non-transferable contingent value right (a “CVR”) was distributed to Aeglea stockholders of record as of the close of business on July 3, 2023, but was not distributed to holders of shares of Common Stock or Series A Preferred Stock issued to the Investors or former stockholders of Spyre in connection with the Transactions. Holders of the CVR will be entitled to receive certain cash payments from proceeds received by us, if any, related to the disposition or monetization of Aeglea’s legacy assets for a period of one year following the closing of the Asset Acquisition.

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 will be recognized as a component of Other income (expense) in the condensed consolidated statement of operations and comprehensive loss in each reporting period. The liability value is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success, and risk-adjusted discount rates, which represent a Level 3 measurement within the fair value hierarchy. The significant inputs used to estimate the fair value of the CVR liability were as follows:

	June 30, 2023
Estimated cash flow dates	11/28/23 - 06/22/26
Estimated probability of success	27% - 100%
Risk-adjusted discount rates	7.37% - 7.94%

The change in fair value between June 22, 2023 and June 30, 2023 was immaterial as none of the significant inputs changed during that time as there were no regulatory updates that would have impacted the probability weights or timing of expected cash flows.

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

	June 30, 2023
Beginning balance as of December 31, 2022	$ —
Fair value at CVR issuance	29,500
Ending Balance as of June 30, 2023	$ 29,500

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):

	June 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 18,861	$ —	$ —	$ 18,861
Total cash equivalents	$ 18,861	$ —	$ —	$ 18,861

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 15,250	$ —	$ —	$ 15,250
Commercial paper	7,021	1	(2)	7,020
U.S. government securities	3,736	—	(1)	3,735
Total cash equivalents	$ 26,007	$ 1	$ (3)	$ 26,005
Marketable securities:				
Commercial paper	$ 16,644	$ 2	$ (25)	$ 16,621
Corporate bonds	3,738	—	(6)	3,732
U.S. government securities	495	—	—	495
Total marketable securities	$ 20,877	$ 2	$ (31)	$ 20,848

As of June 30, 2023, the Company did not hold any available-for-sale securities. 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 December 31, 2022, aggregated by major security type and length of time in a continuous unrealized loss position:

	December 31, 2022					
	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 17,699	$ (27)	$ —	$ —	$ 17,699	$ (27)
U.S. government securities	3,735	(1)	—	—	3,735	$ (1)
Corporate bonds	3,732	(6)	—	—	3,732	(6)
Total marketable securities	$ 25,166	$ (34)	$ —	$ —	$ 25,166	$ (34)

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 June 30, 2023 and December 31, 2022, 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 June 30, 2023 and December 31, 2022.

The financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash deposits. Accounts at each of our three U.S. banking institutions are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 per depositor. At June 30, 2023 and December 31, 2022, the Company had $215.6 million and $23.5 million, respectively, of U.S. cash deposits in excess of the FDIC insured limit. Uninsured foreign cash deposits were immaterial for both periods.

There were no realized gains or losses on marketable securities for the three and six months ended June 30, 2023 and 2022. Interest on marketable securities is included in interest income. Accrued interest receivable on available-for-sale

debt securities was $0.1 million at each of June 30, 2023 and December 31, 2022, and is excluded from the estimate of credit losses.

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

	June 30, 2023	December 31, 2022
Due in one year or less	$ —	$ 20,848
Due thereafter	—	—
Total marketable securities	$ —	$ 20,848

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):

	June 30, 2023	December 31, 2022
Accrued financing fees for the PIPE	$ 12,677	$ —
Accrued compensation	7,240	4,589
Accrued contracted research and development costs	4,450	6,972
Accrued professional and consulting fees	3,674	946
Accrued other	386	330
Total accrued and other current liabilities	$ 28,427	$ 12,837

6. Related Party Transactions

Paragon and Parapyre, a related party of Paragon, together beneficially own more than 5% of our capital stock through their holdings of our common stock and Series A Preferred Stock. Fairmount Funds Management LLC ("Fairmount") beneficially owns more than 5% of our capital stock, has two seats on our Board and beneficially owns more than 5% of Paragon, which is a joint venture between Fairmount and Fair Journey Biologics. Fairmount has appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers. Parapyre is an entity formed by Paragon as a vehicle to hold equity in Spyre.

In connection with the Asset Acquisition, we assumed the rights and obligations of Spyre under the Paragon Agreement. Under the Paragon Agreement, we are obligated to compensate Paragon on a quarterly basis for its services performed under each research program based on the actual costs incurred. As of the date of the Asset Acquisition, Spyre had incurred total expenses of $19.3 million under the Paragon Agreement since inception, inclusive of a $3.0 million research initiation fee that was due upon signing of the Paragon Agreement and $16.3 million of reimbursable expenses under the Paragon Agreement for historical costs incurred by Paragon. As of the acquisition date, $19.3 million was unpaid and was assumed by us through the Asset Acquisition.

In July 2023, we exercised our option for the SPY001 program with the remaining three options for the SPY002, SPY003, SPY004 programs remaining outstanding. Following the execution of the SPY001 License Agreement, we are obligated to pay Paragon up to $22.0 million upon the achievement of specific development and clinical milestones for the first product under the SPY001 License Agreement that achieves such specified milestones.

The following is the summary of expenses related to Paragon and ultimately settled in cash (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,		
	2023	2022	2023	2022	Financial Statement Line Item
Reimbursable costs under the Paragon Agreement	$ 1.2	$ —	$ 1.2	$ —	Research and development

For the three and six months ended June 30, 2022 and 2023, no cash payments were made to Paragon.

Parapyre Option Obligation

The Paragon Agreement provided for an annual equity grant of options to purchase 1% of the then outstanding shares of Spyre's common stock, on a fully diluted basis, on the last business day of each calendar year, at the fair market value determined by the board of directors of Spyre (the "Parapyre Option Obligation"). In connection with the Asset Acquisition, we assumed the rights and obligations of Spyre under the Paragon Agreement, including the Parapyre Option Obligation. As a result, the Parapyre Option Obligation shall continue and Parapyre shall be entitled to receive the equivalent shares of the Company with the same terms. See Note 10 for disclosures related to the Parapyre Option Obligation. For the three and six months ended June 30, 2023, $0.2 million was recognized as stock compensation expense related to the Parapyre Option Obligation.

The following is the summary of Related party accounts payable (in millions):

	June 30, 2023	December 31, 2022
Reimbursable costs under the Paragon Agreement	$ 20.5	$ —
Parapyre Option Obligation liability	0.3	—
Total related party accounts payable	$ 20.8	$ —

7. Asset Acquisition

On June 22, 2023, we acquired Spyre pursuant to the Acquisition Agreement, by and among the Company, Aspen Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("First Merger Sub"), Sequoia Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Second Merger Sub"), and Spyre. Pursuant to the Acquisition Agreement, First Merger Sub merged with and into Spyre, pursuant to which Spyre was the surviving corporation and became a wholly owned subsidiary of the Company (the "First Merger"). Immediately following the First Merger, Spyre merged with and into Second Merger Sub, pursuant to which Second Merger Sub became the surviving entity. Spyre was a pre-clinical stage biotechnology company that was incorporated on April 28, 2023 under the direction of Peter Harwin, a Managing Member of Fairmount, for the purpose of holding rights to certain intellectual property being developed by Paragon. Fairmount is a founder of Paragon.

The Company completed the Asset Acquisition of Spyre, in accordance with the terms of the Acquisition Agreement. Under the terms of the Acquisition Agreement, the Company issued 12,945,385 shares of common stock and 364,887 shares of Series A Preferred Stock to former Spyre security holders. In addition, outstanding and unexercised stock options to purchase 68,365 shares of common stock were assumed from the Amended and Restated Spyre 2023 Equity Incentive Plan.

The issuance of these shares of common stock and Series A Preferred Stock occurred on July 7, 2023. Accordingly, as of June 30, 2023, the Company recorded forward contracts to represent the obligation to issue shares of common stock and shares of Series A Preferred Stock, respectively. The forward contract related to the common stock was recorded as Additional paid-in capital as the instrument is indexed to the Company's common stock. The forward contract related to the Series A Preferred Stock was recorded as a liability, as the underlying stock has a cash redemption feature.

The Company concluded that the arrangement meets the definition of an asset acquisition rather than a business combination, as substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset, Spyre's option (the "Option") to exclusively license IPR&D. We determined that the Option to license IPR&D was a single asset as the Company's strategy relies on developing the entire portfolio of individual treatments to create combination treatments that simultaneously address different mechanisms of irritable bowel disease with a single treatment. The Company also determined that the pipeline candidates within the portfolio are similar in nature and risk profile. In addition, the Company did not obtain any substantive processes, assembled workforce, or employees capable of producing outputs in connection with the Asset Acquisition.

The Company determined that the cost to acquire the asset was $113.3 million which was recorded as acquired IPR&D. The fair value of the consideration issued consisted of the 364,887 shares of Series A Preferred Stock (364,887,000 shares of common stock on an as-converted basis) and 12,945,385 shares of common stock, valued at $291.08 per share and $0.29108 per share, respectively.

The Asset Acquisition cost are shown on the following table (in millions):

	June 22, 2023
Consideration transferred in Series A Preferred Stock and common stock	$ 110.0
Transaction costs incurred by Aeglea	3.2
Fair value of Parapyre Option Obligation assumed by Aeglea	0.1
Total cost to acquire asset	$ 113.3

The allocation of the purchase price to net assets acquired is as a follows:

	June 22, 2023
Acquired in-process research and development	$ 130.5
Cash acquired	3.0
Assumed liabilities	(20.2)
Total cost to acquire asset	$ 113.3

8. Paragon Agreement

In May 2023, Spyre entered into the Paragon Agreement with Paragon and Parapyre. In consideration for the Option granted under the Paragon Agreement, Spyre was obligated to pay Paragon an upfront cash amount of $3.0 million in research initiation fees. In addition, Spyre was obligated to pay incurred reimbursable research costs of $16.3 million to Paragon as of the closing of the Asset Acquisition. Furthermore, the Paragon Agreement provided for an annual equity grant of options to purchase 1% of the then outstanding shares of Spyre's common stock, on a fully diluted basis, on the last business day of each calendar year, during the term of the Paragon Agreement, at the fair market value determined by the board of directors of Spyre. As a result of the Asset Acquisition, we assumed the rights and obligations of Spyre under the Paragon Agreement, including the Parapyre Option Obligation. Pursuant to the Paragon Agreement, on a research program-by-research program basis following the finalization of the research plan for each respective research program, we are required to pay Paragon a nonrefundable fee in cash of $0.8 million. We are also obligated to compensate Paragon on a quarterly basis for its services performed under each research program based on the actual costs incurred. For the period from June 22, 2023 (Asset Acquisition date) to June 30, 2023, we incurred $1.2 million of costs reimbursable to Paragon under the Paragon Agreement. For the three and six months ended June 30, 2023 and 2022, we did not make any payments to Paragon.

On July 12, 2023, we exercised our Option available under the Paragon Agreement with respect to the SPY001 research program and will enter into a SPY001 license agreement (the "SPY001 License Agreement"). Our Option available under the Paragon Agreement with respect to the SPY002, SPY003 and SPY004 programs remains unexercised.

Following the execution of the SPY001 License Agreement, we are also obligated to pay Paragon up to $22.0 million upon the achievement of specific development and clinical milestones for the first product under the SPY001 License Agreement that achieves such specified milestones. Upon execution of the SPY001 License Agreement, we will pay Paragon a $1.5 million fee for nomination of a development candidate, and we are obligated to make a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial. Subject to the execution of the Option with respect to the SPY002, SPY003 or SPY004 research programs, we expect to be obligated to make similar payments upon and following the execution of license agreements with respect to the these research programs, respectively.

Prior to the Asset Acquisition, Spyre had incurred total expenses of $19.3 million under the Paragon Agreement, inclusive of a $3.0 million research initiation fee that was due upon signing of the Paragon Agreement and $16.3 million of reimbursable expenses under the Paragon Agreement for historical costs incurred by Paragon. As of the acquisition date, $19.3 million was unpaid and was assumed by us through the Asset Acquisition.

9. Series A Non-Voting Convertible Preferred Stock

On June 22, 2023, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock with the Secretary of State of the State of Delaware (the "Certificate of Designation") in connection with the Asset Acquisition and the PIPE. The Certificate of Designation authorizes the issuance of 1,086,341 shares of Series A Preferred Stock, par value $0.0001 per share.

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 our Common Stock. Except as provided in the 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, we 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 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 (the "Conversion Proposal") 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 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 our stockholders immediately before such transaction do not hold at least a majority of our 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.

The Company has agreed to hold a stockholders' meeting to submit the following matters to its stockholders for their consideration: (i) the approval of the Conversion Proposal, and (ii) if deemed necessary or appropriate by the Company or as otherwise required by law or contract, the approval of an amendment to the Certificate of Incorporation to authorize sufficient shares of common stock for the conversion of the Series A Preferred Stock issued pursuant to the Acquisition Agreement and/or to effectuate a reverse stock split of all outstanding shares of common stock at a reverse stock split ratio to be reasonably determined by the Company for the purpose of maintaining compliance with Nasdaq listing standards. In connection with these matters, the Company filed with the SEC a preliminary proxy statement and other relevant materials. The stockholder meeting and reverse stock split have not occurred as of June 30, 2023. The Series A Preferred Stock is recorded outside of stockholders' (deficit) equity because, if conversion to common stock is not approved by the stockholders, the Series A Preferred Stock will be redeemable at the option of the holders for cash equal to the closing price of the common stock per share of common stock underlying the Series A Preferred Stock, on the last trading day prior to the holder's redemption request. As of June 30, 2023, the redemption value of the Company's outstanding Series A Preferred Stock was $325.0 million based on the closing stock price of the Company's common stock on June 30, 2023 of $0.4505 per share. The Company determined that the conversion and redemption features of the Series A Preferred Stock do not require bifurcation as derivatives.

Following stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock will automatically convert into 1,000 shares of common stock, subject to certain limitations, including that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (established by the holder between 0% and 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

On June 26, 2023, the Company completed a private placement of 721,452 shares of Series A Preferred Stock in exchange for gross proceeds of $210.0 million, or net proceeds of $197.3 million, after deducting placement agent and other offering costs.

On July 7, 2023, the Company issued 364,887 shares of Series A Preferred Stock as part of its consideration transferred in connection with the Asset Acquisition that closed on June 22, 2023.

On August 8, 2023, the Company filed a preliminary proxy statement with the SEC to solicit approval of the Conversion Proposal, among other matters, at a special meeting of stockholders.

10. Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity

Registered Direct Offering

In May 2022, the Company issued and sold 10,752,688 shares of common stock at an offering price of $1.60 per share and pre-funded warrants to purchase up to 17,372,312 shares of common stock at an offering price of $1.5999 per warrant (representing the price per share of common stock sold in the offering minus the $0.0001 exercise price per warrant) in a registered direct offering pursuant to a shelf registration statement on Form S-3. The net proceeds to the Company from this offering were approximately $42.9 million, after deducting placement agent fees and offering costs of $2.1 million.

Pre-Funded Warrants

In February 2019, April 2020 and May 2022, the Company issued pre-funded warrants to purchase the Company's common stock in underwritten public offerings at the offering price of the common stock, less the $0.0001 per share exercise price of each warrant. The warrants were recorded as a component of stockholders' (deficit) equity within additional paid-in capital and have no expiration date. Per the terms of the warrant agreements, the outstanding warrants to purchase shares of common stock may not be exercised if the holder's ownership of the Company's common stock would exceed 4.99% ("Maximum Ownership Percentage"), or 9.99% for certain holders. By written notice to the Company, each holder may increase or decrease the Maximum Ownership Percentage to any other percentage (not in excess of 19.99% for the majority of such warrants). The revised Maximum Ownership Percentage would be effective 61 days after the notice is received by the Company.

As of June 30, 2023, the following pre-funded warrants for common stock were issued and outstanding:

Issue Date	Expiration Date	Exercise Price	Number of Warrants Outstanding
February 8, 2019	None	$ 0.0001	—
April 30, 2020	None	$ 0.0001	—
May 20, 2022	None	$ 0.0001	13,281,250
Total pre-funded warrants			13,281,250

As of August 4, 2023, an additional 7,031,250 pre-funded warrants have been exercised.

Stock-Based Compensation

2016 Equity Incentive Plan

The 2016 Equity Incentive Plan ("2016 Plan") 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 (through 2028) equal to (a) 4.0% of the number of issued and outstanding shares of common stock on December 31 of the immediately preceding year, or (b) a lesser amount as approved by the Company's board of directors each year. As a result of this provision, on January 1, 2023 and January 1, 2022, an additional 2,614,013 and 1,974,205 shares, respectively, became available for issuance under the 2016 Plan.

In July 2020, the Company granted 228,200 restricted stock units ("RSUs"), to certain employees, with vesting terms subject to regulatory, commercial, and clinical milestones, in addition to a service condition. As of June 30, 2023, none of these RSUs had vested and all RSUs were forfeited since the performance milestones were not met within the required time frame. No stock-based compensation expense was recognized on these awards.

On June 22, 2023, concurrent with the closing of the Asset Acquisition, the Company's board of directors approved an amendment of the 2016 Plan to eliminate the per-participant annual award limits originally intended to comply with the qualified performance-based compensation exception set forth in Section 162(m) of the Internal Revenue Code, in light of the repeal of such exception pursuant to the Tax Cuts and Jobs Act of 2017. In addition, the Company approved 68,000,955 options contingent on stockholder approval to certain members of the board of directors, legacy Aeglea employees and consultants under the 2016 Plan. These awards are in excess of the shares available for issuance under the 2016 Plan and require stockholder approval before being granted. Accordingly, no expense has been recognized on these contingent awards since they are contingent on stockholder approval.

As of June 30, 2023, the 2016 Plan had 5,384,315 shares available for future issuance.

2018 Equity Inducement Plan

On June 22, 2023, the Company's board of directors approved an increase of 70,000,000 in the number of shares reserved for issuance to the 2018 Equity Inducement Plan and granted 63,417,415 inducement awards to new hires. The grant-date fair value of these inducement awards will be recognized as expense on a pro-rata basis over the vesting period.

The awards have an exercise price of $0.30 per option, vest ratably over four years, and have a ten-year exercise period from the grant date.

Spyre 2023 Equity Incentive Plan

On June 22, 2023, in connection with the Asset Acquisition, the Company assumed the Amended and Restated Spyre 2023 Equity Incentive Plan (the "Spyre Equity Plan") and its outstanding and unexercised stock options which were converted to options to purchase 68,365 shares of Aeglea common stock. The acquisition-date fair value of these grants will be recognized as an expense on a pro-rata basis over the vesting period.

Parapyre Option Obligation

On June 22, 2023, in connection with the Asset Acquisition, the Company assumed the Parapyre Option Obligation which provided for an annual equity grant of options to purchase 1% of the then outstanding shares of Spyre's common stock, on a fully diluted basis, on the last business day of each calendar year during the term of the Paragon Agreement, at the fair market value determined by the board of directors of Spyre. As a result of the Asset Acquisition the Parapyre Option Obligation shall continue and Parapyre shall be entitled to receive the equivalent shares of the Company with the same terms. As of June 30, 2023, the pro-rated estimated fair value of the options to be granted on December 31, 2023, was approximately $0.3 million, of which $0.1 million was recognized as part of the liabilities assumed with the Asset Acquisition. For the three and six months ended June 30, 2023, $0.2 million was recognized as stock compensation expense related to the Parapyre Option Obligation. As of June 30, 2023, the unamortized expense related to the Parapyre Option Obligation was $1.3 million.

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

	Three Months Ended June 30,			
	2023		2022	
	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value
Stock options	63,417,415	$ 0.30	429,000	$ 0.96

2016 Employee Stock Purchase Plan

Under the Company's 2016 Employee Stock Purchase Plan ("2016 ESPP"), the Company issued and sold 44,816 shares for aggregate cash proceeds of less than $0.1 million during the six months ended June 30, 2023. There were 64,743 shares issued and sold under the 2016 ESPP for aggregate cash proceeds of $0.2 million during the six months ended June 30, 2022.

Stock-based Compensation Expense

Total stock-based compensation expense related to all plans was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 394	$ 691	$ 1,171	$ 1,392
General and administrative	1,517	1,327	2,449	2,726
Total stock-based compensation expense	$ 1,911	$ 2,018	$ 3,620	$ 4,118

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 2016 Plan, and the shares purchasable under the 2016 ESPP during the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
2016 Plan				
Expected term (in years)	6.03	5.98	6.03	6.01
Expected volatility	117%	82%	115%	82%
Risk-free interest	3.98%	2.96%	3.99%	2.07%
Dividend yield	—	—	—	—
2016 ESPP				
Expected term (in years)	—	—	0.49	0.49
Expected volatility	—	—	181%	76%
Risk-free interest	—	—	4.99%	1.09%
Dividend yield	—	—	—	—

11. Strategic License Agreements

On March 21, 2021, the Company entered into an exclusive license and supply agreement with Immedica Pharma AB ("Immedica") (the "Immedica Agreement"). By entering into this agreement, the Company agreed to provide Immedica the following goods and services:

i. Deliver an exclusive, sublicensable, license and know-how (the "License") to develop and commercialize pegzilarginase (the "Product") in the territory comprising the members states of the European Economic Area ("EEA"), United Kingdom ("UK"), Switzerland, Andorra, Monaco, San Marino, Vatican City, Turkey, Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Bahrain, and Oman (the "Territory");

ii. Complete the global pivotal PEACE (Pegzilarginase Effect on Arginase 1 Deficiency Clinical Endpoints) Phase 3 trial ("PEACE Trial") and related Biologics License Application ("BLA") package to file with the United States Food and Drug Administration ("FDA"), which will be leveraged by Immedica in obtaining the necessary regulatory approvals in the Territory; and

iii. Perform a Pediatric Investigation Plan trial ("PIP Trial") in order for Immedica to be able to receive certain regulatory approvals within the Territory.

In addition, the Company and Immedica formed a Joint Steering Committee ("JSC") to provide oversight to the activities performed under the agreement; however, the substance of the Company's participation in the JSC does not represent an additional promised service, but rather, a right of the Company to protect its own interests in the arrangement.

Further, the Company agreed to supply to Immedica, and Immedica agreed to purchase from the Company, substantially all commercial requirements of the Product. The terms of the agreement do not provide for either (i) an option to Immedica to purchase the Product from the Company at a discount from the standalone selling price or (ii) minimum purchase quantities. Finally, Immedica will bear (i) all costs and expenses for any development or commercialization of the Product in the Territory subject to the License exclusive of the Company's promised goods and services summarized above and (ii) all costs and fees associated with applying for regulatory approval of the Product in the Territory.

The Company received a non-refundable payment of $21.5 million and Immedica agreed to provide payment of 50% of the Company's costs incurred in performing the PIP Trial up to a maximum of $1.8 million. In addition, the Company had the ability to receive regulatory and commercial milestone payments. The Company was also entitled to receive royalties in the mid-20% range on net sales of the Product in the Territory. In July 2021, the Company modified the agreement with Immedica to provide certain additional services in relation to the PEACE Trial and BLA package performance obligation in exchange for the reimbursement of up to $3.0 million of the actual costs incurred in relation to such incremental services.

The Company concluded that Immedica meets the definition to be accounted for as a customer because the Company is delivering intellectual property and other services within the Company's normal course of business, in which the parties are not jointly sharing the risks and rewards. Therefore, the Company concluded that the promises summarized above represent transactions with a customer within the scope of ASC 606. The Company determined that the following promises represent distinct promised services, and therefore, performance obligations: (i) the License, (ii) the PEACE Trial and BLA package, and (iii) the PIP Trial.

Specifically, in making these determinations, the Company considered the following factors:

- As of inception of the agreement, the Company had completed the Phase 1/2 clinical trial related to the Product and were conducting the PEACE Trial. Accordingly, the Company is not promising, nor expecting, to perform additional research and development activities pursuant to the agreement that would either significantly modify, customize or be considered highly interdependent or interrelated with pegzilarginase.
- The License represents functional intellectual property given the functionality of the License is not expected to change substantially as a result of the company's ongoing activities.
- The services necessary to complete the PEACE Trial, BLA package and PIP Trial could be performed by other parties.

Given that Immedica is not obligated to purchase any minimum amount or quantities of Product, the supply of Product for commercial use to Immedica was determined to be an option for Immedica, rather than a performance obligation of the Company at contract inception and will be accounted for if and when exercised. The Company also determined that Immedica's option to purchase the Product does not create a material right as the expected pricing is not at a discount.

The Company determined that the upfront fixed payment amount of $21.5 million must be included in the transaction price. Additionally, the Company determined at inception of the arrangement that 50% of the probable estimated costs to be incurred in relation to the PIP Trial exceeded $1.8 million and included the full reimbursement amount of $1.8 million in the transaction price. Upon subsequent re-evaluation due to changing facts and circumstances, the Company determined the probable estimated costs are now less than the maximum allowable reimbursement and a portion of the variable consideration was constrained, which did not materially impact the revenue recognized to date. Additionally, upon the modification of the agreement in July 2021, the Company determined that the probable estimated costs to perform the additional services related to the PEACE Trial and BLA package exceeds the maximum allowable reimbursement of $3.0 million. Therefore, the Company included an estimated total of $3.6 million that was due in relation to the PIP Trial, PEACE Trial, and BLA package in the transaction price and it is probable that a significant reversal will not occur in the future. In total, the modified transaction price was determined to be $25.1 million.

The Company has allocated $9.6 million and $3.5 million of the modified transaction price to the PEACE Trial and BLA package and PIP Trial performance obligations, respectively, based on the stand-alone selling prices ("SSP"), which were based on the estimated costs that a third-party would charge in performing such services on a stand-alone basis. The SSP for the License was established at inception of the arrangement using a residual value approach due to the uniqueness of and lack of observable data related to the License, and without a specific analog from which to make reliable estimates, resulting in an allocation of $12.0 million.

The potential regulatory milestone payments that the Company is eligible to receive were excluded from the transaction price, as the milestone amounts were fully constrained based on the probability of achievement, since the milestones relate to successful achievement of certain regulatory approvals, which might not be achieved. The Company determined that the royalties and commercial milestone payments relate predominantly to the license of intellectual property and are therefore excluded from the transaction price under the sales- or usage-based royalty exception of Topic 606. The Company will reevaluate the transaction price, including all constrained amounts, at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, the Company will adjust its estimate of the transaction price as necessary. The Company will recognize the royalties and commercial milestone payments as revenue when the associated sales occur, and relevant sales-based thresholds are met. The Company assessed the arrangement with Immedica and concluded that a significant financing component does not exist.

The Company recognized revenue allocated to the License performance obligation at a point in time and upon transfer of the License. The Company completed the transfer of the know-how necessary for Immedica to benefit from the License in June 2021 and recognized $12.0 million of revenue at that time. The development fee allocated to the PEACE Trial, BLA package and PIP Trial performance obligations is recognized over time using an input method of costs incurred related to the performance obligations.

For the three and six months ended June 30, 2023, the Company recognized $0.7, and $0.9 million, respectively, under the Immedica Agreement. The total revenue generated in the three months ended June 30, 2023, was attributable to drug supply and royalties from an early access program in France. The total revenue generated in the six months ended June 30, 2023, was attributable to the PEACE Phase 3 and PIP trials, drug supply, and royalties from an early access program in France. For the three and six months ended June 30, 2022, the Company recognized revenue of $0.6 million, and $2.0 million, respectively related to the PEACE Trial and BLA package performance obligation. As of June 30, 2023, and 2022, the Company has recorded deferred revenue of $ 3.3 million and $2.7 million, respectively, associated with the Immedica agreement, of which $0.9 million and $0.3 million was classified as current, respectively.

On July 27, 2023, the Company announced that it had entered into an agreement to sell the global rights to pegzilarginase to Immedica and concurrently terminated the existing Immedica Agreement. Any remaining deferred revenue is expected to be recognized as part of the gain on disposal of the assets.

Contract Balances from Customer Contract

The timing of revenue recognition, billings and cash collections results in contract assets and contract liabilities on the balance sheets. The Company recognizes license and development receivables based on billed services, which are derecognized upon reimbursement. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Contract liabilities are recognized as revenue after control of the goods or services is transferred to the customer and all revenue recognition criteria have been met.

The following table presents changes in the Company's contract liabilities for the periods presented (in thousands):

Six Months Ended June 30, 2023	December 31, 2022	Additions	Deductions	June 30, 2023
Contract liabilities:				
Deferred revenue	$ 2,696	$ 628	$ (53)	$ 3,271

The Company had no contract assets during the six months ended June 30, 2023 and 2022.

12. Net Loss Per Share

The Company computes net loss attributable per common stockholder using the two-class method required for participating securities. The Company considers convertible preferred stock to be participating securities. In the event that the Company paid out distributions, holders of convertible preferred stock would participate in the distribution.

The two-class method is an earnings (loss) allocation method under which earnings (loss) per share is calculated for common stock and participating security considering a participating security's rights to undistributed earnings (loss) as if all such earnings (loss) had been distributed during the period. The holders of Series A Preferred Stock do not have an obligation to fund losses and therefore the Series A Preferred Stock was excluded from the calculation of basic net loss per share. The Company included in the calculation of basic net loss per share, contingently issuable common shares related to the Asset Acquisition because they will be issued for no consideration due to the consideration already having been satisfied as of June 30, 2023.

Basic and diluted net loss per share is computed by dividing the net loss by the weighted-average number of common stock and pre-funded warrants outstanding during the period, without consideration of potential dilutive securities. The pre-funded warrants are included in the computation of basic net loss per share as the exercise price is negligible and they are fully vested and exercisable. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as 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 potentially dilutive securities would be anti-dilutive.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Options to purchase common stock	16,363,183	8,566,549	13,937,881	8,113,849
Unvested restricted stock units	—	181,500	9,519	186,243
Series A Preferred Stock (on an as-converted basis)	39,640,000	—	19,930,000	—

13. Restructuring Charges

Severance and Stock Compensation

On April 12, 2023, based on the review of the inconclusive interim results from our Phase 1/2 clinical trial of pegtarviliase for the treatment of Classical Homocystinuria and other business considerations, the Company announced

that it had initiated a process to explore strategic alternatives to maximize stockholder value and engaged an independent exclusive financial advisor to support this process.

As a result, the Company implemented a restructuring plan resulting in an approximate 83% reduction of the Company's existing headcount by June 30, 2023. The Company recognized restructuring expenses consisting of one-time cash severance payments and other employee-related costs of $6.4 million during the three and six months ended June 30, 2023. Cash payments for employee related restructuring charges of $2.2 million were paid as of June 30, 2023. In addition, the Company recognized $1.0 million in non-cash stock-based compensation expense related to the accelerated vesting of stock-based awards for certain employees. The Company recorded these restructuring charges based on each employee's role to the respective research and development and general and administrative operating expense categories on its condensed consolidated statements of operations and comprehensive loss.

The following table summarizes the changes in the Company's accrued restructuring balance (in thousands):

	Beginning Balance December 31, 2022	Charges	Payments	Ending Balance June 30, 2023
Severance liability	$ —	$ 6,448	$ (2,200)	$ 4,248

Sale of Assets

During the second quarter of 2023, the Company sold various lab equipment, consumables, and furniture and fixtures for total consideration of $0.5 million. After recording the disposal of all property and equipment net of proceeds, the Company recorded a $0.7 million and $0.2 million loss on disposal of long lived assets which is included in Research and development and General and administrative expenses, respectively.

Lease Right-of-use Asset and Leasehold Improvement Impairment

Effective June 30, 2023, the Company abandoned its leased office space in Austin, Texas. As a result, the Company recognized an impairment losses of $0.9 million related to the operating lease right-of-use asset and $1.7 million related to leasehold improvements. As of June 30, 2023, the Company was in default of its lease obligations by abandoning the leased space. As a result, the full remaining lease liability is classified as a current liability as the lessor can call all future required payments to be made immediately.

A summary of the charges related to the restructuring activities as of June 30, 2023 is as follows (in thousands):

	Severance and related	Stock compensation	Loss on disposal of long lived assets	Lease asset impairment	Total Restructuring Costs
Research and development	$ 3,182	$ 123	$ 749	$ 1,405	$ 5,459
General and administrative	3,266	870	182	1,175	5,493
Total	$ 6,448	$ 993	$ 931	$ 2,580	$ 10,952

14. Subsequent Events

On July 7, 2023, the Company settled its forward contract liability by issuing the underlying Series A Preferred Stock to the former Spyre shareholders.

On July 27, 2023, the Company announced that it has entered into an agreement to sell the global rights to pegzilarginase, an investigational treatment for the rare metabolic disease Arginase 1 Deficiency, to Immedica for $15.0 million in upfront cash proceeds and up to $100.0 million in contingent milestone payments. The sale of pegzilarginase to Immedica supersedes and terminates the previous license agreement between the Company and Immedica.

The milestone payments are contingent on formal reimbursement decisions by national authorities in key European markets and pegzilarginase approval by the FDA, among other events. The upfront payment and contingent milestone payments if paid, net of expenses and adjustments, will be distributed to holders of Aeglea's CVR pursuant to the CVR Agreement resulting from the Asset Acquisition.

On August 7, 2023, the Company terminated its building lease in Austin, Texas. The negotiated termination agreement obligates the Company to pay the lessor a $2.0 million termination fee in exchange for releasing the Company of all further obligations under the lease.

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 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, 2022 filed with the SEC, on March 2, 2023. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." As used in this report, unless the context suggests otherwise, "we", "us", "our", "the Company" or "Aeglea" refers to Aeglea BioTherapeutics, Inc. and its subsidiaries, including Spyre Therapeutics, LLC.

Acquisition of Spyre

On June 22, 2023, we acquired Spyre pursuant to the Acquisition Agreement, by and among the Company, Aspen Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("First Merger Sub"), Sequoia Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Second Merger Sub"), and Spyre. Pursuant to the Acquisition Agreement, First Merger Sub merged with and into Spyre, pursuant to which Spyre was the surviving corporation and became a wholly owned subsidiary of the Company (the "First Merger"). Immediately following the First Merger, Spyre merged with and into Second Merger Sub, pursuant to which Second Merger Sub became the surviving entity. Spyre was a pre-clinical stage biotechnology company that was incorporated on April 28, 2023 under the direction of Peter Harwin, a Managing Member of Fairmount, for the purpose of holding rights to certain intellectual property being developed by Paragon. Fairmount is a founder of Paragon.

Through the Asset Acquisition, we received the Option to license the IPR&D related to four research programs. On July 12, 2023 we exercised the Option with respect to one of these research programs to exclusively license intellectual property rights related to such research program directed to antibodies that selectively bind to α4β7 integrin and methods of using these antibodies, including methods of treating IBD using SPY001. If this research program is pursued non-provisionally and matures into issued patents, we would expect those patents to expire no earlier than 2044 subject to any disclaimers or extensions. The license agreement pertaining to such research program is currently being finalized on previously agreed terms. Furthermore, as of the date hereof, the Option remains unexercised with respect to the IPR&D related to the three remaining research programs under the Paragon Agreement.

Overview

Following the Asset Acquisition, we have significantly reshaped the business into a preclinical stage biotechnology company focused on developing next generation therapeutics for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Crohn's disease ("CD"). Through the Paragon Agreement, our portfolio of novel and proprietary monoclonal antibody product candidates has the potential to address unmet needs in IBD care by improving efficacy, safety, and/or dosing convenience relative to products currently available or product candidates in development. We have purposely engineered our product candidates to bind potently and selectively to target epitopes with extended half-lives. We plan to use combinations of our proprietary antibodies and patient enrichment strategies via companion diagnostics to enhance efficacy. We intend to deliver our product candidates through convenient, infrequently self-administered, subcutaneous ("SC") injection as a pre-filled pen.

In accordance with ASC 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. If our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock, as described in our Certificate of Designation relating to the Series A Preferred Stock. The cash redemption is not in our control and raises substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements assume the Company will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Our Strategy

Our goal is to develop next-generation therapeutics for the treatment of IBD, relying on three strategic pillars:

- Advancing novel, potentially best-in-class, long-acting antibodies against validated IBD targets,
- Evaluating rational therapeutic combinations of potentially best-in-class antibodies, and
- Developing genetic- or biomarker-based companion diagnostics to match treatment targets to IBD sub-populations.

Inflammatory Bowel Disease

IBD is a chronic condition characterized by inflammation within the gastrointestinal tract. It encompasses two main disorders: UC and CD. UC primarily affects the colon and the rectum. Inflammation occurs in the innermost lining of the colon leading to ulcers. Symptoms include bloody diarrhea, abdominal pain, bowel urgency, and frequent bowel movements. CD can affect any part of the gastrointestinal tract, from the mouth to the anus. It is characterized by inflammation that extends through multiple layers of the bowel wall. Symptoms include abdominal pain, diarrhea, weight loss, fatigue, and complications such as strictures or fistulas. Both conditions can significantly impact patients' quality of life in terms of physical health, emotional well-being, and the unpredictability of symptom onset.

IBD affects millions of individuals worldwide, with increasing prevalence and incidence in both developed and developing countries. In the United States, it is estimated that approximately 1.7 million individuals currently have IBD, with approximately 70,000 patients newly diagnosed every year. The prevalence of UC in the United States is approximately 900,000 individuals, and the prevalence of CD in the United States is approximately 800,000 individuals. The market for IBD therapeutics is expected to experience steady growth, driven by rising disease prevalence, increasing diagnosis rates, and evolving treatment paradigms.

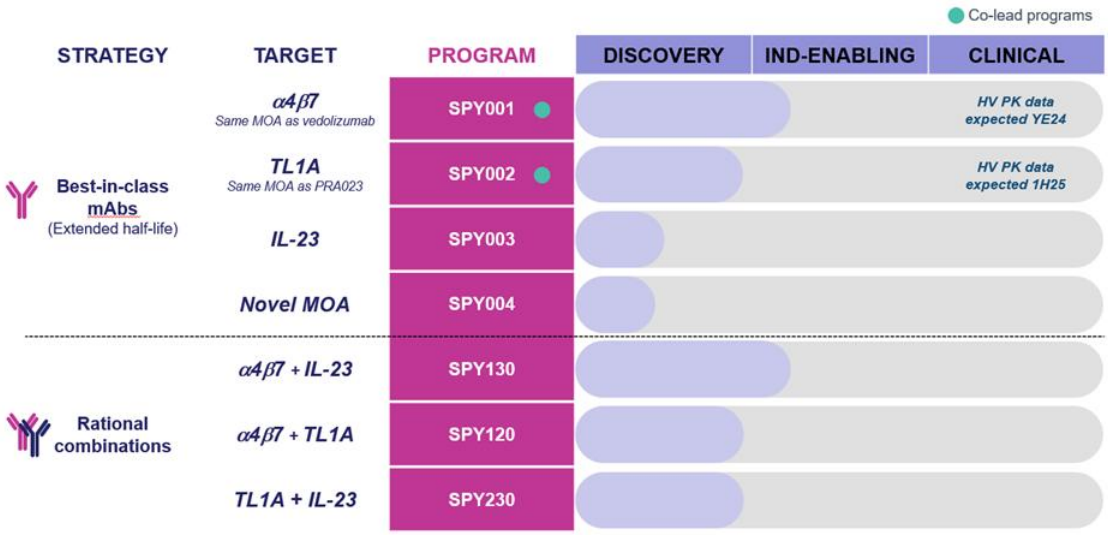
A range of pharmaceutical options exists, including anti-inflammatory drugs, immunosuppressants, and biologics. Treatment plans are often tailored to the individual patient's disease severity, location, and response to therapy. In some cases, surgical interventions such as bowel resection or ostomy formation may be necessary to manage complications or improve quality of life.

Despite available treatments, there remain substantial unmet needs in IBD management, including:

- Inadequate response or loss of response to existing therapies,
- Side effects and safety concerns associated with long-term medication use,
- Limited options for patients with refractory or severe disease, and
- Adherence to frequent and/or inconvenient dosing regimens.

Our Portfolio

We are advancing a broad pipeline of potentially best-in-class monoclonal antibodies ("mAbs") in connection with the research programs with respect to which we have exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Paragon Agreement and plan to develop a companion diagnostic for each program. The following table summarizes these programs*.



** We exercised the Option to acquire intellectual property license rights related to the SPY001 program on July 12, 2023.*

Although we hold the Option to acquire intellectual property license rights related to the SPY002, SPY003 and SPY004 programs, such Option remains unexercised.

For a discussion of the risks associated with our portfolio, see the section of this report entitled “Risk Factors.”

SPY001 – anti-α4β7 mAb

Our most advanced product candidate, SPY001, is a highly potent, highly selective, and fully human monoclonal immunoglobulin G1 antibody designed to bind selectively to the α4β7 integrin. The α4β7 integrin is a protein found on the surface of immune cells known as lymphocytes. This integrin regulates the migration of lymphocytes to the gut where they contribute to the inflammatory process in IBD. By binding to the α4β7 integrin, SPY001 is designed to prevent the interaction of these lymphocytes with MAdCAM-1, a molecule expressed on endothelial cells lining the blood vessels in the gut. This interaction is responsible for guiding lymphocytes from the bloodstream into the gut tissue, where they cause inflammation. By blocking the interaction between α4β7 integrin and MAdCAM-1, SPY001 aims to reduce the recruitment of lymphocytes to the gut, leading to a decrease in inflammation. Since it specifically targets the gut immune system, SPY001 is designed to help minimize systemic immunosuppressive effects unrelated to IBD pathology.

Vedolizumab is an anti-α4β7 integrin mAb marketed by Takeda as Entyvio. It is available in the United States as an intravenously administered product with an every 8-week maintenance dosing regimen. A SC version with an every 2-week dosing regimen is under review by the FDA for use in the maintenance setting and is approved in Europe and Japan. Vedolizumab is one of the leading therapies for moderate-to-severe IBD given its exquisite safety profile as a gut selective mechanism and its high efficacy rates in UC (particularly in the maintenance setting where it has the highest remission rates among approved biologics). In the induction setting, exposure-response data suggests that higher exposures may increase the likelihood of early remission in UC. We believe that there is a significant opportunity for a SC regimen with a more infrequent dosing schedule (every eight to twelve weeks) in the maintenance settings, and potential efficacy upside in induction.

Our preclinical development program has demonstrated that SPY001 binds to the same epitope as vedolizumab with similar potency and selectivity. Both SPY001 and vedolizumab potently block MAdCAM-1 adhesion and avoid interactions with α4β1 to prevent adhesion to VCAM-1, which can be associated with the risk of progressive multifocal leukoencephalopathy. Additionally, our preclinical studies have demonstrated that SPY001 binds to memory T-helper cells from human donors with a comparable potency as vedolizumab.

SPY001 is engineered with half-life extension technology. This approach relies on modifying the Fc domain to improve the pharmacokinetic (“PK”) profile of the antibody and support infrequent dosing as a convenient SC injection. An evaluation of SPY001's PK in non-human primates suggests an increase in half-life of approximately 2-fold relative to vedolizumab, potentially supporting a SC dosing administration of every eight to twelve weeks in humans.

We aim to achieve the following target product profile for SPY001 in IBD:

- Less frequent administration: Lower the frequency of administration by incorporating half-life extension technology and deliver SPY001 through a single SC injection every eight to twelve weeks.
- High concentration, citrate-free formulation: Deliver at least 300 mg in a single 2 mL injection suitable for a pre-filled pen without the need for citrate to enhance patient comfort.
- Potential for increased induction efficacy in UC: Target greater exposure in the induction setting given exposure-response relationships observed with vedolizumab in UC.

SPY001 is currently progressing through IND-enabling studies and is expected to enter first-in-human ("FIH") studies in the first half of 2024. We believe SPY001 has the potential to meaningfully transform the standard of care in IBD as a potent, low-frequency and self-administered SC injection.

SPY002 – anti-TL1A mAb

Our co-lead product candidate, SPY002, is a highly potent, highly selective, and fully human mAb designed to bind to tumor necrosis factor-like ligand 1A ("TL1A"). TL1A is a protein that plays a role in regulating the immune system and is found to be elevated in the gut tissue of individuals with IBD. TL1A interacts with its receptor, death receptor 3 ("DR3"), which is expressed in various immune cells, including T cells. This interaction triggers signaling pathways that contribute to inflammation and immune system activation, leading to IBD symptomology. SPY002 has been designed to block the interaction between TL1A and DR3 and thereby inhibit the downstream signaling events and dampen the inflammatory response. By neutralizing TL1A, SPY002 has the potential to modulate the immune response in IBD patients, potentially reducing disease activity and promoting mucosal healing.

TL1A is a clinically validated target that has been studied in multiple Phase 2 trials in UC and CD. Merck's anti-TL1A molecule (MK-7240, formerly PRA023) was studied in a randomized controlled Phase 2 trial where it showed a 25% placebo-adjusted clinical remission rate at week 12 and a placebo-adjusted endoscopic improvement rate of 31% for patients with UC. MK-7240 was additionally studied in a Phase 2a open label trial in CD where it showed a 49% clinical remission rate at week 12 compared to a prespecified 16% historical placebo rate and a 26% endoscopic response compared to a prespecified 12% historical placebo rate. Roivant is also advancing an anti-TL1A molecule (RVT-3101) that showed a 21% placebo-adjusted clinical remission rate and a 21% placebo-adjusted endoscopic response in a Phase 2b study in UC patients. In the maintenance setting at week 56, RVT-3101 showed a compelling clinical remission rate of 36% (absolute) at the expected Phase 3 dose. Both MK-7240 and RVT-3101 lack any half-life extension technologies and are dosed every four weeks in the maintenance setting.

Like SPY001, SPY002 is engineered with half-life extension technology to support infrequent, self-administration as a convenient SC injection. It is expected that these modifications along with a high concentration formulation, will enable dosing every eight weeks or less frequently in humans.

We aim to achieve the following target product profile for SPY002 in IBD and other inflammatory diseases:

- Less frequent administration: Lower the frequency of administration by incorporating half-life extension technology and deliver SPY002 through a single SC injection every eight weeks or less frequently.
- High potency: High affinity to TL1A trimers, enabling lower doses.
- High concentration, citrate-free formulation: Deliver at least 300 mg in a single 2 mL injection suitable for a pre-filled pen.

We expect to enter FIH studies in the second half of 2024. We believe SPY002 has the potential to be a best-in-class TL1A antibody compared to others in development as a highly potent, highly selective, and infrequently self-administered SC injection.

SPY003 – anti-IL-23 mAb

Our third program, SPY003, is a discovery stage program designed to bind to Interleukin 23 ("IL-23"). IL-23 is a cytokine that is produced by immune cells and is involved in immune response regulation. IL-23 promotes the differentiation and activation of Th17 cells. Th17 cells produce other 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.

Several IL-23 mAbs have been approved or are in late-stage development for IBD including Skyrizi (AbbVie), Tremfya (Johnson & Johnson), and mirikizumab (Lilly).

We aim to achieve the following target product profile for SPY003 in IBD:

- Less frequent administration: Lower the frequency of administration by incorporating half-life extension technology and deliver SPY003 through a single SC injection every eight weeks or less frequently.
- High concentration, citrate-free formulation: Deliver at least 300 mg in a single 2 mL injection suitable for a pre-filled pen.

SPY004 – novel MOA mAb

SPY004 is an undisclosed novel mechanism of action ("MOA") and incorporates half-life extension modifications.

Our combination programs – SPY120, SPY130, and SPY230

We aim to advance rational combinations of our therapeutic antibodies into clinical studies. SPY120 combines SPY001 (α4β7) and SPY002 (TL1A), SPY130 combines SPY001 (α4β7) and SPY003 (IL-23), and SPY230 combines SPY002 (TL1A) and SPY003 (IL23). We believe these combinations target orthogonal biology and could lead to greater remission rates in IBD.

Clinical proof-of-concept for the potential of combination therapy in IBD was demonstrated by Johnson & Johnson's VEGA study which evaluated their anti-TNFα antibody, Simponi, in combination with their anti-IL-23 antibody, Tremfya, in patients with UC. The combination resulted in an absolute clinical remission rate of 47% in the induction setting, which was nearly additive of the remission rates observed with either TNFα (25%) or IL-23 (24%) alone. We believe there is potential to build on this result by combining mechanisms that have shown greater efficacy rates in specific indications and settings and that exhibit a superior safety profile relative to the TNFα class.

Our precision immunology approach

We aim to develop genetic- or biomarker-based companion diagnostics across our portfolio of therapeutics to aid patients and physicians in selecting the optimal treatment regimen. Clinical proof-of-concept for the potential of companion diagnostic ("CDx") approaches in IBD was demonstrated by both Prometheus (now Merck) and Roivant for their anti-TL1A programs. In Phase 2 studies, UC patients that were CDx positive were more likely to respond to anti-TL1A therapy as evidenced by a 7-13% increase in clinical remission rate at week 12 compared to all-comers. We are in discussions with several potential partners with access to large scale IBD biobanks to support CDx development across our portfolio.

Our Team and Investors

Our portfolio of potentially best-in-class antibodies were discovered and developed by Paragon. Spyre acquired rights to its portfolio from Paragon, a group of leading entrepreneurial scientists and investors with extensive mAb experience. Its scientific founders' discoveries have also led to the successful creation of other biotechnology companies, including Cogent Biosciences, Inc., Viridian Therapeutics, Inc., Dianthus Therapeutics, Inc., and Apogee Therapeutics, Inc.

On June 22, 2023, we announced the completion of the Asset Acquisition with the sole focus on advancing our pipeline of next-generation antibodies for IBD with respect to which we have exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Paragon Agreement. Concurrent with the closing of the Asset Acquisition, we completed a $210.0 million private placement of our Series A Preferred Stock.

We have a strong management team and group of employees with diverse backgrounds and significant experience in developing novel treatments for patients at biopharmaceutical companies such as AbbVie, BridgeBio Pharma, Genentech, and Johnson & Johnson. Together, our team has a proven track record in the discovery, development, and commercialization of numerous approved therapeutics.

Our Relationship with Paragon and Parapyre

Paragon and Parapyre, a related party of Paragon, together beneficially own more than 5% of our capital stock collectively through their holdings of our common stock and Series A Preferred Stock. Fairmount beneficially owns more than 5% of our capital stock, has two seats on our Board and beneficially owns more than 5% of Paragon, which is a joint venture between Fairmount and Fair Journey Biologics. Fairmount has appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers. Parapyre is an entity formed by Paragon as a vehicle to hold equity in Spyre.

In connection with the Asset Acquisition, we assumed the rights and obligations of Spyre under the Paragon Agreement. Under the Paragon Agreement, we are obligated to compensate Paragon on a quarterly basis for its services performed under each research program based on the actual costs incurred. As of the date of the Asset Acquisition, Spyre had incurred total expenses of $19.3 million under the Paragon Agreement since inception, inclusive of a $3.0 million research initiation fee that was due upon signing of the Paragon Agreement and $16.3 million of reimbursable expenses under the Paragon Agreement for historical costs incurred by Paragon. As of the acquisition date, $19.3 million was unpaid and was assumed by us through the Asset Acquisition. For the three months ended June 30, 2023, we recognized an additional $1.2 million in expenses that are due to Paragon under the Paragon Agreement. As of June 30, 2023, we had $20.5 million in outstanding amounts due to Paragon under the Paragon Agreement.

In July 2023, we exercised our option for the SPY001 program with the remaining three options for the SPY002, SPY003, SPY004 programs remaining outstanding.

In connection with the Asset Acquisition, the Company assumed the Parapyre Option Obligation which provided for an annual equity grant of options to purchase 1% of the then outstanding shares of Spyre's common stock, on a fully diluted basis, on the last business day of each calendar year during the term of the Paragon Agreement, at the fair market value determined by the board of directors of Spyre. As a result of the Asset Acquisition the Parapyre Option Obligation shall continue and Parapyre shall be entitled to receive the equivalent shares of the Company with the same terms. As of June 30, 2023, the pro-rated estimated fair value of the options was approximately $0.3 million, of which $0.1 million was recognized as part of the liabilities assumed with the Asset Acquisition. For the three and six months ended June 30, 2023, $0.2 million was recognized as stock compensation expense related to the Parapyre Option Obligation.

Commercial

Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs. Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Manufacturing

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We are currently in the process of novating certain agreements with third parties for the performance of future clinical manufacturing and toxicology activities from Paragon to us. The initial forms of these agreements are generally non-specific master services agreements that allow an entity to begin the process of future manufacturing or toxicology services, respectively. As clinical development activities are commenced by us, the agreements will be revised to provide for the specific deliverables and associated costs that are needed under our development plan.

Competition

We expect to face intense competition from other biopharmaceutical companies that are developing agents for the treatment of inflammatory diseases. If approved for the treatment of patients with moderate-to-severe IBD, our portfolio of products would compete with TNF antibodies including Humira (AbbVie), Remicade (Johnson & Johnson), and Simponi (Johnson & Johnson); IL-12/23 and IL-23 antibodies including Stelara (Johnson & Johnson) and Skyrizi (AbbVie); α4β7 antibody Entyvio (Takeda); JAK inhibitors including Xeljanz (Pfizer), Rinvoq (AbbVie); and S1P1 receptor modulating therapies including Zeposia (Bristol Myers Squibb).

We are aware of several companies with product candidates in development for the treatment of patients with IBD, including Merck's MK-7240, Roivant's RVT-3101, and Teva's TEV-48574 TL1A antibodies; additional IL-23s including Tremfya (Johnson & Johnson) and mirikizumab (Lilly); additional S1P1 modulator etrasimod (Pfizer); and oral anti-integrin agents including Morphic Therapeutic's MORF-057, and Gilead's GS-1427, and a discovery program at Dice Therapeutics (Lilly).

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the

governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

United States Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") and their implementing regulations, as well as other federal, state, local, and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

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

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. Similar processes exist in countries outside the United States that we will be required to follow if we choose to execute trials in other countries.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their

informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries. Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with cGCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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

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

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

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical study investigators. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected suspected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan ("PSP") within sixty days after an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews the BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

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

Expedited Development and Review Programs

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

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

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

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

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

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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

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

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

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"),

which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. In September 2021, the FDA issued two guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. FDA-approved interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state laws, which differ by state.

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

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

Other Healthcare Laws and Compliance Requirements

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

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and

practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal FCA or federal civil monetary penalties.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which impose criminal and civil penalties and can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that “caused” the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements or representations relating to healthcare matters.

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

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

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

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, and their respective implementing regulations imposes privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually

identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with the U.S. Department of Health and Human Services ("HHS") to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

In addition, state laws govern the privacy and security of personal information, including health-related information, in certain circumstances. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act, which went into effect on January 1, 2020, has created new data privacy obligations for covered companies and provided new privacy rights to California residents.

Coverage and Reimbursement

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which

may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

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

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union ("EU") provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of its product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare reform

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

The ACA, which was enacted in 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2032. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The United States American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government

program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives.

In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the United States government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. The effects of the IRA on its business and the healthcare industry in general is not yet known.

President Biden has also issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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

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

Other Government and Regulation Outside of the United States

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

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

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities

in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

The collection and use of personal health data and other personal data regarding individuals in the EEA is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (“EU GDPR”) and related data protection laws in individual EEA member states, including additional requirements relating to health, genetic and biometric data implemented through national legislation. Similar processing of personal health data and other personal data regarding individuals in the UK is governed by the UK General Data Protection Regulation ("UK GDPR") and the UK Data Protection Act 2018. In this document, “GDPR” refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EEA/UK that are not considered by the European Commission ("EC") and the UK government as providing an adequate level of data protection (third countries), including the United States. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the EC approved standard contractual clauses ("SCCs") and the UK International Data Transfer Agreement/Addendum (“UK IDTA”). Where relying on the SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. The international transfer obligations under the EEA/UK data protection regimes will require effort and cost and may result in us needing to make strategic considerations around where EEA/UK personal data is located and which service providers we can utilize for the processing of EEA/UK personal data. Although the UK is regarded as a third country under the EU GDPR, the EC has issued a decision recognizing the UK as providing adequate protection under the EU GDPR (“Adequacy Decision”) and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK government has also now introduced a Data Protection and Digital Information Bill (“UK Data Protection Bill”) into the UK legislative process with the intention for this bill to reform the UK’s data protection regime following Brexit. If passed, the final version of the UK Data Protection Bill may have the effect of further altering the similarities between the UK and EU data protection regime. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

On March 25, 2022, the EC and the United States announced that they have agreed in principle on a new Trans-Atlantic Data Privacy Framework. Following this statement, on October 7, 2022, President Biden signed an Executive Order on ‘Enhancing Safeguards for United States Signals Intelligence Activities’, which implemented the agreement in principle. On that basis, the EC prepared a draft Adequacy Decision and launched its adoption procedure. While this new EU-United States privacy framework is expected to enter into force in 2023, there is still some uncertainty around the new framework.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA member states/UK may result in significant monetary fines for noncompliance of up to €20 million (£17.5 million for the UK) or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EEA member states/UK may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data subject to the EEA/UK data protection regimes. Guidance developed at both the EU level and at the national level in individual EU member states concerning implementation and compliance practices are often updated or otherwise revised.

Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines, penalties and litigation in connection with European activities, which could in turn have a negative effect on our reputation and materially harm our business.

Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation (EU) No. 536/2014 (the “CTR”), European Medical Agency ("EMA") disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

Drug and Biologic Development Process

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

Under the former regime, which will expire after a transition period of one or three years, respectively, as outlined below in more detail, before a clinical trial can be initiated it must be approved in each EU member state where there is a site at which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the national competent authority in the applicable EU member state(s) and one or more ethics committees. The national competent authority of all EU member states in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent ethics committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU member state before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant national competent authorities and ethics committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the national competent authority and to the ethics committees of the EU member state where they occur.

A more unified procedure applies under the CTR. A sponsor can submit a single application for approval of a clinical trial through a centralized EU clinical trials portal ("CTIS”). One national competent authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application, and will consult and coordinate with the other concerned EU member states. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU member states. However, a concerned EU member state may in limited circumstances declare an “opt-out” from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU database. The CTR foresees a three-year transition period. On January 31, 2023, submission of initial clinical trial applications via CTIS became mandatory, and by January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS.

Under both the former regime and the CTR, national laws, regulations, and the applicable Good Clinical Practice and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki.

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

Drug Marketing Authorization

In the EU, medicinal products are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. To obtain regulatory approval of a product under the EU regulatory systems, we must submit an MAA under either the EU centralized procedure, or one of the national procedures in the EU.

Centralized Authorization Procedure

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

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

Decentralized and Mutual Recognition Procedures

Medicines that fall outside the mandatory scope of the centralized procedure can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state, or they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization (mutual recognition procedure).

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

Risk Management Plan

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

MA Validity Period

In the EU, an MA has an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed

with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Exceptional Circumstances/Conditional Approval

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

Data and Market Exclusivity

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

If granted, the data exclusivity period begins on the date of the product's first MA in the EU and prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product). An additional one-year period of marketing exclusivity is possible if, during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. Additionally, a standalone one-year period of data exclusivity can be granted where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials, when examining an application by another applicant for or holder of an MA for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized.

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

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless such a waiver or a deferral has been granted. Medicinal products that are granted an MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six month extension of the protection under a supplementary protection certificate ("SPC"),

provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when an MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

PRIME Designation

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

Post-Approval Regulation

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

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

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

MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of PSURs in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The EMA can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC’s decision provides can undermine the ongoing validity of the MA.

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

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable

EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU member states may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") as approved by the national competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the EU. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment.

Anti-Corruption Legislation

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

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

Other Markets

The UK formally left the EU on January 31, 2020 and the transition period, during which EU laws continued to apply to the UK, expired on December 31, 2020. This means EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Northern Ireland Protocol. Following the end of the transition period, the EU and the UK concluded a trade and cooperation agreement ("TCA"), which applied provisionally from January 1, 2021 and entered into force on May 1, 2021.

The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). Except in respect of the new CTR, the regulatory regime in Great Britain therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new framework which will be put in place by the Medicines and Healthcare products Regulatory Agency ("MHRA"), from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of

marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization.

On February 27, 2023, the UK government and the EC announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the “Windsor Framework”. This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law.

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

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

Employees and Human Capital Resources

As of June 30, 2023, we had 14 employees, all of whom were employed full time. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

Corporate Developments

In the second quarter of 2023, we began exploring strategic alternatives with the goal of maximizing stockholder value. We engaged Wedbush Securities Inc. as an exclusive financial advisor to assist in the process of exploring strategic alternatives, including an acquisition, merger, reverse merger, other business combination, sales of assets or other strategic transactions. Additionally, we reduced our workforce and retained approximately 10 employees required to support the evaluation of strategic alternatives and ongoing business activities. We also announced the departures of Michael C. Hanley, MBA, chief business officer, Linda Neuman, MD, MBA, chief medical officer, Jeffrey Goldberg, the President and Chief Executive Officer, and Jim Kastenmayer, the General Counsel. In connection with Mr. Goldberg’s departure, the Board appointed Mr. Jonathan Alspaugh, the Company’s Chief Financial Officer, as the Company’s President and principal executive officer. On June 22, 2023, we acquired the net assets of Spyre, a privately held biotechnology company founded to transform the treatment of IBD by pursuing potentially best-in-class long-acting antibodies, rational therapeutics combinations, and precision immunology approaches. The Board appointed Cameron Turtle, DPhil, as Chief Operating Officer, effective as of the closing of the Asset Acquisition on June 22, 2023. Including Dr. Turtle, we increased our workforce to a total of 14 employees concurrently with the closing of the Asset Acquisition.

Severance and Stock Compensation

The Company recognized restructuring expenses consisting of one-time cash severance payments and other employee-related costs of $6.4 million during the three and six months ended June 30, 2023. Cash payments for employee related restructuring charges of $2.2 million were paid as of June 30, 2023. In addition, the Company recognized $1.0 million in non-cash stock-based compensation expense related to the accelerated vesting of stock-based awards for certain employees. The Company recorded these restructuring charges based on each employee’s role to the respective research and development and general and administrative operating expense categories on its condensed consolidated statements of operations and comprehensive loss.

Sale of Assets

During the second quarter of 2023, the Company sold various lab equipment, consumables, and furniture and fixtures for total consideration of $0.5 million. After recording the disposal of all property and equipment net of proceeds, the Company recorded a $0.7 million and $0.2 million loss on disposal of long lived assets which is included in Research and development and General and administrative expenses, respectively.

Lease Right-of-use Asset Impairment

Effective June 30, 2023, the Company abandoned its leased office space in Austin, Texas. As a result, the Company recognized an impairment loss of $2.6 million related to the operating lease right-of-use asset and the related leasehold improvements .

A summary of the charges related to the restructuring activities as of June 30, 2023 is as follows (in thousands):

	Severance and related	Stock compensation	Loss on disposal of long lived assets	Lease asset impairment	Total Restructuring Costs
Research and development	$ 3,182	$ 123	$ 749	$ 1,405	$ 5,459
General and administrative	3,266	870	182	1,175	5,493
Total	$ 6,448	$ 993	$ 931	$ 2,580	$ 10,952

Licensing of Pegzilarginase

In March 2021, we licensed to Immedica the rights to the commercialization of pegzilarginase in the European Economic Area, United Kingdom, Switzerland, Andorra, Monaco, San Marino, Vatican City, Turkey, Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Bahrain, and Oman. The Immedica Agreement includes a non-refundable upfront payment of $21.5 million from Immedica and development services provided to Immedica, up to $3.0 million. Under the terms of the Immedica Agreement, we were eligible to receive additional regulatory and commercial milestone payments and were entitled to receive royalties in the mid-20% range on net sales of the product in countries included in the Immedica Agreement.

In July 2023, we entered into an agreement to sell the global rights to pegzilarginase to Immedica and concurrently terminating the existing Immedica license agreement.

For the three and six months ended June 30, 2023, we recognized revenue of $0.7 and $0.9 million, respectively, under the Immedica Agreement. The total revenue generated was attributable to the PEACE Phase 3 trial and drug supply and royalties from an early access program in France. For the three months and six months ended June 30, 2022, we recognized $0.6 million and $2.0 million, respectively, relating to the PEACE Phase 3 trial and BLA package performance.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, 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 condensed consolidated financial statements. The most significant estimates and assumptions that management considers in the preparation of the Company's financial statements relate to accrued research and development costs; the valuation of consideration transferred in acquiring IPR&D; the discount rate, probabilities of success, and timing of estimated cash flows in the valuation of the CVR liability; inputs used in the Black-Scholes model for stock-based compensation expense; estimated future cash flows used in calculating the impairment of right-of-use lease assets; and estimated cost to complete performance obligations related to revenue recognition. Our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this quarterly report.

Other than the disclosure below, there have been no significant changes in 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 Operations included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Impairment of ROU Assets and Leasehold Improvements

We are required to test for impairment of our long-lived assets when events arise that would call into question the recoverability of an asset group. We determined that the abandonment of our leased office space in Austin, Texas would meet this criteria. Accordingly, we tested for impairment using a discounted future cash flow model using estimated cash flows that could be obtained through a hypothetical sub-letting of the leased space.

Convertible Preferred Stock Issued through PIPE

We record shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company has applied the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities, and has therefore classified the Series A Preferred Stock outside of stockholders' (deficit) equity because, if conversion to common stock is not approved by the stockholders, the Series A Preferred Stock will be redeemable at the option of the holders for cash equal to the closing price of the common stock on the last trading day prior to the holder's redemption request. We determined that the conversion and redemption are outside of our control. Additionally, we determined the conversion and redemption features did not require bifurcation as derivatives.

Contingent Value Rights Liability

On July 3, 2023, we issued a CVR to Legacy Stockholders, but these were not issued to holders of shares of common stock or preferred stock issued to former stockholders of Spyre or the Investors in connection with the Transactions. Each CVR entitles the holder thereof to receive cash payments in the future calculated on the monetization or disposal of legacy Aeglea assets within the CVR period. Certain contingent payments under the CVR Agreement qualify as derivatives under ASC 815, Derivatives and Hedging, and are recorded as a liability on the balance sheet as of June 30, 2023. The CVR liability is considered a Level 3 instrument that is initially measured at its estimated fair value on the transaction date and subsequently remeasured at each reporting date with changes recorded in the consolidated statement of operations. The determination of the initial and subsequent fair value of the CVR liability requires significant judgment by management. Changes in any of the inputs not related to facts and circumstances existing as of the transaction date may result in a significant fair value adjustment, which can impact the results of operations in the period in which the adjustment is made.

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023, and 2022, together with the changes in those items in dollars and as a percentage:

	Three Months Ended June 30,		Dollar Change	% Change
	2023	2022		
	(dollars in thousands)			
Revenue:				
Development fee and royalty	$ 688	$ 625	$ 63	10%
Total revenue	688	625	63	10%
Operating expenses:				
Research and development	17,386	15,373	2,013	13%
General and administrative	12,062	7,675	4,387	57%
Acquired in-process research and development	130,486	—	130,486	*
Total operating expenses	159,934	23,048	136,886	*
Loss from operations	(159,246)	(22,423)	(136,823)	*
Interest (expense) income	350	104	246	*
Change in fair value of forward contract liability	(58,170)	—	(58,170)	*
Other (expense) income, net	(8)	5	(13)	*
Loss before income tax expense	(217,074)	(22,314)	(194,760)	*
Income tax expense	(7)	(9)	2	*
Net loss	$ (217,081)	$ (22,323)	$ (194,758)	*

* Percentage not meaningful

Development Fee and Royalty Revenue. For the three months ended June 30, 2023, we recognized $0.7 million of revenue in connection with the Immedica Agreement. The total revenue generated was attributable to the drug supply and royalties from an early access program in France. For the three months ended June 30, 2022, we recognized $0.6 million of development fee revenue in connection with the Immedica Agreement, which was attributable to the PEACE Phase 3 trial and BLA package.

Research and Development Expenses. Our Research and development expenses incurred during the three months ended June 30, 2023 primarily relate to costs with winding down our clinical studies. Wind down costs include final patient visits, collection and analysis of final patient data, the creation and submission of final research reports, site and pharmacy closeouts, and formally closing the studies with regulatory agencies. Research and development expenses increased by $2.0 million, or 13%, to $17.4 million for the three months ended June 30, 2023, from $15.4 million for the three months ended June 30, 2022. The change in research and development expenses was primarily due to:

- a $2.4 million increase in restructuring costs net of savings;
- a $1.2 million increase in expenses associated with the Paragon Agreement; partially offset by
- a $0.6 million increase in manufacturing costs for AGLE-325; partially offset by
- a $1.6 million decrease in toxicology costs related to pegtarviliase.

General and Administrative Expenses. General and administrative expenses increased by $4.4 million, or 57%, to $12.1 million for the three months ended June 30, 2023, from $7.7 million for the three months ended June 30, 2022. The increase in general and administrative expenses was due to a $5.3 million increase due to restructuring costs net of restructuring savings partially offset by a $0.9 million decrease due to a reduction of commercial activities due to a decline in regulatory pathway activities.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses were $130.5 million for the three months ended June 30, 2023, as the Spyre transaction was determined by management to be an asset acquisition in which the product candidates have no alternative future use, in accordance with U.S. GAAP. There was no such expense during the three months ended June 30, 2022.

Change in fair value of forward contract liability. Non-cash expenses associated with the change in fair value of the forward contract liability were $58.2 million for the three months ended June 30, 2023. This expense represents the change in fair value of the underlying Series A Preferred Stock between June 22, 2023 and June 30, 2023. There was no such expense during the three months ended June 30, 2022.

Comparison of the Six Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023, and 2022, together with the changes in those items in dollars and as a percentage:

	Six Months Ended June 30,		Dollar Change	% Change
	2023	2022		
	(dollars in thousands)			
Revenue:				
Development fee and royalty	$ 886	$ 1,987	$ (1,101)	(55)%
Total revenue	886	1,987	(1,101)	(55)%
Operating expenses:				
Research and development	31,162	32,351	(1,189)	(4)%
General and administrative	17,290	16,500	790	5%
Acquired in-process research and development	130,486	—	130,486	*
Total operating expenses	178,938	48,851	130,087	*
Loss from operations	(178,052)	(46,864)	(131,188)	*
Interest income	770	139	631	*
Change in fair value of forward contract liability	(58,170)	—	(58,170)	*
Other expense, net	(80)	1	(81)	*
Loss before income tax expense	(235,532)	(46,724)	(188,808)	*
Income tax benefit (expense)	29	(35)	64	*
Net loss	$ (235,503)	$ (46,759)	$ (188,744)	*

* Percentage not meaningful

Development Fee and Royalty Revenue. For the six months ended June 30, 2023, we recognized $0.9 million of revenue in connection with the Immedica Agreement. The total revenue generated was attributable to the PEACE Phase 3 trial and drug supply and royalties from an early access program in France. For the three months ended June 30, 2022, we recognized $2.0 million of development fee revenue in connection with the Immedica Agreement, which was attributable to the PEACE Phase 3 trial and BLA package.

Research and Development Expenses. Our Research and development expenses incurred during the first half of the six months ended June 30, 2023 primarily relate to clinical study costs associated with our legacy assets. Research and development expenses incurred during the second half of the six months ended June 30, 2023 primarily relate to costs with winding down our clinical studies. Wind down costs include final patient visits, collection and analysis of final patient data, the creation and submission of final research reports, site and pharmacy closeouts, and formally closing the studies with regulatory agencies. Research and development expenses decreased by $1.2 million, or 4%, to $31.9 million for the six months ended June 30, 2023, from $32.4 million for the six months ended June 30, 2022. The change in research and development expenses was primarily due to:

- a $3.2 million decrease in pegzilarginase activities associated with the PEACE Phase 3 trial and BLA submission activities;
- a $1.6 million decrease in toxicology costs related to pegtarviliase;
- a $0.5 million decrease in compensation due to reductions in headcount made prior to the restructuring; partially offset by
- a $2.4 million increase in restructuring costs net of savings; and
- a $1.2 million increase in expenses associated with the Paragon Agreement.
- a $0.6 million increase in manufacturing costs for AGLE-325.

General and Administrative Expenses. General and administrative expenses increased by $0.8 million, or 5%, to $17.3 million for the six months ended June 30, 2023, from $16.5 million for the six months ended June 30, 2022. The increase in general and administrative expenses was due to a $2.6 million increase in due to restructuring costs net of restructuring savings, partially offset by a $1.8 million decrease in pegzilarginase expense primarily driven by a reduction in commercial readiness activities.

Acquired In-process Research and Development Expenses. Acquired in-process research and development expenses were $130.5 million for the six months ended June 30, 2023, as the Spyre transaction was determined by management to be an asset acquisition, in accordance with U.S. GAAP, in which the product candidates have no alternative future use. There was no such expense during the six months ended June 30, 2022.

Change in fair value of forward contract liability. Non-cash expenses associated with the change in fair value of the forward contract liability were $58.2 million for the three months ended June 30, 2023. This expense represents the change in fair value of the underlying Series A Preferred Stock between June 22, 2023 and June 30, 2023. There was no such expense during the three months ended June 30, 2022.

Liquidity and Capital Resources

Sources of liquidity

We are a preclinical 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 sale of any products. Since our inception and through June 30, 2023, we have funded our operations primarily by raising an aggregate of approximately $716.2 million of gross proceeds 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.

In March 2021, we entered into the Immedica Agreement, pursuant to which Immedica licensed the product rights for commercialization of pegzilarginase in the European Economic Area, United Kingdom, Switzerland, Andorra, Monaco, San Marino, Vatican City, Turkey, Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Bahrain, and Oman. In April 2021, we received an upfront payment of $21.5 million from Immedica. Under the terms of the Immedica Agreement, we were also eligible to receive regulatory and commercial milestone payments and entitled to receive royalties in the mid-20 % range on the net sales of the product in countries included in the Immedica Agreement. In July 2021, the Immedica Agreement was modified to include additional development services, up to $3.0 million, to support the PEACE Phase 3 trial and BLA package performance obligation. On July 27, 2023, we announced that we had entered into an agreement to sell the global rights to pegzilarginase to Immedica for $15.0 million in upfront cash proceeds and up to $100.0 million in contingent milestone payments. The sale of pegzilarginase to Immedica supersedes and terminates the previous license agreement between us and Immedica.

In July 2020, we filed and the SEC declared effective a shelf registration statement on Form S-3 (the "2020 Registration Statement"), for the potential offering, issuance and sale by us of up to $400.0 million of our common stock, preferred stock, debt securities, warrants, subscription rights and units consisting of all or some of these securities.

In May 2022, we sold 10,752,688 shares of common stock and pre-funded warrants to purchase up to 17,372,312 shares of common stock in a registered direct offering (the "2022 RDO"), for gross proceeds of $45.0 million, resulting in net proceeds of $42.9 million after deducting placement agent fees and offering costs. The shares of common stock and pre-funded warrants sold in the 2022 RDO were offered pursuant to the 2020 Registration Statement.

Also in May 2022, we entered into a sales agreement (the "2022 Sales Agreement") with JonesTrading Institutional Services LLC, as sales agent, to issue and sell shares of our common stock for an aggregate offering price of $60.0 million under an at-the-market offering program with JonesTrading Institutional Services LLC. As of the date of the filing of this report, $60.0 million of our common stock remained available for sale pursuant to the 2022 Sales Agreement. Any sales of common stock to be sold under the 2022 Sales Agreement will be made pursuant to the 2020 Registration Statement.

In connection with the Asset Acquisition, in June 2023, we completed a PIPE transaction with the sale of Series A Preferred Stock to a group of Investors. We sold an aggregate of 721,452 shares of Series A Preferred Stock for an aggregate purchase price of approximately $210.0 million before deducting placement agent and other offering expenses of approximately $12.7 million.

Our primary use of cash is to fund the development of our product candidates, prepare for the potential commercialization 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 preclinical 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 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.

Future funding requirements and operational plan

Due to our significant research and development expenditures, we have generated substantial losses in each period since inception. We have an accumulated deficit of $661.1 million as of June 30, 2023. We anticipate that we will continue to generate losses into the foreseeable future as we develop our product candidates, seek regulatory approval of those candidates and begin to commercialize any approved products. Until such time as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings, research grants, collaborations, license and development agreements, or other sources. We currently have no debt, credit facility or additional committed capital. To the extent that we raise additional equity, the ownership interest of our stockholders will be diluted.

Based on our available cash and cash equivalents of $235.4 million as of June 30, 2023, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date the accompanying condensed consolidated financial statements included in this Form 10-Q are issued. If our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock, as described in our Certificate of Designation relating to the Series A Preferred Stock. The cash redemption is not in our control and raises substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements assume we will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Cash flows

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

	Six Months Ended June 30,	
	2023	2022
Net cash, cash equivalents, and restricted cash (used in) provided by:		
Operating activities	$ (34,277)	$ (46,936)
Investing activities	24,510	26,509
Financing activities	210,002	42,816
Effect of exchange rate on cash, cash equivalents, and restricted cash	24	(95)
Net increase in cash, cash equivalents, and restricted cash	$ 200,259	$ 22,294

Cash used in operating activities

Cash used in operating activities for the six months ended June 30, 2023 was $34.3 million and reflected a net loss of $235.5 million. Our net loss was offset in part by non-cash expenses of $130.5 million for acquired IPR&D, $58.2 million change in fair value of forward contract liability, $3.6 million for stock-based compensation, $2.6 million loss on disposal of long-lived assets, $1.0 million for depreciation and amortization, and $0.9 million loss on lease abandonment. The net change in operating assets and liabilities of $4.6 million was primarily related to a $3.4 million decrease in prepaids and other current assets, a $2.0 million increase in accounts payable, a $0.6 million increase in deferred revenue, partially offset by a $1.3 million increase in development receivables.

Cash used in operating activities for the six months ended June 30, 2022 was $46.9 million and reflected a net loss of $46.8 million. Our net loss was offset in part by a non-cash expense of $4.1 million for stock-based compensation and $1.0 million for depreciation and amortization. The net change in operating assets and liabilities of $5.5 million was primarily related to a $2.4 million increase in prepaid and other current assets, a $1.7 million decrease in accrued compensation costs and a $0.9 million decrease in deferred revenue.

Cash provided by investing activities

Cash provided by investing activities for the six months ended June 30, 2023 was $24.5 million and consisted of $21.0 million in maturities and sales of marketable securities and $3.0 million cash assumed from the Asset Acquisition.

Cash provided by investing activities for the six months ended June 30, 2022 was $26.5 million and consisted of $54.3 million in maturities and sales of marketable securities, partially offset by $27.8 million in purchases of marketable securities.

Cash provided by financing activities

Cash provided by financing activities for the six months ended June 30, 2023 was $210.0 million, which primarily consists of the gross proceeds from the issuance of the Series A Preferred Stock related to the PIPE.

Cash provided by financing activities for the six months ended June 30, 2022, was $42.8 million, which consisted of $45.0 million from the registered direct offering of our common stock and pre-funded warrants in May 2022, offset by $2.0 million of placement agent fees and offering costs, and $0.2 million sale of common stock under our 2016 Employee Stock Purchase Plan, partially offset by $0.3 million in principal payments made on our finance lease obligations.

Contractual Obligations and Other Commitments

Effective, June 30, 2023, the Company abandoned its leased corporate headquarters and laboratory space located in Austin, Texas. As a result, the Company recognized an impairment loss related to the operating right-of-use asset of $0.9 million. On August 7, 2023, the Company terminated its building lease in Austin, Texas. The termination agreement obligates the Company to pay the lessor a $2.0 million termination fee in exchange for releasing the Company of all further obligations under the lease.

We have entered into agreements in the normal course of business with contract research organizations for clinical trials and contract manufacturing organizations, and with vendors for nonclinical research studies and other services and products for operating purposes. These contractual obligations are cancelable at any time by us, generally upon 30 to 60 days' prior written notice to the vendor.

Recently Adopted Accounting Pronouncements

We early adopted the Financial Accounting Standards Board's Accounting Standards Update 2020-06, "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), effective as of January 1, 2023 using the modified retrospective method. Among other amendments, ASU 2020-06 eliminates the cash conversion and beneficial conversion feature models in ASC 470-20 that require an issuer of certain convertible debt and preferred stock to separately account for embedded conversion features as a component of equity, as well as changed the accounting for diluted earnings-per-share for convertible instruments and contracts that may be settled in cash or stock. Additionally, ASU 2020-06 requires that the if-converted method, which is more dilutive than the treasury stock method, be used for all convertible instruments. We applied ASU 2020-06 to all Series A Preferred Stock during 2023, accordingly the Company did not apply the cash conversion or beneficial conversion feature models in its analysis of the Series A Preferred Stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. 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. 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 due to the low risk profile of our investments, a 10% change in interest rates would not have a material effect on the total market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

As of June 30, 2023, we held $235.4 million in cash and cash equivalents, all of which was denominated in U.S. dollar assets, and consisting primarily of investments in money market funds, commercial paper, and corporate bonds.

We are also exposed to market risk related to changes in foreign currency exchange rates, as a result of 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. For the six months ended June 30, 2023, 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.

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 on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Financial Condition and Capital Requirements

There is no guarantee that our Asset Acquisition will increase stockholder value.

In June 2023, we acquired Spyre. We cannot guarantee that implementing the Asset Acquisition and related transactions will not impair stockholder value or otherwise adversely affect our business. The Asset Acquisition poses significant integration challenges between our businesses and management teams which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Asset Acquisition to our stockholders.

We will need to raise additional capital, and if we are unable to do so when needed, we will not be able to continue as a going concern.

This Quarterly Report includes disclosures regarding our management's assessment of our ability to continue as a going concern. As of June 30, 2023, we had $235.4 million of cash and cash equivalents. We will need to raise additional capital to continue to fund our operations and service our debt obligations in the future. If we are unable to raise additional capital when needed, we will not be able to continue as a going concern. If our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock, as described in our certificate of designation relating to the Series A Preferred Stock. The cash redemption is not in our control and raises substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements assume the Company will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

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 rising interest rates and the current downturn in the U.S. capital markets and the biotechnology sector in general. Competition for additional capital among biotechnology companies may be particularly intense during this present economic downturn. 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 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 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 preclinical 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 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. For example, as of the filing of this Quarterly Report, we are subject to the limitations set forth in Instruction I.B.6 of Form S-3 (the "baby shelf restrictions").

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

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 the research programs with respect to which we have exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Paragon Agreement 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 drug product are not commercially feasible, we will need to develop or procure our drug 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 three and six months ended June 30, 2023, we reported a net loss of $217.1 million and $235.5 million, respectively. For the years ended December 31, 2022 and 2021, we reported a net loss of $83.8 million and $65.8 million, respectively. As of June 30, 2023, we had an accumulated deficit of $661.1 million. We expect that our current cash and cash equivalents, including approximately $210.0 million we received on June 26, 2023 from the sale of our Series A Preferred Stock in the PIPE. We will need to raise substantial additional capital to continue to fund our operations in the future. If our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock, as described in our certificate of designation relating to the Series A Preferred Stock. The cash redemption is not in our control and raises substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements assume the Company will continue as a going concern through the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

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 clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through 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 preclinical development and initiate the 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 preclinical 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 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 common stockholder. 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 June 2023, we sold 721,452 shares of our Series A Preferred Stock in the PIPE to the Investors for gross proceeds of approximately $210.0 million. Subject to receiving the requisite stockholder approval and certain beneficial ownership limitations set by each preferred stockholder, each share of Series A Preferred Stock will automatically convert into an aggregate of approximately 1,000 shares of our Common Stock. We are required to solicit the consent of our stockholders with regard to conversion of the shares of Series A Preferred Stock issued in the PIPE. If our stockholders fail to approve such matters, we may be subject to financial penalties that could materially harm our business, including the forced settlement of shares of Series A Preferred Stock for cash, as described in the Certificate of Designation.

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 addressed by our programs.

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

Our competitors have developed, are developing or will develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance.

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

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

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

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

- regulators or institutional review boards ("IRBs"), the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trial sites deviating from trial protocol, or dropping out of a trial;
- clinical trials of any programs may fail to show safety or efficacy, produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any programs may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our programs may be greater than we anticipate;
- the quality of our programs or other materials necessary to conduct clinical trials of our programs may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of our programs for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our programs;
- our failure to establish an appropriate safety profile for a program based on clinical or preclinical data for such programs as well as data emerging from other therapies in the same class as our programs; and
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

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

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

We are substantially dependent on the success of our two most advanced programs, SPY001 and SPY002, and our anticipated clinical trials of such programs may not be successful.

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our two most advanced programs, SPY001 and SPY002. We exercised our Option with respect to the SPY001 program on July 12, 2023 and we continue to hold the unexercised Option with respect to the SPY002 program. We are investing a majority of our efforts and financial resources into the research and development of these programs. We anticipate initiating a Phase 1 clinical trial in healthy volunteers of SPY001 in the first half of 2024 and of SPY002 in the second half of 2024, each subject to the filing of an IND or foreign equivalent and regulatory approval. The success of our programs is dependent on observing a longer half-life of our programs in humans than other mAbs currently marketed and in development as we believe this longer half-life has the potential to result in a more favorable dosing schedule for our programs, assuming they successfully complete clinical development and obtain marketing approval. This is based in part on the assumption that the longer half-life we have observed in non-human primates ("NHPs") will translate into an extended half-life of our programs in humans. To the extent we do not observe this extended half-life when we dose humans with our programs, it would significantly and adversely affect the clinical and commercial potential of our programs.

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

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

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

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, such as the expected timing for the anticipated commencement of our Phase 1 clinical trials in IBD, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our programs may be delayed or never achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

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

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

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

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

condition, results of operations and prospects.

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

Before obtaining marketing approval from regulatory authorities for the sale of any program, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our program in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of NHPs to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly and, if the shortage continues, could also result in delays to our development timelines. Furthermore, a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their programs performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their programs. In addition, we expect to rely on patients to provide feedback on measures such as itch and quality of life, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and from site to site within a clinical trial.

We cannot be sure that the FDA will agree with our clinical development plan. We plan to use the data from our planned Phase 1 trials of SPY001 and SPY002 in healthy volunteers to support Phase 2 trials in IBD and other I&I indications. If the FDA requires us to conduct additional trials or enroll additional patients, our development timelines may be delayed. We cannot be sure that submission of an IND, BLA or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our programs for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements ("GCPs") or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO) and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us.

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

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

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

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

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

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

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

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our preclinical studies in NHPs have not shown any such characteristics to date, we have not yet initiated any clinical trials in humans. If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more programs altogether. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend any clinical trials of any program at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies and trials have later been found to cause side effects that prevented their further development. Other potential products have shown side effects in preclinical studies, which side effects do not present themselves in clinical trials in humans. Even if the side effects do not preclude the program from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our programs may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our programs may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

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

If any of the foregoing events occur or if one or more of the research programs with respect to which we have exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Paragon Agreement prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected programs. For example, we are initially focused on our most advanced programs, SPY001 and SPY002. As a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable programs. If we do not accurately evaluate the commercial potential or target market for a particular program, we may relinquish valuable rights to that program through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such program.

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

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. There are several approved products and product candidates in later stages of development for the treatment of IBD. 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. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates half-life extension for our targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. An extended half-life may make it more difficult for patients to change treatments and there is a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Market acceptance of our programs will depend on many factors, including factors that are not within our control.

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

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

We are developing product candidates for the same indication: IBD, and may in the future develop our programs for other I&I indications. Each such program targets a different mechanism of action. However, developing multiple programs for a single indication may negatively impact our business if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple programs are approved for the same indication, they may compete for market share, which could limit our future revenue.

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

We currently intend to conduct our Phase 1 clinical trial for the SPY001 program and for the SPY002 program in Australia and we may choose to conduct one or more of our future clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

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

Risks Related to Government Regulation

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

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the programs involved. We cannot commercialize programs in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize programs outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our programs, including our most advanced programs, SPY001 and SPY002, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our programs are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our programs may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our programs could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a program is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our programs; we may be unable to demonstrate that a program's clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our programs may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our programs; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of

future clinical trial results may result in our failing to obtain regulatory approval to market our programs, which would significantly harm our business, results of operations and prospects.

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

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

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

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

The ACA includes the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

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

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

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

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority

may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our programs and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our programs. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our programs, if approved. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

We intend to seek approval to market our programs in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our programs, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any programs that we may develop will depend in part on the extent to which reimbursement for these programs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor’s product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our programs are approved and we are found to have improperly promoted off-label uses of those programs, we may become subject to significant liability, which would materially adversely affect our business and financial condition.

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

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

We may seek Fast Track Designation for one or more of our programs. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular program is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protection, confidentiality agreements and the Paragon Agreement to protect the intellectual property related to our programs and technologies and to prevent third parties from competing with us. Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, programs and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. We own and have licensed rights to pending patent applications and expect to continue to file patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on programs worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our

technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications.

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

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

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

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

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

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

inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts

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

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, a European Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court 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. Although we do not currently own any European patents or applications, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

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

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our programs in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months

after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. For example, certain intellectual property we license from the University of Texas at Austin includes inventions that were made with U.S. government support. The U.S. government therefore 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 our competitive position on our programs for an adequate amount of time.

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

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

Our 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.

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, the research programs with respect to which we have exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Paragon Agreement and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our programs. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our programs and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

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

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

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

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

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may be involved in mergers, acquisitions or similar transactions and may have relationships with other

commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our current or future programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our programs.

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

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on CMOs to manufacture our programs. We have not yet caused our programs to be manufactured on a commercial scale and may not be able to do so for any of our programs, if approved. We currently have a sole source relationship for our supply of the SPY001 program. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, it could have a negative effect on the clinical development of our programs and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our programs. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our programs or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our programs, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of programs or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our programs or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our programs at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our programs by the FDA, result in higher costs or adversely impact commercialization 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 experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a 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 preclinical stage biotechnology company with a limited operating history, and, as of June 30, 2023, we had 14 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 of our management team 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 employees 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 such as our scientific advisory board, to assist us in formulating our discovery and nonclinical and clinical development and commercialization strategy. Our consultants and advisors, including members of our scientific advisory board, 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 programs in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our programs before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any of our programs. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our programs, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our programs will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our programs and ultimately commercialize our programs in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We will adopt a code of conduct, which will become effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, but it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

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

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our programs could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

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

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

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

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

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

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. 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. Our NOLs and other tax attributes arising before our conversion from a Delaware limited liability company to a Delaware corporation in 2015 also may be limited by the Separate Return Limitation Year rule, which could increase our U.S. federal tax liability. 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 third parties who we work with are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition and results of operations.

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

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

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. The U.S. Congress is considering legislation that would restore the current deductibility of research and development expenditures; however, we have no assurance that the provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

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

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new programs or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

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

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

Risks Related to Our Common Stock

Pursuant to the terms of the Acquisition Agreement, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve this matter, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

Under the terms of the Securities Purchase Agreement, we agreed to call and hold a meeting of our stockholders to obtain the requisite approval for the conversion of all outstanding shares of Series A Preferred Stock issued in the Asset Acquisition and PIPE into shares of our common stock, as required by the Nasdaq listing rules, within 75 days from the closing of the PIPE and, if such approval is not obtained at that meeting, to seek to obtain such approval at an annual or special stockholders meeting to be held at least every 90 days thereafter until such approval is obtained, which would be time consuming and costly. Additionally, if our stockholders do not timely approve the conversion of our Series A Preferred Stock, then the holders of our Series A Preferred Stock may be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock at such time, as described in our Certificate of Designation relating to the Series A Preferred Stock. If we are forced to settle a significant amount of the Series A Preferred Stock, it could materially affect our results of operations, including raising a substantial doubt about our ability to continue as a going concern within one year from the issuance of this quarterly report.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. To maintain the listing of our common stock on The Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others, a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement").

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements or the Minimum Bid Price Requirement, The Nasdaq Capital Market may take steps to delist our common stock, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Minimum Bid Price Requirement, or prevent future non-compliance with The Nasdaq Capital Market's listing requirements.

On July 13, 2023, we received approval (the "Approval") from Nasdaq to transfer the listing of our common stock from The Nasdaq Global Market to The Nasdaq Capital Market (the "Transfer"). The Nasdaq Capital Market operates in substantially the same manner as The Nasdaq Global Market, but with less stringent listing requirements, although listed companies must meet certain financial requirements and comply with Nasdaq's corporate governance requirements. In connection with the Approval, we have been granted an additional 180-calendar day grace period, or until January 8, 2024, to regain compliance with the Minimum Bid Price Requirement. To regain compliance with the Minimum Bid Price Requirement and qualify for continued listing on The Nasdaq Capital Market, the minimum bid price per share of our common stock must be at least $1.00 for at least ten consecutive business days during the additional 180-calendar day grace period. If we do not regain compliance during this additional grace period, our common stock would be subject to delisting by Nasdaq. As part of our Transfer application, we notified Nasdaq that in order to regain compliance with the Minimum Bid Price Requirement during the additional grace period, we intend to implement a reverse stock split at a ratio ranging from 1-for-10 shares up to a ratio of 1-for-25 shares, determined by our board of directors, which was approved by our stockholders on June 6, 2023. If our common stock becomes subject to delisting as a result of our failure to regain compliance with the Minimum Bid Price Requirement by January 8, 2024, we may appeal the decision to a Nasdaq Hearings Panel. In the event of an appeal, our common stock would remain listed on The Nasdaq Capital Market pending a written decision by the Nasdaq Hearings Panel following a hearing. In the event that the Nasdaq Hearings Panel determines not to continue our listing and our common sock is delisted from The Nasdaq Capital Market, our common stock may trade on the OTC Bulletin Board or other small trading markets, such as the pink sheets.

We are actively monitoring our stock price and will consider any and all options available to regain compliance. The alternatives to trading on the Nasdaq Stock Market or another national securities exchange are generally considered to be less efficient and less broad-based than the national securities exchanges and the liquidity of our common stock will likely be reduced if it fails to regain compliance with the Minimum Bid Price Requirement.

There can be no assurance that we will be successful in maintaining the listing of our common stock on The Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

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 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 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 the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock. This provision of the Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum 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 provides 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.

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.

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.

Concurrently and in connection with the execution of the Acquisition Agreement, certain former Spyre securityholders, as of immediately prior to the Asset Acquisition, and certain of our directors and officers as of immediately prior to the Asset Acquisition entered into lock-up agreements with us , pursuant to which each such stockholder, will be subject to a 180-day lockup on the sale or transfer of shares of our common stock held by each such stockholder, at the closing of the Asset Acquisition, including those shares received by former Spyre securityholders in the Asset Acquisition. Upon expiration of this 180-day lockup period, these shares will become eligible for sale in the public market.

On June 22, 2023, we also entered into a registration rights agreement (the "Registration Rights Agreement") with the Investors. Pursuant to the Registration Rights Agreement, we are obligated to prepare and file a resale registration statement with the SEC within 45 calendar days following the closing of the PIPE (the "Filing Deadline"). We will use our reasonable best efforts to cause this registration statement to be declared effective by the SEC within 30 calendar days of the Filing Deadline (or within 60 calendar days if the SEC reviews the registration statement). Once such registration statement is declared effective, the shares subject to the registration statement will no longer constitute restricted securities and may be sold freely in the public markets, subject to lapse on any related contractual restrictions related thereto of any Investor.

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 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 potential 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 are granted and 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 will be 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

The market price of our Common Stock has historically been volatile, and the market price of our Common Stock may drop 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 early-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;
- 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.

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.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting, and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. 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. 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.

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.

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. 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. This requires that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner for each period.

We or any subsequent testing by our independent registered public accounting firm may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. 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.

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.

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.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosure.

Not applicable.

Item 5. Other Information.

Not applicable.

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	Incorporate by 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.	8-K	001-37722	06/23/2023	2.1	
3.1	Restated Certificate of Incorporation	S-1/A	333-205001	9/14/2015	3.2	
3.2	Amended and Restated Bylaws	8-K	001-37722	12/19/2022	3.1	
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock	8-K	001-37722	06/23/2023	3.1	
10.1	Securities Purchase Agreement, dated as of June 22, 2023, by and among Aeglea BioTherapeutics, Inc. and each purchaser thereto	8-K	001-37722	06/23/2023	10.1	
10.2	Form of Registration Rights Agreement, by and among Aeglea BioTherapeutics, Inc. and each purchaser thereto	8-K	001-37722	06/23/2023	10.2	
10.3+	Offer Letter, dated June 22, 2023, by and between Aeglea BioTherapeutics, Inc. and Cameron Turtle					X
10.4#	Antibody Discovery and Option agreement, dated May 25, 2023, by and between Paragon Therapeutics, Inc., Parapyre Holding LLC and Spyre Therapeutics, Inc.					X
10.5+	First Amendment to the Aeglea BioTherapeutics, Inc. 2016 Equity Incentive Plan					X
10.6+	First Amendment to the Aeglea BioTherapeutics, Inc. 2018 Equity Inducement Plan					X
10.7+	Amended and Restated Spyre 2023 Equity Incentive Plan					X
10.8+	Form of Stock Option Agreement under the Aeglea BioTherapeutics, Inc. 2018 Equity Inducement Plan					X
10.9#	Asset Purchase Agreement, dated July 27, 2023, by and between Aeglea BioTherapeutics, Inc. and Immedica Pharma AB					X
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					X

Exhibit Number	Description	Form	File No	Incorporate by Date of Filing	Exhibit No.	Filed Herewith
32.1(1)	Certification of the Principal Executive and 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
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 on Form 10-Q for the quarter ended June 30, 2023, formatted in Inline XBRL and contained in Exhibit 101					

+ Indicates management contract or compensatory plan.
# Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
(1) The certifications on Exhibit 32 hereto are deemed 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 Section 13 or 15(d) 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: August 11, 2023

AEGLEA BIOTHERAPEUTICS, INC.

By: /s/ Jonathan Alspaugh
Jonathan Alspaugh
President and Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and duly Authorized Signatory)

Exhibit 10.3

June 22, 2023

Cameron Turtle

Re: Offer of Employment

Dear Cameron:

On behalf of Aeglea BioTherapeutics, Inc. (the "Company"), I am very pleased to offer you a position as Chief Operating Officer of the Company (the "Role") pursuant to this letter agreement (the "Agreement"), provided you accept such offer as indicated by your signature below.

Your employment with the Company in the Role will commence as of June 22, 2023 (the "Effective Date"). Should you not commence services by the Effective Date or if this Agreement is otherwise terminated on or prior to the Effective Date, you hereby agree that this Agreement shall be void *ab initio* and of no force or effect.

1. Position. While serving in the Role, you will initially report to the Board of Directors of the Company (the "Board"), and have such duties, authorities, and responsibilities as are customarily associated with the Role. This is a full-time employment position. It is understood and agreed that, commencing as of the Effective Date you will not engage in any other employment, consulting or other business activities (whether full-time or part-time), except as expressly authorized in writing by the Board. Notwithstanding the foregoing, you may engage in religious, charitable and other community activities so long as such activities do not unreasonably interfere or conflict with your obligations to the Company.

2. Base Salary. Upon and following the Effective Date, as cash compensation for your services, the Company will pay you an initial base salary of $450,000 per year, payable in accordance with the Company's standard payroll schedule and subject to applicable deductions and withholdings. Your base salary will be subject to periodic review and potential adjustment in the Board's discretion. Your base salary in effect at any given time is referred to herein as the "Base Salary."

3. Annual Bonus. Commencing as of the Effective Date, you will be eligible to receive an annual performance bonus targeted at 50% of your Base Salary. The target annual bonus in effect at any given time is referred to herein as "Target Bonus." Your 2023 annual bonus will be prorated based on your period of employment following the Effective Date. The actual bonus amount is discretionary and may be subject to achievement of performance targets established by the Compensation Committee of the Board for such year. To earn an annual bonus, you must be (except as otherwise provided herein) employed by the Company as of the payment date of such bonus. Any annual bonus will be paid no later than March 15th of the calendar year following the calendar year to which such bonus relates.

4. Inducement Grant. Subject to approval by the Company's Board and as a material inducement to you agreeing to become employed by the Company, the Company will grant you nonqualified stock options to purchase 44,650,058 shares of the Company's common stock as soon as practicable following the Effective Date and with an exercise price equal to the fair market value of the underlying shares on the date of grant as determined by the Board (the "Inducement Options"). The Inducement Options will be governed by the terms of the related award agreement, the Company's 2018 Equity Inducement Plan and the terms and conditions approved by the Board. The Inducement Options will be granted in compliance with NASDAQ Listing Rule 5635(c)(4) as a material inducement to you entering into employment with the Company. For the avoidance of doubt, the Inducement Options are in full satisfaction of those certain Replenishment Options referenced in that certain Consulting Agreement entered into between you and Spyre Therapeutics, Inc. as of May 8, 2023 (the "Consulting Agreement"). You acknowledge and agree that you are not entitled to any other compensation pursuant to the Consulting Agreement.

5. Benefits/Paid Time Off. Commencing as of the Effective Date, you will be eligible, subject to the terms of the applicable plans and programs, to participate in the employee benefits and insurance programs generally made available to the Company's full-time employees. Details of such benefits programs, including applicable employee contributions and waiting periods, if applicable, will be made available to you when such benefit(s) become available. You will be entitled to paid time off consistent with the terms of the Company's paid time off policy, as in effect from time to time. The Company reserves the right to modify, limit, amend or cancel any of its benefits plans or programs at any time.

6. Expense Reimbursement. The Company will reimburse you for all reasonable and necessary expenses incurred by you in connection with performing your duties as an employee of the Company and that are pre-approved by the Company, provided that you comply with any Company policy or practice on submitting, accounting for and documenting such expenses.

7. Location. Your primary work location will be remotely in California, provided that you may be required to engage in reasonable travel for business, consistent with the Company's business needs. You may change your remote work location with prior written notice to and approval from the Company.

8. At-Will Employment; Date of Termination. At all times, your employment with the Company is "at will," meaning you or the Company may terminate it at any time for any or no reason, subject to the terms of this Agreement. Although your job duties, title, reporting structure, compensation and benefits, as well as the Company's benefit plans and personnel policies and procedures, may change from time to time (subject to the terms of this Agreement), the "at will" nature of your employment may only be changed in an express written agreement signed by you and an authorized officer of the Company (subject to approval by the Board or the Compensation Committee of the Board). Your last day of employment for any reason is referred to herein as the "Date of Termination." In the event that you elect to end your employment other than for Good Reason, the Company requires you to provide at least 30 days' advance written notice to the Company; and in the event that the Company terminates you without "Cause", you shall be given at least 30 days advance written notice by the Company. Notwithstanding the foregoing, the Company may unilaterally accelerate the Date of Termination, and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

To the extent applicable, you shall be deemed to have resigned from all officer and board member positions that you hold with the Company or any of its respective subsidiaries and affiliates upon the termination of your employment for any reason. You shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

9. Accrued Obligations. In the event of the ending of your employment for any reason, the Company shall pay you (i) your Base Salary and, if applicable, any accrued but unused vacation, through the Date of Termination, and (ii) the amount of any documented expenses properly incurred by you on behalf of the Company prior to any such termination and not yet reimbursed. (the "Accrued Obligations").

10. Severance Pay and Benefits Outside of the Change in Control Period. As explained below, under certain circumstances you will be entitled to severance equal to the Severance Amount (as defined below), accelerated vesting of a portion of your unvested equity awards, plus continued employee benefits pursuant to COBRA (as defined below):

In the event that the Company terminates your employment without Cause outside of the Change in Control Period (as such capitalized terms are defined in Appendix A), then, in addition to the Accrued Obligations, and subject to (i) your execution and non-revocation of a separation agreement and release in a form acceptable to the Company, which shall include a general release of claims against the Company and all related persons and entities and a reaffirmation of the Continuing Obligations (as defined below) and shall provide that if you breach the Continuing Obligations, all payments of the Severance Amount (as defined below) shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven (7) day revocation period:

(a) The Company shall pay you an amount equal to 12 months of your Base Salary plus any bonus earned but unpaid for the year immediately prior to the year of termination (such salary and bonus together, the "Severance Amount").

(b) Notwithstanding anything to the contrary in any applicable equity-based award agreement or plan, the unvested portion of your then outstanding equity-based awards subject to time-based vesting (the "Time-Based Equity Awards") that would have vested within the 12-month period following the Termination Date shall immediately accelerate and become vested or nonforfeitable as of the later of (i) the Date of Termination or (ii) the effective date of the Separation Agreement and Release (such later date being the "Accelerated Vesting Date"); provided that no such acceleration of vesting shall occur if the Date of Termination precedes the one-year anniversary of the Effective Date; and provided further that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between the Date of Termination and the Accelerated Vesting Date.

(c) Subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay to the group health plan provider(s), the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 10(a) and (c), to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over 12 months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

Notwithstanding anything to the contrary in this Agreement, for the avoidance of doubt:

(i) if your employment ends for any reason other than a termination by the Company without Cause, you will be entitled to the Accrued Obligations and will not be entitled to any further compensation from the Company; and

(ii) if your employment ends due to your death or disability, you will receive the Accrued Obligations but will not be eligible for severance pay, accelerated vesting, or benefits, whether pursuant to Section 10, Section 11 or otherwise.

11. Severance Pay and Benefits Within the Change in Control Period. As explained below, under certain circumstances in the event of a Change in Control you would be entitled to accelerated vesting of your unvested equity awards:

In the event that the Company terminates your employment without Cause or you resign for Good Reason, in each case within the Change in Control Period, then, in addition to you being entitled to the Accrued Obligations, and subject to your execution and non-revocation of the Separation Agreement and Release and it becoming fully effective, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven-day revocation period, the Company shall (i) provide you the severance pay and benefits set forth in Section 10, subject to the terms and conditions set forth in Section 10, and (ii) notwithstanding anything to the contrary in any applicable equity-based award agreement or plan, all of your Time-Based Equity Awards shall immediately accelerate and become fully vested or nonforfeitable as of the Accelerated Vesting Date; provided that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between the Date of Termination and the Accelerated Vesting Date.

For the avoidance of doubt, Section 10 and Section 11 of this Agreement are mutually exclusive and in no event shall you be entitled to payments or benefits pursuant to both Section 10 and Section 11 of this Agreement.

12. Continuing Obligations.

(d) **PIIA Agreement**. As a condition of your employment, you are required to enter into a Proprietary Information and Inventions Assignment Agreement, which is enclosed with this Agreement (the "PIIA Agreement"), which must be signed prior to the Effective Date. For purposes of this Agreement, the obligations in this Section 12 and those that arise in the PIIA Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(e) **Third Party Agreements and Rights**. You hereby confirm that you are not bound by the terms of any agreement with any previous employer or other party which would prevent you from performing your obligations hereunder. You represent to the Company that your execution of this Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party. In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(f) **Litigation and Regulatory Cooperation**. You shall cooperate fully with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while you were engaged or employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information. Your full cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being reasonably available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your engagement and employment, you also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. The Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 12(c).

(g) **Relief**. You agree that it would be difficult to measure any damages caused to the Company which might result from your breach of any of the Continuing Obligations, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, you agree that if you breach, or propose to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

13. Golden Parachute Taxes.

(h) **Best After-Tax Result**. In the event that any payment or benefit received or to be received by you pursuant to this Agreement or otherwise ("Payments") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this subsection (a), be subject to the excise tax imposed by Section 4999 of the Code, any successor provisions, or any comparable federal, state, local or foreign excise tax ("Excise Tax"), then, subject to the provisions of Section 14, such Payments shall be either (A) provided in full pursuant to the terms of this Agreement or any other applicable agreement, or (B) provided as to such lesser extent which would result in the Payments being $1.00 less than the amount at which any portion of the Payments would be subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state, local and foreign income, employment and other taxes and the Excise Tax (including, without limitation, any interest or penalties on such taxes), results in the receipt, on an after-tax basis, of the greatest amount of payments and benefits provided for hereunder or otherwise, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Unless the Company and you otherwise agree in writing, any determination required under this Section shall be made by independent tax counsel designated by the Company and reasonably acceptable to you ("Independent Tax Counsel"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required under this Section, Independent Tax Counsel may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code; provided that Independent Tax Counsel shall assume that you pay all taxes at the highest marginal rate. The Company and you shall furnish to Independent Tax Counsel such information and documents as Independent Tax Counsel may reasonably request in order to make a determination under this Section. The Company shall bear all costs that Independent Tax Counsel may reasonably incur in connection with any calculations contemplated by this Section. In the event that Section 13(a)(ii)(B) above applies, then based on the information provided to you and the Company by Independent Tax Counsel, the cutback described hereunder will apply as to compensation not subject to Section 409A of the Code prior to compensation subject to Section 409A of the Code and will otherwise apply on a reverse chronological basis from payments latest in time. If the Internal Revenue Service (the "IRS") determines that any Payment is subject to the Excise Tax, then Section 13(b) hereof shall apply, and the enforcement of Section 13(b) shall be the exclusive remedy to the Company.

(i) **Adjustments**. If, notwithstanding any reduction described in Section 13(a) hereof (or in the absence of any such reduction), the IRS determines that you are liable for the Excise Tax as a result of the receipt of one or more Payments, then you shall be obligated to surrender or pay back to the Company within one-hundred 120 days after a final IRS determination, an amount of such payments or benefits equal to the "Repayment Amount." The Repayment Amount with respect to such Payments shall be the smallest such amount, if any, as shall be required to be surrendered or paid to the Company so that your net proceeds with respect to such Payments (after taking into account the payment of the Excise Tax imposed on such Payments) shall be maximized. Notwithstanding the foregoing, the Repayment Amount with respect to such Payments shall be zero if a Repayment Amount of more than zero would not eliminate the Excise Tax imposed on such Payments or if a Repayment Amount of more than zero would not maximize the net amount received from the Payments. If the Excise Tax is not eliminated pursuant to this Section 13(b), you shall pay the Excise Tax.

14. Section 409A.

(j) Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this Agreement or otherwise on account of your separation from service would be considered deferred compensation otherwise subject to the additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision (without interest), and the balance of the installments shall be payable in accordance with their original schedule.

(k) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(l) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the termination of your employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-l(h).

(m) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(n) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

15. Withholding; Tax Effect. All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or the Board related to tax liabilities arising from your compensation.

16. Recoupment. Amounts paid or payable under this Agreement shall be subject to the provisions of any applicable clawback or recoupment policies or procedures adopted by the Company, which clawback or recoupment policies may provide for forfeiture and/or recoupment of amounts paid or payable under this Agreement. No forfeiture or recoupment under such policies or procedures will give rise to a right to resign for Good Reason under this Agreement or any other agreement between you and the Company.

17. Interpretation and Enforcement. This Agreement, together with Appendix A, the PIIA Agreement and the other agreements referenced herein, constitute the complete agreement between you and the Company, contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company, and, for the avoidance of doubt, the Consulting Agreement. The terms of this Agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this Agreement or arising out of, related to, or in any way connected with this Agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by California law, excluding laws relating to conflicts or choice of law and Disputes arising in connection with any equity incentive plan, which shall be governed by the terms of the applicable equity incentive plan. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the State of California in connection with any Dispute or any claim related to any Dispute, except for Disputes arising under any equity incentive plan.

18. Assignment. Neither you nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further, that if you remain employed or become employed by the Company, the purchaser or any of their affiliates in connection with any such transaction, then you shall not be entitled to any payments, benefits or vesting pursuant to Section 10 or pursuant to Section 11 of this Agreement solely as a result of such transaction. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of your and its respective successors, executors, administrators, heirs and permitted assigns.

19. Waiver; Amendment. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized representative of the Company.

20. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

21. Conditions. As with any employee, you must submit satisfactory proof of your identity and your legal authorization to work in the United States on or prior to the Effective Date.

22. Other Terms. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of your employment to the extent necessary to effectuate the terms contained herein. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement. This Agreement may be executed in separate counterparts. When both counterparts are signed, they shall be treated together as one and the same document. PDF copies of signed counterparts shall be equally effective as originals.

I look forward to working with you to make the Company a great success.

Sincerely,

/s/ Jonathan Alspaugh

Name: Jonathan Alspaugh
Title: President and Chief Financial Officer

Accepted and acknowledged:

/s/ Cameron Turtle

Cameron Turtle

Date: June 22,2023

aeglea

Appendix A

1. "Cause" shall mean (i) your dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business that results in or is reasonably anticipated to result in material harm to the Company; (ii) your conviction or please of no contest to: (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) your failure to perform in all material respects your assigned duties and responsibilities to the reasonable satisfaction of the Board, which failure continues, in the reasonable judgment of the Board, for 30 days after written notice given to you describing such failure; (iv) your gross negligence, willful misconduct that results in or is reasonably anticipated to result in material harm to the Company; or (v) your violation of any material provision of any agreement(s) between you and the Company or any written Company policies including, without limitation, agreements relating to non-solicitation, non-disclosure and/or assignment of inventions or policies related to ethics or workplace conduct.

2. "Change in Control" shall have the meaning provided for the term "Corporate Transaction" under the Company's 2016 Equity Incentive Plan (or the meaning provided to any word of similar import under any successor plan).

3. "Change in Control Period" shall mean the 12-month period that immediately follows the first event constituting a Change in Control.

4. "Good Reason" shall mean that you have complied with the Good Reason Process (hereinafter defined) following the occurrence, without your written consent, of any of the following events: (i) a material diminution in your base salary or Target Bonus except for across-the-board salary and target bonus reductions of no more than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (ii) a material change in the geographic location at which you are required to provide services to the Company or a requirement that you change your remote location to a location outside the state of California; (iii) a material reduction in your duties, authority or responsibilities; (iv) the failure of the Company to obtain the assumption of this Agreement by a successor; or (v) the material breach of this Agreement (or any other agreements with you) by the Company.

5. "Good Reason Process" shall mean that (i) you reasonably determine in good faith that a "Good Reason" condition has occurred; (ii) you notify the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) you cooperate in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) you terminate your employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

Exhibit 10.4

ANTIBODY DISCOVERY AND OPTION AGREEMENT

This Antibody Discovery and Option Agreement ("**Agreement**") is entered into and effective as of May 25, 2023 (the "**Effective Date**"), by and among Paragon Therapeutics, Inc., a Delaware corporation ("**Paragon**"), Parapyre Holding LLC, a Delaware limited liability company ("**Parapyre**") and Spyre Therapeutics, Inc. ("**Spyre**"), a Delaware corporation. Paragon, Parapyre and Spyre are also referred to herein individually as a "**Party**", or collectively as the "**Parties**."

Recitals

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

Whereas, Spyre desires to engage each of Paragon and Parapyre to identify, evaluate and develop one or more antibody candidates directed to certain mutually agreed therapeutic targets of interest to Spyre;

Whereas, Paragon and Parapyre are willing to perform certain antibody discovery and development activities for Spyre; and

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

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

Agreement

ARTICLE 1
DEFINED TERMS

1.1"**Actual Annual Costs**" shall have the meaning set forth in Section 5.2(b).

1.2"**Affiliate**" shall mean any entity, other than Spyre or Fairmount Funds Management LLC and its affiliated funds, controlled by, controlling, or under common control with a Party hereto. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" or "under common control") means the direct or indirect ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) in the equity of, or the right to appoint more than fifty percent (50%) of the directors or management of, such corporation or other business entity.

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

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

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

1.6"**Budget**" means the agreed budget for the activities set forth in the applicable Research Plan.

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

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

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

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

1.11 "**Confidential Information**" of a Party shall mean any and all non-public scientific, business, regulatory or technical information that is disclosed or made available by or on behalf of one Party (the "**Disclosing Party**") to any other Party (a "**Receiving Party**") in connection with this Agreement, whether in writing, orally, visually or otherwise. Notwithstanding any provision of this Agreement to the contrary, all Project Antibody Inventions and Project Antibody Technology shall be the Confidential Information of all Parties, and each Party shall be deemed as both the "Disclosing Party" and the "Receiving Party" with respect thereto; provided that if Spyre does not exercise its Option or the Parties do not enter into a License Agreement in accordance with this Agreement, then the Project Antibody Inventions and Project Antibody Technology shall thereafter be the Confidential Information of Paragon.

1.12"**Control**" (including any variations such as "**Controlled**" and "**Controlling**") shall mean, with respect to any Technology or Intellectual Property Rights, possession by a Party and the ability (whether by ownership, license or otherwise) to grant a license or a sublicense of or under such Technology or Intellectual Property Rights without violating the terms of any agreement or other arrangement with any Third Party.

1.13"**Cost Advance**" shall have the meaning set forth in Section 5.2(a).

1.14"**Cover**" or "**Covering**" means, with respect to a Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, importation, or exportation of such product would infringe a valid and unexpired claim of such Patent.

1.15"**Deliverables**" has the meaning set forth in Section 2.1(c).

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

1.17"**Derived Antibody Patent**" means any Patent that Covers the composition of matter of, or any method of specifically making or using, any Derived Antibody.

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

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

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

1.21"**Dispute**" shall have the meaning provided in Section 11.7.

1.22"**Election Notice**" shall have the meaning provided in Section 4.3.

1.23"**Field**" shall mean the prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas, except with respect to IL-23, where "**Field**" shall mean the prophylaxis, palliation, treatment and diagnosis of human disease and disorders in the therapeutic area of inflammatory bowel disease.

1.24"**Indemnified Party**" shall have the meaning provided in Section 10.3.

1.25"**Indemnifying Party**" shall have the meaning provided in Section 10.3.

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

1.27"**JDC"** shall have the meaning provided in Section 3.1.

1.28"**Know-How**" shall mean all technical information and know-how in any tangible or intangible form, including (a) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or

processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (b) all data, instructions, processes, formulae, strategies, and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical, or otherwise and whether related to safety, quality control, manufacturing or other disciplines. Notwithstanding the foregoing, Know-How excludes Patent claims.

1.29"**License Agreement**" shall have the meaning set forth in Section 4.4(b).

1.30"**License Template**" shall have the meaning set forth in Sectdion 4.4(a).

1.31"**Losses**" shall have the meaning provided in Section 10.1.

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

1.33"**Option**" shall have the meaning provided in Section 4.1.

1.34"**Option Period**" shall have the meaning provided in Section 4.3.

1.35"**Paragon Indemnitee**" shall have the meaning provided in Section 10.1.

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

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

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

1.39"**Paragon Platform Technology**" means Paragon Platform Know-How, Paragon Platform Know-How Improvements and Paragon Platform Patents.

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

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

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

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

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

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

1.46"**Project Antibody Samples**" shall have the meaning provided in Section 2.1(c).

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

1.48"**Project Antibody Technology**" shall mean (a) the Project Antibody Inventions; (b) the Project Antibody Patents, (c) the Sequence Information and Results; and (d) all Intellectual Property Rights therein.

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

1.50"**Research Plan**" has the meaning set forth in Section 2.1(b).

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

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

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

1.54"**Selected Target**" has the meaning set forth in Section 2.1(a)."**Sequence Information**" means electronic files containing all Project Antibody sequences generated under a given Research Program.

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

1.56"**Spyre Indemnitee**" shall have the meaning provided in Section 10.2.

1.57"**Spyre Shares**" means shares of common stock, par value $0.001, of Spyre.

1.58"**Target**" means a protein molecule that (a) [***], and (b) [***].

1.59"**Term**" shall have the meaning provided in Section 9.1.

1.60"**Territory**" shall mean worldwide.

1.61"**Third Party**" shall mean any person or entity other than Paragon, Parapyre or Spyre or an Affiliate of any of Paragon, Parapyre or Spyre.

1.62"**Third Party Claim**" shall have the meaning provided in Section 10.1.

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

ARTICLE 2
CONDUCT OF RESEARCH PROGRAM

2.1Research Program.

(a) Target Selection. The Parties intend to initiate one or more Research Programs, each focused on a particular Target (each, a "**Selected Target**"). No more than one (1) Selected Target will be included in any Research Program, unless the Parties otherwise agree in writing (e.g., in the case of a Research Program seeking to develop [***]). As of the Effective Date, the Parties have agreed to the Selected Targets listed on Exhibit A. Additional Targets may be added to the Selected Targets by mutual written agreement of the Parties, it being understood that each Party may accept or reject a new Selected Target in its sole discretion and no Party shall be obligated under this Agreement to agree to any further Selected Targets. The Parties acknowledge that, prior to any agreement with respect to a Selected Target and a Research Plan, it is intended that the Parties may initiate, from time-to-time, "proof-of-concept" studies [***] at no up-front Research Initiation Fee to Spyre; provided, that the costs of any such "proof-of-concept" studies may be recaptured by Paragon within the specified Research Plan and associated fees, in each case, as agreed by the Parties.

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

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

(d) Conduct of Research Program. During the Research Term, Paragon and Parapyre shall (a) perform the activities assigned to them under the applicable Research Plan in a professional, diligent and good scientific manner, in compliance with all Applicable Law, and in compliance with the applicable Research Plans; (b) ensure that its Representatives and subcontractors diligently perform the applicable Research Program in a manner in accordance with generally accepted industry practices by appropriately trained personnel who are experienced in the relevant fields and in compliance with Applicable Law; (c) keep Spyre fully informed regarding the progress and results of the Research Program; (d) promptly provide Spyre with any additional information regarding the Research Program that Spyre reasonably requests; (e) participate in teleconference(s) at a time(s) agreed upon by the Parties to provide an update to Spyre on the performance of the Research Program; and (f) give Spyre prompt written notice with respect to information known or believed by Paragon and Parapyre to be likely to materially impede or otherwise adversely affect the performance of the Research Program.

2.2Subcontractors. Paragon and Parapyre may perform some of the activities under a Research Program through one or more subcontractors, provided that Paragon and Parapyre shall at all times be fully responsible for the compliance of such subcontractors with this Agreement and for the performance of their obligations under this Agreement.

2.3Research Books and Records; Audit. Paragon shall maintain complete and accurate records related to the activities performed by Paragon and Parapyre under a Research Program. All such books and records shall be retained by Paragon until the later of: (a) [***] after the end of the applicable stage of research; and (b) such longer period as may be required by Applicable Law. Upon Spyre's request and at [***] expense, Paragon shall provide copies of such records or such records shall be made available for Spyre's reasonable review, audit and inspection upon reasonable notice and with reasonable frequency.

ARTICLE 3
GOVERNANCE

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

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

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

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

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

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

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

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

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

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

3.5Disbandment. The JDC shall remain in effect from the date on which it is established in accordance with Section 3.1 until, on a Research Program-by-Research Program basis, the earlier of (a) expiration of the Term and (b) Spyre's exercise of the Option in accordance with Section 4.3.

ARTICLE 4
OPTION; LICENSE

4.1Grant of Option. Subject to the terms and conditions of this Agreement, on a Research Program-by-Research Program basis, Paragon hereby grants to Spyre, during the Term and subject to delivery of the Election Notice in accordance with Section 4.3, an exclusive option

("**Option**"), to be granted an exclusive license to all of Paragon's right, title, and interest in and to the Project Antibody Technology under the applicable Research Program to Develop and Commercialize Project Antibodies, Derived Antibodies and Products in the Field in the Territory.

4.2Limited License Grant During Option Period. Subject to the terms and conditions of this Agreement, on a Research Program-by-Research Program basis, and effective only during the Term, Paragon hereby grants to Spyre a limited, exclusive, royalty-free license, without the right to sublicense, under the Project Antibody Technology arising from such Research Program solely to evaluate the Option and for the purpose of allowing Spyre to determine whether to exercise the Option with respect to such Research Program.

4.3Option Exercise. On a Research Program-by-Research Program basis, Spyre may, in its sole discretion, exercise the Option at any time during the period beginning on the initiation of activities under such Research Program and ending [***] days following Spyre's receipt of the Deliverables for such Research Program, or such longer period as agreed upon by the Parties ("**Option Period**") by delivering written notice of such exercise to Paragon ("**Election Notice**"). If Spyre fails to exercise an Option in accordance with this Section 4.3 prior to expiration of the applicable Option Period, then, upon such expiration, such Option shall terminate and be of no further force or effect.

4.4License Template; Execution After Option Exercise.

(a) Within [***] days of the Effective Date, the Parties shall negotiate [***] and use [***] to agree upon a form of agreement template ("**License Template**") to be used in connection with Spyre's exercise of its Option with respect to a given Research Program. The License Template will be consistent with the economic and other terms set forth in Exhibit B, and upon mutual agreement by the Parties on the form of the License Template, will be attached to this Agreement and replace the terms on the existing Exhibit B. If the Parties are unable to reach agreement on the definitive terms of the License Template within such [***] period, the matter will be resolved in accordance with Section 11.7.

(b) Within [***]days of Spyre's exercise of its Option with respect to a Research Program as set forth in Section 4.3, the Parties shall use [***] to finalize and execute a definitive written agreement consistent with the License Template (the "**License Agreement**") with respect to such Research Program.

ARTICLE 5
PAYMENTS

5.1Research Initiation Fee. Spyre shall pay to Paragon, on a Research Program-by-Research Program basis, a one-time nonrefundable fee of $750,000 (the "**Research Initiation Fee**") no later than [***] days following finalization of the Research Plan for such Research Program. For clarity, the Research Initiation Fee is nonrefundable and separate from any Development Costs (including Pre-Effective Date Development Costs) or Cost Advance paid or

owing with respect to a particular Research Program.

5.2Development Costs.

(a) On a quarterly basis for each Research Program, Spyre will advance to Paragon any Development Costs contemplated in the Budget, including [***], and any [***] reasonably expected to be incurred by Paragon in the performance of the Research Program during the upcoming [***] (less any pre-payments for [***] from earlier [***] that Paragon reasonably anticipates will be carried over to such upcoming [***]) (the "**Cost Advance**"). Spyre will pay the Cost Advance within [***] days after receipt of Paragon's invoice for such Development Costs. The Parties acknowledge that Paragon has incurred approximately $10,000,000 in Development Costs prior to the Effective Date, as a result of work performed by Paragon at risk on one or more Research Programs (the "**Pre-Effective Date Development Costs**"), which amount includes for Research Initiation Fees of $3,000,000 for a total of four Research Programs. Spyre shall reimburse Paragon for the Pre-Effective Date Development Costs no later than [***] days after the later of (i) the Effective Date and (ii) Spyre's receipt of a written invoice that details the Pre-Effective Date Development Costs and includes reasonable documentation therefor.

(b) Within [***] days after the end of each Calendar Year, Paragon will calculate and provide to Spyre a written reconciliation of its actually-incurred Third Party Costs (incurred in a manner consistent with the Budget) for the prior Calendar Year ("**Actual Annual Costs**") against that portion of the Cost Advance for such Third Party Costs for that Calendar Year, including reasonable documentation of such Actual Annual Costs. The form of such reconciliation shall be subject to JDC review and approval. If the amounts paid for anticipated Third Party Costs in the Cost Advance exceeds the Actual Annual Costs, then Paragon will credit such excess payment against Development Costs contemplated in the Budget and reasonably expected to be incurred by Paragon in the performance of the Research Program during any upcoming Calendar Year and Spyre will deduct such amount from its next quarterly Cost Advance. If the Cost Advance is less than the Actual Annual Costs, then Paragon will invoice Spyre for the difference and Spyre will pay such amount together with its next quarterly Cost Advance. If no further amounts will be owed to Paragon hereunder, Paragon will refund such amount. For clarity, the above reconciliation will not apply to Annual Development Fees.

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

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

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

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

5.7Annual Equity Grant. During the Term, on an annual basis, Spyre will grant Parapyre a number of options to purchase 1% of the then outstanding shares of Spyre's common stock, par value $0.001 ("**Shares**"), on a fully-diluted basis, at the then fair market value of the Shares as determined by the board of directors of Spyre (each grant, an "**Equity Grant**"); provided, that if the Company undergoes a reverse merger transaction the rights and obligations of this Section 5.7 shall continue and Parapyre shall be entitled to receive the equivalent shares of the ultimate public company parent, as applicable. Each Equity Grant shall be effected on the last Business Day of each Calendar Year. If the Term ends prior to the end of a Calendar Year, the Equity Grant for such Calendar Year shall be pro-rated for such Calendar Year and such Equity Grant shall be effected within five Business Days of the end of the Term.

ARTICLE 6
INTELLECTUAL PROPERTY RIGHTS

6.1Ownership.

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

(b) Project Antibody Technology. Subject to the rights and licenses granted to Spyre in this Agreement, as between the Parties, Paragon or its Affiliates shall own all right, title and interest in and to all Project Antibody Technology, irrespective of inventorship.

6.2Patent Prosecution, Maintenance and Enforcement – Project Antibody Patents.

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

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

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

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

ARTICLE 7
PROTECTION OF CONFIDENTIAL INFORMATION

7.1Confidentiality. Except to the extent expressly authorized by this Agreement, the Receiving Party agrees that, during the Term and for [***] years thereafter, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party may disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Representatives who have a need for such information, provided that the Receiving Party shall advise such Representatives of the confidential nature thereof, shall ensure that each such Representative is bound in writing by obligations of confidentiality and non-use at least as stringent as those contained in this Agreement, and shall be responsible for the compliance of its Representatives with the terms of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information of the Disclosing Party. The Receiving Party shall [***] notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the Disclosing Party.

7.2Exceptions. The Receiving Party's obligations under Section 7.1 shall not apply to any Confidential Information of the Disclosing Party that the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available; (b) is known by the Receiving Party at the time of receiving such information from the Disclosing Party; (c) is hereafter furnished to the Receiving Party by a Third Party, as a matter of right and without

restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the aid, use or application of any Confidential Information of the Disclosing Party.

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

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

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

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

7.5Use of Names. No Party shall use any other Party's name or trademarks in any advertising, sales, or promotional material or in any publication without the prior written consent of such other Party or Parties.

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

7.7Publicity. Except to the extent required by Applicable Law or the rules of any stock exchange or listing agency, no Party shall issue a press release announcing that they have entered into an Antibody discovery partnership, without the other Parties' prior written consent, which shall not be unreasonably withheld.

ARTICLE 8
REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMER

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

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

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

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

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

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

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

(c) it has the unencumbered right to the Paragon Platform Technology and the right, power and authority to use the Paragon Platform Technology in performance of the Research Plans and the performance of its obligations under this Agreement, in each case in accordance with the terms hereof;

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

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

(f) none of Paragon, its Representatives, or any other person used by Paragon in the performance of the Agreement has been or is (i) debarred, convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (ii) listed by any government or regulatory agencies as ineligible to participate in any Federal healthcare programs (as that term is defined in 42 U.S.C. 1320a-7b(f)) or government procurement or non-procurement programs, or excluded, debarred, suspended or otherwise made ineligible to participate in any such program, or (iii) convicted of a

criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Paragon agrees to inform Spyre in writing promptly if Paragon or any person who is performing activities on its behalf under the Agreement is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending or threatened.

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

ARTICLE 9
TERM AND TERMINATION

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

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

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

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

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

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

9.4Termination for a Bankruptcy Event. Each Party will have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to any other Party. "**Bankruptcy Event"** means the occurrence of any of the following: (a) the institution of any

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

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

9.6Accrued Rights; Survival. The expiration or termination of this Agreement for any reason shall not release any Party from any liability or obligation that, at the time of such expiration or termination, has already accrued to any other Party or that is attributable to a period prior to such expiration or termination, nor will expiration or any termination of this Agreement preclude any Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement. In the event of expiration or any termination of this Agreement, the following provisions of this Agreement shall survive such expiration or termination in accordance with their respective terms and conditions: Article 5, Article 7, Article 10 and Article 11, as well as Sections 2.3, 6.1, 6.2(a), 6.4, 9.3, 9.5 and 9.6.

ARTICLE 10
INDEMNIFICATION; LIMITATION OF LIABILITY

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

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

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

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

ARTICLE 11
MISCELLANEOUS

11.1Independent Contractor Relationship. Each of Paragon's and Parapyre's relationship with Spyre is that of an independent contractor, and nothing in this Agreement should be construed to create a partnership, joint venture or employer-employee relationship. No Party is an agent of any other Party or authorized to make any representation, contract or commitment on behalf of any other Party.

11.2Force Majeure. No Party will be charged with any liability for delay or failure in performance of an obligation under this Agreement (other than any obligation to pay monies when due) to the extent such delay or failure is due to a cause beyond the reasonable control of the affected Party, such as war, riots, labor disturbances, epidemic, pandemic, fire, explosion, and compliance in good faith with any Applicable Law. The Party affected will give prompt written notice to the other Parties of the nature of the cause of any material delay or failure to

perform, its anticipated duration and any action being taken to avoid or minimize the effect. The Party affected will use its diligent efforts to avoid or remove such causes of delay or failure to perform and to mitigate the effect of such occurrence, and will continue performance in accordance with the terms of this Agreement whenever such causes are removed. The Party affected will give prompt written notice to the other Parties of such resumed performance. If any such failure or delay in a Party's performance hereunder continues for more than [***] days, any of the other Parties may terminate this Agreement upon written notice to the affected Party.

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

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

11.5Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

11.6Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned by any Party without the prior written consent of the other Parties (which consent shall not be unreasonably withheld); provided, however, that any Party may assign this Agreement and its rights and obligations hereunder without the other Parties' consent to its successor to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.

11.7Dispute Resolution. The Parties recognize that a *bona fide* dispute as to certain matters may arise from time to time during the Term relating to any Party's rights or obligations hereunder or otherwise relating to the validity, enforceability or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any disputes relating to Article 7 (Confidentiality) hereof or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties'

respective Intellectual Property Rights (hereinafter, a "**Dispute**"). In the event of the occurrence of any Dispute, the Parties will follow the following procedures in an attempt to resolve the dispute or disagreement:

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

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

(c) If, within [***] days of initial receipt of the Notice of Dispute, the Dispute has not been resolved, or if, for any reason, the meeting described in Section 11.7(b) hereof has not been held within [***] days of initial receipt of the Notice of Dispute, then the Parties agree that such Dispute will be finally resolved through binding arbitration to be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the Expedited Procedures in those Rules, as specifically modified by the provisions of this Section 11.7(c). The arbitration will be conducted by a panel of three arbitrators. Within [***] days after the initiation of the arbitration, each Party will nominate one person to act as arbitrator, and the two arbitrators so named will then jointly appoint the third arbitrator within [***] days of their appointment, who will serve as chairman of the panel. All three arbitrators must be independent Third Parties having at least [***] years of dispute resolution experience (which may include judicial experience) or legal or business experience in the biotech or pharmaceutical industry. If any Party fails to nominate its arbitrator, or if the arbitrators selected by the Parties cannot agree on a person to be named as chairman within such [***]-day period, JAMS will make the necessary appointments for such arbitrator(s) or the chairman. Once appointed by a Party, such Party will have no *ex parte* communication with its appointed arbitrator. The place of arbitration will be in Boston, Massachusetts or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrators have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 *et seq.*, and judgment upon the award rendered by the arbitrators may be entered in any court having competent jurisdiction thereof. The existence, content and results of any arbitration proceedings pursuant to this Section 11.7 will be deemed the Confidential Information of all Parties.

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

(e) The Parties agree that any disputes relating to Article 7 (Confidentiality) hereof or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights

shall be subject to the exclusive jurisdiction of the state and federal courts in New York, New York and each Party hereby submits to such jurisdiction.

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

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

If to Paragon or Parapyre:	Paragon Therapeutics, Inc. 221 Crescent Street Building 17, Suite 102B Waltham, MA 02453 Attn: President
If to Spyre:	Spyre Therapeutics, Inc. 221 Crescent Street, Building 17, Suite 102B Waltham, MA 02453 Attn: President

11.10Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity shall be construed to include such person’s or entity’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve”

or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "or". The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against any Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language. To the extent there is any inconsistency or conflict between the terms and conditions of this Agreement and any Research Plan, the terms and conditions of this Agreement will prevail.

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

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

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

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

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

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

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

In Witness Whereof, the Parties hereto have executed this Antibody Discovery and Option Agreement on the Effective Date.

Paragon Therapeutics, Inc.

By: /s/ K. Evan Thompson
Name: K. Evan Thompson
Title: President
Date: May 25, 2023

Spyre Therapeutics, Inc.

By: /s/ K. Evan Thompson
Name: K. Evan Thompson
Title: President
Date: May 25, 2023

Parapyre Holding LLC

By: /s/ K. Evan Thompson
Name: K. Evan Thompson
Title: President
Date: May 25, 2023

FIRST AMENDMENT TO THE
AEGLEA BIOTHERAPEUTICS, INC.
2016 EQUITY INCENTIVE PLAN

WHEREAS, Aeglea Biotherapeutics, Inc., a Delaware corporation (the "Company") maintains the Aeglea Biotherapeutics, Inc. 2016 Equity Incentive Plan (as amended, the "Plan"); and

WHEREAS, pursuant to Section 24 of the Plan, the Board of Directors (the "Board") may amend the Plan at any time.

NOW, THEREFORE, pursuant to its authority under Section 24 of the Plan, the Board hereby amends the Plan as follows, effective as of June 22, 2023 (the "Amendment Effective Date"):

1. Section 2.5 of the Plan is hereby amended and restated in its entirety to read as follows:

"**2.5 Limitations**. No more than 8,200,000 Shares shall be issued pursuant to the exercise of ISOs."

2. This First Amendment shall be governed by and construed in accordance with the laws of the State of Delaware (excluding its conflict of law rules).

3. All capitalized terms used but not otherwise defined herein shall have the meaning assigned to them in the Plan. Except as expressly amended hereby, the Plan shall remain in full force and effect in accordance with its terms.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has executed this First Amendment to the Aeglea Biotherapeutics, Inc. 2016 Equity Incentive Plan, effective as of the Amendment Effective Date.

AEGLEA BIOTHERAPEUTICS, INC.

By: /s/ Jonathan Alspaugh
Name: Jonathan Alspaugh
Title: President and Chief Financial Officer

Exhibit 10.6

FIRST AMENDMENT TO THE
AEGLEA BIOTHERAPEUTICS, INC.
2018 EQUITY INDUCEMENT PLAN

WHEREAS, Aeglea Biotherapeutics, Inc., a Delaware corporation (the "Company") maintains the Aeglea Biotherapeutics, Inc. 2018 Equity Inducement Plan (the "Plan"); and

WHEREAS, pursuant to Section 17 of the Plan, the Board of Directors (the "Board") may amend the Plan at any time and for any purpose as permitted by law, including to increase the maximum number of Shares for which awards may be granted under the Plan.

NOW, THEREFORE, pursuant to its authority under Section 17 of the Plan, the Board hereby amends the Plan as follows, effective as of June 22, 2023 (the "Amendment Effective Date"):

1. Section 2.1 of the Plan is hereby amended and restated in its entirety to read as follows:

> "**2.1 Number of Shares Available**. Subject to Sections 2.4 and 15 and any other applicable provisions hereof, the total number of Shares reserved and available for grant and issuance pursuant to this Plan is 71,100,000."

2. This First Amendment shall be governed by and construed in accordance with the laws of the State of Delaware (excluding its conflict of law rules).

3. All capitalized terms used but not otherwise defined herein shall have the meaning assigned to them in the Plan. Except as expressly amended hereby, the Plan shall remain in full force and effect in accordance with its terms.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has executed this First Amendment to the Aeglea Biotherapeutics, Inc. 2018 Equity Inducement Plan, effective as of the Amendment Effective Date.

AEGLEA BIOTHERAPEUTICS, INC.

By: /s/ Jonathan Alspaugh
Name: Jonathan Alspaugh
Title: President and Chief Financial Officer

Exhibit 10.7

SPYRE THERAPEUTICS, INC.

2023 EQUITY INCENTIVE PLAN

AMENDED BY THE BOARD OF DIRECTORS: MAY 19, 2023

1. Purpose.

The purpose of this 2023 Equity Incentive Plan (the "**Plan**") of Spyre Therapeutics, Inc., a Delaware corporation (the "**Company**"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "**Code**") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "**Board**").

2. Eligibility.

All of the Company's employees, officers, directors, consultants and advisors are eligible to be granted options, restricted stock, restricted stock units ("**RSUs**") and other stock-based awards (each, an "**Award**") under the Plan. Each person who receives an Award under the Plan is deemed a "**Participant**".

3. Administration and Delegation.

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "**Committee**"). All references in the Plan to the "**Board**" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers. The Board may abolish any Committee at any time, and notwithstanding any delegation of authority, the Board will always retain full authority to take any action permitted under the Plan.

(c) Delegation to Officers. To the extent permitted by applicable law, the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, *provided that* the Board shall fix the terms of the Awards to be granted by such officers (including the exercise price of such Awards, which may include a formula by which the exercise price will be determined) and the maximum number of shares subject to Awards that the officers may grant; *provided further, however*, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) or to any "officer" of the Company (as defined by Rule 16a-1 under the Exchange Act). The Board may rescind any such delegation at any time.

4. Stock Available for Awards.

(a) Number of Shares. Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 2,049,133 shares of common stock of the Company (the "**Common Stock**"), all of which may be granted as Incentive Stock Options (as hereinafter defined). If any Award expires, lapses, or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at or below the original issuance price), in any case in a manner that results in any shares of Common Stock covered by such Award not being issued or being so reacquired by the Company, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock delivered (whether by actual delivery or attestation) or tendered to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award and/or to satisfy any applicable tax withholding obligation (including shares retained by the Company from the Award being exercised or purchased and/or creating the tax obligation) shall again be available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options) the foregoing provisions shall be subject to any limitations under the Code. Shares of Common Stock issued under the Plan may consist in whole or in part of authorized but unissued shares, shares purchased on the open market, or treasury shares. At no time while there is any Option (as defined below) outstanding and held by a Participant who was a resident of the State of California on the date of grant of such Option, shall the total number of shares of Common Stock issuable upon exercise of all outstanding options and the total number of shares provided for under any stock bonus or similar plan or agreement of the Company exceed the applicable percentage as calculated in accordance with the conditions and exclusions of Section 260.140.45 of the California Code of Regulations (the "**California Regulations**"), based on the shares of the Company which are outstanding at the time the calculation is made.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted prior to such merger or consolidation by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a) hereof, except as may be required by reason of Section 422 and related provisions of the Code.

5. Stock Options.

(a) General. The Board may grant options to purchase Common Stock (each, an "**Option**") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. An Option that is not intended to be an Incentive Stock Option shall be designated a "**Nonstatutory Stock Option**".

(b) Incentive Stock Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "**Incentive Stock Option**") shall only be granted to employees of the Company (including any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code but excluding any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest). All Options intended to qualify as Incentive Stock Options shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code, and without limiting generality of the foregoing, such Options shall be deemed to include terms that comply with the eligibility standards described section 422(b) of the Code. Subject to the remaining provisions of this Section 5(b), if an Option intended to qualify as an Incentive Stock Option does not so qualify, the Board may, at its discretion, amend the Plan and Award with respect to such Option so that such Option qualifies as an Incentive Stock Option. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Participant during any calendar year (under all plans of the Company and any affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with the rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Award. Neither the Company nor the Board shall have any liability to a Participant, or any other party, (i) if an Option (or any part thereof) which is intended to qualify as an Incentive Stock Option fails to qualify as such or (ii) for any action or omission by the Company or Board that causes an Option not to qualify as an Incentive Stock Option, including without limitation the conversion of an Incentive Stock Option to a Nonstatutory Stock Option or the grant of an Option intended as an Incentive Stock Option that fails to satisfy the requirements under the Code applicable to an Incentive Stock Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option and specify the exercise price in the applicable option agreement. The exercise price shall be not less than 100% of the Fair Market Value on the date the Option is granted. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a "parent corporation" or "subsidiary corporation" thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively) (such employee, a "**10% Holder**"), the per share exercise price shall be no less than 110% of the Fair Market Value on the date the Option is granted.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement, *provided that* the term of any Option shall not exceed 10 years. In the case of an Incentive Stock Option granted to a 10% Holder, the term of the Option shall not exceed five years.

(e) Exercise of Option; Notification of Disposition. Options may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares for which the Option is exercised. Unless otherwise determined by the Board, an Option may not be exercised for a fraction of a share of Common Stock. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise. If an Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any shares of Common Stock acquired from the Option if such disposition or transfer is made (i) within two years from the grant date with respect to such Option or (ii) within one year after the transfer of such shares to the Participant (other than any such disposition made in connection with a Reorganization Event). Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(i) in cash or by check, payable to the order of the Company;

(ii) when the Common Stock is registered under the Exchange Act, except as may otherwise be provided in the applicable option agreement, by (A) delivery of an irrevocable and unconditional undertaking by a creditworthy broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(iii) when the Common Stock is registered under the Exchange Act and to the extent provided for in the applicable option agreement or approved by the Board, in its sole discretion, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board ("**Fair Market Value**"), *provided* (A) such method of payment is then permitted under applicable law, (B) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (C) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(iv) to the extent permitted by applicable law and provided for in the applicable option agreement or approved by the Board, in its sole discretion, by (A) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (B) payment of such other lawful consideration as the Board may determine;

(v) to the extent provided for in the applicable option agreement or approved by the Board, in its sole discretion, by having the Company retain from the shares of Common Stock otherwise issuable upon the exercise of such Option a number of shares valued at their Fair Market Value; or

(vi) by any combination of the above permitted forms of payment or any other lawful consideration as approved by the Board in its sole discretion.

(g) Early Exercise of Options. The Board may provide in the terms of an option agreement that the Participant may exercise an Option in whole or in part prior to the full vesting of the Option in exchange for unvested shares of Restricted Stock (as defined below) with respect to any unvested portion of the Option so exercised. Shares of Restricted Stock acquired upon the exercise of any unvested portion of an Option shall be subject to such terms and conditions as the Board shall determine.

6. Restricted Stock; Restricted Stock Units.

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("**Restricted Stock**"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. Instead of granting Awards for Restricted Stock, the Board may grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered at or following the time such Award vests ("**Restricted Stock Units**" or "**RSUs**").

(b) Terms and Conditions. The Board shall determine and set forth in the applicable award agreement the terms and conditions of Restricted Stock or RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(i) Dividends. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares to the extent such dividends have a record date that is on or after the date on which the Participant to whom such Restricted Stock is granted becomes the record holder of such Restricted Stock, unless otherwise provided by the Board. Unless otherwise provided by the Board, if any dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock other than an ordinary cash dividend, the shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made as provided in the applicable award agreement, but no later than the end of the calendar year in which the dividends are paid to shareholders of that class of stock or, if later, the 15th day of the third month following the later of (A) the date the dividends are paid to shareholders of that class of stock and (B) the date the dividends are no longer subject to forfeiture.

(ii) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "**Designated Beneficiary**"). In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.

(d) Additional Provisions Relating to Restricted Stock Units.

(i) Settlement. Upon or following the vesting of a Restricted Stock Unit, the Participant shall be entitled to receive from the Company one share of Common Stock or an amount of cash or other property equal to the Fair Market Value of one share of Common Stock on the settlement date, as the Board shall determine and as provided in the applicable award agreement. The Board may provide that settlement of Restricted Stock Units shall occur upon or as soon as reasonably practicable after the vesting of the Restricted Stock Units or shall instead be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A of the Code.

(ii) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units unless and until shares are delivered in settlement thereof.

(iii) Dividend Equivalents. To the extent provided by the Board, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and may be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are paid, as determined by the Board, subject, in each case, to such terms and conditions as the Board shall establish and set forth in the applicable award agreement. "**Dividend Equivalents**" means a right granted to a Participant to receive the equivalent value (in cash or shares of Common Stock) of dividends paid on shares of Common Stock.

7. Other Stock-Based Awards.

Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants ("**Other Stock-Based Awards**"), including without limitation stock appreciation rights ("**SARs**") (which shall be subject to the same limitations applicable to awards of Nonstatutory Stock Options) and Awards entitling recipients to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price, transfer restrictions, vesting conditions and other terms and conditions applicable thereto.

8. Adjustments for Changes in Common Stock and Certain Other Events.

(a) In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the number and class of securities and exercise price per share of each outstanding Option, (iii) the number of shares subject to and the repurchase price per share subject to each other outstanding Award, and (iv) the terms of each other outstanding Award shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board; *provided that*, unless otherwise determined by the Board, such changes to the Options shall comply with section 1.424-1 of the Treasury Regulations. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then a Participant who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events.

(i) Definition. A "**Reorganization Event**" means the consummation of: (A) the dissolution or liquidation of the Company, (B) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (C) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the surviving or resulting entity (or its ultimate parent, if applicable), (D) the acquisition of all or a majority of the outstanding voting stock of the Company in a single transaction or a series of a related transactions by a person or group of persons, or (E) any other acquisition of the business of the Company, as determined by the Board; *provided, however*, that the first firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale by the Company of its equity securities, as a result of or following which the Common Stock shall be public, any subsequent public offering or another capital raising event, or a merger effected solely to change the Company's domicile shall not constitute a "Reorganization Event."

(ii) Consequences of a Reorganization Event on Awards. In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards on such terms as the Board determines: (A) provide that Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof); *provided that*, unless otherwise determined by the Board, such assumption or substitution of the Options shall comply with section 1.424-1 of the Treasury Regulations, (B) upon written notice to a Participant, provide that the Participant's unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant within a specified period following the date of such notice, (C) provide that outstanding Awards shall become vested, exercisable, realizable, or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (D) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "**Acquisition Price**"), make or provide for a cash payment to a Participant equal to the excess, if any, of (I) the Acquisition Price times the number of shares of Common Stock subject to the Participant's Awards (to the extent the exercise price does not exceed the Acquisition Price) over (II) the aggregate exercise price of all such outstanding Awards and any applicable tax withholdings, in exchange for the termination of such Awards, (E) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof and any applicable tax withholdings) and (F) any combination of the foregoing. In taking any of the actions permitted under this Section 8(b), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

For purposes of clause (A) above, an Option shall be considered assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent in value (as determined by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

9. General Provisions Applicable to Awards.

(a) Transferability of Awards. Except as the Board may otherwise determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, retirement, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) Withholding. The Company shall not be obligated to deliver certificates, release from forfeiture, otherwise recognize a Participant's unrestricted ownership in an Award or the cash or property proceeds therefrom, until the Company satisfies all applicable federal, state, and local or other income and employment tax withholding obligations. In its sole discretion, the Company may satisfy such withholding obligations by any of the following means or by a combination of such means: (i) causing the Participant to tender to the Company cash payment; (ii) withholding cash from an Award settled in cash; (iii) withholding from amounts otherwise payable by the Company to the Participant, including but not limited to additional withholding on the Participant's salary or wages, or from proceeds from the sale of Common Stock issued pursuant to an Award; (iv) delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value; *provided, however*, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), and *provided, further*, shares surrendered to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements; or (v) by such other method as determined by the Board.

(f) Amendment of Award.

(i) The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or settlement, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (A) the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant's rights under the Plan, (B) the change is permitted under Section 8 hereof, or (C) the change is to ensure that an Option intended to qualify as an Incentive Stock Option qualifies as such.

(ii) The Board may, without stockholder approval, amend any outstanding Award granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Award. The Board may also, without stockholder approval, cancel any outstanding award (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled award.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is determined by the Board to be necessary to the lawful issuance and sale of any securities hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such shares at to which such requisite authority shall not have been obtained.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

10. Miscellaneous.

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding any other provision of the Plan, unless otherwise determined by the Board or required by any applicable laws, the Company shall not be required to deliver to any Participant certificates evidencing shares of Common Stock issued in connection with any Award and instead such shares of Common Stock may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on any stock certificates issued under the Plan deemed necessary or appropriate by the Board in order to comply with applicable laws.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the expiration of 10 years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time; *provided that* if at any time the approval of a Company stockholder is required as to any modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options or pursuant to any other applicable law or regulation, the Board may not effect such modification or amendment without stockholder approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 10(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, *provided* the Board determines that such amendment does not materially and adversely affect the rights of Participants under the Plan.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to this Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Code Section 409A. Unless otherwise expressly provided for in an Award, the Plan and Award will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award is silent on terms necessary for compliance, such terms as deemed necessary by the Board in its sole discretion are hereby incorporated by reference into the Award. Without limiting the generality of the foregoing, if shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule. The Company shall have no liability to a Participant, or any other party, if an Award that is intended to be exempt from, or compliant with, Section 409A of the Code is not so exempt or compliant or for any other action taken by the Board.

(g) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than such state.

(h) Data Privacy. As a condition of receipt of any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among, as applicable, the Company and its subsidiaries and affiliates for the exclusive purpose of implementing, administering and managing the Participant's participation in the Plan. The Company and its subsidiaries and affiliates may hold certain personal information about a Participant, including but not limited to, the Participant's name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares of stock held in the Company or any of its subsidiaries and affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering the Plan and Awards (the "**Data**"). The Company and its subsidiaries and affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Participant's participation in the Plan, and the Company and its subsidiaries and affiliates may each further transfer the Data to any third parties assisting the Company in the implementation, administration and management of the Plan. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. Through acceptance of an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant's participation in the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or the Participant may elect to deposit any shares of Common Stock. The Data related to a Participant will be held only as long as is necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data held by the Company with respect to such Participant, request additional information about the storage and processing of the Data with respect to such Participant, recommend any necessary corrections to the Data with respect to the Participant or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Board's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws his or her consents as described herein. For more information on the consequences of refusal to consent or withdrawal of consent, Participants may contact their local human resources representative.

(i) Restrictions on Shares; Clawback Provisions. Shares of Common Stock acquired in respect of Awards shall be subject to such terms and conditions as the Board shall determine, including, without limitation, restrictions on the transferability of shares of Common Stock, the right of the Company to repurchase shares of Common Stock, the right of the Company to require that shares of Common Stock be transferred in the event of certain transactions, tag-along rights, bring-along rights, redemption and co-sale rights and voting requirements. Such terms and conditions may be additional to those contained in the Plan and may, as determined by the Board, be contained in the applicable Award Agreement or in an exercise notice, stockholders' agreement or in such other agreement as the Board shall determine, in each case in a form determined by the Board. The issuance of such shares of Common Stock shall be conditioned on the Participant's consent to such terms and conditions and the Participant's entering into such agreement or agreements. All Awards (including any proceeds, gains or other economic benefit actually or constructively received by Participant upon any receipt or exercise of any Award or upon the receipt or resale of any shares of Common Stock underlying the Award) shall be subject to the provisions of any clawback policy implemented by the Company, including, without limitation, any clawback policy adopted to comply with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such clawback policy and/or in the applicable Award Agreement.

SPYRE THERAPEUTICS, INC.

2023 EQUITY INCENTIVE PLAN

CALIFORNIA SUPPLEMENT

Pursuant to Section 10(e) of the Plan, the Board has adopted this supplement for purposes of satisfying the requirements of Section 25102(o) of the California Law:

Any Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "**California Participant**") shall be subject to the following additional limitations, terms and conditions:

1. Additional Limitations on Options.

(a) Minimum Vesting Rate. Except in the case of Options granted to California Participants who are officers, directors, managers, consultants or advisors of the Company or its affiliates (which Options may become exercisable at whatever rate is determined by the Board), Options granted to California Participants shall become exercisable at a rate of not less than 20% per year over five years from the date of grant; *provided, that*, such Options may be subject to such reasonable forfeiture conditions as the Board may choose to impose and which are not inconsistent with Section 260.140.41 of the California Regulations.

(b) Minimum Exercise Price. The exercise price of Options granted to California Participants may not be less than 85% of the Fair Market Value of the Common Stock on the date of grant in the case of a Nonstatutory Stock Option or less than 100% of the Fair Market Value of the Common Stock on the date of grant in the case of an Incentive Stock Option; *provided, however*, that if the California Participant is a person who owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary corporations, the exercise price shall be not less than 110% of the Fair Market Value of the Common Stock on the date of grant.

(c) Maximum Duration of Options. No Options granted to California Participants shall have a term in excess of 10 years measured from the Option grant date.

(d) Minimum Exercise Period Following Termination. Unless a California Participant's employment is terminated for cause (as defined by applicable law, the terms of any contract of employment between the Company and such Participant, or in the instrument evidencing the grant of such Participant's Option), in the event of termination of employment of such Participant, such Participant shall have the right to exercise an Option, to the extent that he or she was otherwise entitled to exercise such Option on the date employment terminated, as follows: (i) at least six months from the date of termination, if termination was caused by such Participant's death or "permanent and total disability" (within the meaning of Section 22(e)(3) of the Code) and (ii) at least 30 days from the date of termination, if termination was caused other than by such Participant's death or "permanent and total disability" (within the meaning of Section 22(e)(3) of the Code).

(e) Limitation on Repurchase Rights. If an Option granted to a California Participant gives the Company the right to repurchase shares of Common Stock issued pursuant to the Plan upon termination of employment of such Participant, the terms of such repurchase right must comply with Section 260.140.41(k) of the California Regulations.

2. Additional Limitations for Restricted Stock.

(a) Minimum Purchase Price. The purchase price for Restricted Stock granted to a California Participant shall be not less than 85% of the Fair Market Value of the Common Stock at the time such Participant is granted the right to purchase shares under the Plan or at the time the purchase is consummated; *provided, however*, that if such Participant is a person who owns stock possessing more than 10% of the total combined voting power or value of all classes of stock of the Company or its parent or subsidiary corporations, the purchase price shall be not less than 100% of the Fair Market Value of the Common Stock at the time such Participant is granted the right to purchase shares under the Plan or at the time the purchase is consummated.

(b) Limitation of Repurchase Rights. If Restricted Stock granted to a California Participant gives the Company the right to repurchase shares of Common Stock issued pursuant to the Plan upon termination of employment of such Participant, the terms of such repurchase right must comply with Section 260.140.42(h) of the California Regulations.

3. Additional Limitations for Other Stock-Based Awards.

The terms of all Awards granted to a California Participant under Section 7 of the Plan shall comply, to the extent applicable, with Section 260.140.41 or Section 260.140.42 of the California Regulations.

4. Additional Requirement to Provide Information to California Participants.

The Company shall provide to each California Participant and to each California Participant who acquires Common Stock pursuant to the Plan, not less frequently than annually, copies of annual financial statements (which need not be audited). The Company shall not be required to provide such statements to key employees whose duties in connection with the Company assure their access to equivalent information.

5. Additional Limitations on Timing of Awards.

No Award granted to a California Participant shall become exercisable, vested or realizable, as applicable to such Award, unless the Plan has been approved by the holders of a majority of the Company's outstanding voting securities within 12 months before or after the date the Plan was adopted by the Board.

6. Additional Limitations Relating to Definition of Fair Market Value.

For purposes of Section 1(b) and 2(a) of this supplement, "Fair Market Value" shall be determined in a manner not inconsistent with Section 260.140.50 of the California Regulations.

7. Additional Restriction Regarding Recapitalizations, Stock Splits, Etc.

For purposes of Section 8 of the Plan, in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination, reclassification or other distribution of the Company's securities, the number of securities allocated to each California Participant must be adjusted proportionately and without the receipt by the Company of any consideration from any California Participant.

Exhibit 10.8

NOTICE OF STOCK OPTION GRANT
AEGLEA BIOTHERAPEUTICS, INC.
2018 EQUITY INDUCEMENT PLAN

Unless otherwise defined herein, the terms defined in the Aeglea BioTherapeutics, Inc. (the "***Company***") 2018 Equity Inducement Plan (the "***Plan***") shall have the same meanings in this Notice of Stock Option Grant (the "***Notice of Grant***") and the attached Stock Option Agreement (the "***Option Agreement***"). You have been granted an Option to purchase shares of Common Stock of the Company under the Plan subject to the terms and conditions of the Plan, this Notice of Grant and the attached Option Agreement.

Name: _____

Address: _____

_____

_____

Date of Grant: _____

Vesting Commencement Date: _____

Exercise Price per Share: _____

Total Number of Shares: _____

Type of Option:

Expiration Date: _____; This Option expires earlier if your Service terminates earlier, as described in the Stock Option Agreement.

Vesting Schedule: For so long as Optionee continuously provides services to the Company (or any Subsidiary or Parent of the Company) as an employee, officer, director, contractor or consultant, this Option will vest and become exercisable with respect to the Shares as follows: _____.

Additional Terms: If this box is checked, the additional terms and conditions set forth on Attachment 1 hereto (as executed by the Company) are applicable and are incorporated herein by reference. No document need be attached as Attachment 1 if the box is not checked.

Except as specifically provided in your Offer Letter, the Option Agreement or the Plan, in the event that your employment or engagement with the Company terminates, all unvested options will be forfeited immediately. Any offer will be in accordance with the terms of such plans or arrangements as they may be amended from time to time. As a condition to participation in any such plans or arrangements, you agree that the opportunity to participate shall not form part of your entitlement to remuneration or benefits pursuant to your Offer Letter or any additional agreement entered into between you and the Company or any Subsidiary and you agree that you shall not be entitled to seek any equitable relief or to receive any compensation or damage in consequence of any loss or potential loss which you may suffer in consequence of the loss or termination of your employment for any reason whatsoever (including wrongful or unfair dismissal or their equivalents). By accepting this Option, you and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan, the Notice of Grant and the Option Agreement. By accepting this Option, you consent to electronic delivery as set forth in the Option Agreement.

Signature: _____ By:

Print Name: _____ Name: _____

Title: _____

STOCK OPTION AGREEMENT

AEGLEA BIOTHERAPEUTICS, INC.
2018 EQUITY INDUCEMENT PLAN

You have been granted an Option by Aeglea BioTherapeutics, Inc. (the "***Company***") under the 2018 Equity Inducement Plan (the "***Plan***") to purchase Shares (the "***Option***"), subject to the terms, restrictions and conditions of the Plan, the Notice of Stock Option Grant (the "***Notice of Grant***") and this Stock Option Agreement (the "***Agreement***").

1. Grant of Option. You have been granted an Option for the number of Shares set forth in the Notice of Grant at the exercise price per Share set forth in the Notice of Grant (the "***exercise price***"). In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Agreement, the terms and conditions of the Plan shall prevail.

2. Termination Period.

(a) General Rule. If your Service terminates for any reason except death or Disability, and other than for Cause, then this Option will expire at the close of business at Company headquarters on the date three months after your termination of Service (subject to the expiration detailed in Section 6). If your Service is terminated for Cause, this Option will expire upon the date of such termination. The Company determines when your Service terminates for all purposes under this Agreement. You acknowledge and agree that the Vesting Schedule may change prospectively in the event that your service status changes between full and part-time status in accordance with Company policies relating to work schedules and vesting of awards. You acknowledge that the vesting of the Shares pursuant to this Notice is earned only by continuing Service.

(b) Death; Disability. If you die before your Service terminates (or you die within three months of your termination of Service other than for Cause), then this Option will expire at the close of business at Company headquarters on the date 12 months after the date of death (subject to the expiration detailed in Section 6). If your Service terminates because of your Disability, then this Option will expire at the close of business at Company headquarters on the date 12 months after your termination date (subject to the expiration detailed in Section 6).

(c) No Notice. You are responsible for keeping track of these exercise periods following your termination of Service for any reason. The Company will not provide further notice of such periods. In no event shall this Option be exercised later than the Expiration Date set forth in the Notice of Grant.

3. Exercise of Option.

(a) Right to Exercise. This Option is exercisable during its term in accordance with the Vesting Schedule set forth in the Notice of Grant and the applicable provisions of the Plan and this Agreement. In the event of your death, Disability, or other cessation of Service, the exercisability of the Option is governed by the applicable provisions of the Plan, the Notice of Grant and this Agreement. This Option may not be exercised for a fraction of a Share.

(b) Method of Exercise. This Option is exercisable by delivery of an exercise notice in a form specified by the Company (the "***Exercise Notice***"), which shall state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "***Exercised Shares***"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice shall be delivered in person, by mail, via electronic mail or facsimile or by other authorized method to the Secretary of the Company or other person designated by the Company. The Exercise Notice shall be accompanied by payment of the aggregate exercise price as to all Exercised Shares. This Option shall be deemed to be exercised upon receipt by the Company of a fully executed Exercise Notice accompanied by the aggregate exercise price and any applicable tax withholding due upon exercise of the Option in all and any relevant jurisdictions.

(c) Exercise by Another. If another person wants to exercise this Option after it has been transferred to him or her in compliance with this Agreement, that person must prove to the Company's satisfaction that he or she is entitled to exercise this Option. That person must also complete the proper Exercise Notice form (as described above) and pay the exercise price (as described below) and any applicable tax withholding due upon exercise of the Option (as described below) in all and any relevant jurisdictions.

4. Method of Payment. Payment of the aggregate exercise price shall be by any of the following, or a combination thereof, at your election:

(a) your personal check, wire transfer, or a cashier's check;

(b) certificates for shares of Company stock that you own, along with any forms needed to effect a transfer of those shares to the Company; the value of the shares, determined as of the effective date of the Option exercise, will be applied to the Option exercise price. Instead of surrendering shares of Company stock, you may attest to the ownership of those shares on a form provided by the Company and have the same number of shares subtracted from the Option shares issued to you. However, you may not surrender, or attest to the ownership of, shares of Company stock in payment of the exercise price of your Option if your action would cause the Company to recognize compensation expense (or additional compensation expense) with respect to this Option for financial reporting purposes;

(c) cashless exercise through irrevocable directions to a securities broker approved by the Company to sell all or part of the Shares covered by this Option and to deliver to the Company from the sale proceeds an amount sufficient to pay the Option exercise price and any withholding taxes. The balance of the sale proceeds, if any, will be delivered to you. The directions must be given by signing a special notice of exercise form provided by the Company; or

(d) other method authorized by the Company.

5. Non-Transferability of Option. In general, except as provided below, only you may exercise this Option prior to your death. You may not transfer or assign this Option, except as provided below. For instance, you may not sell this Option or use it as security for a loan. If you attempt to do any of these things, this Option will immediately become invalid. You may, however, dispose of this Option in your will or in a beneficiary designation. However, the Committee (as defined in the Plan) may, in its sole discretion, allow you to transfer this Option as a gift to one or more family members. For purposes of this Agreement, "family member" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in- law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law (including adoptive relationships), any individual sharing your household (other than a tenant or employee), a trust in which one or more of these individuals have more than 50% of the beneficial interest, a foundation in which you or one or more of these persons control the management of assets, and any entity in which you or one or more of these persons own more than 50% of the voting interest. In addition, the Committee may, in its sole discretion, allow you to transfer this Option to your spouse or former spouse pursuant to a domestic relations order in settlement of marital property rights. The Committee will allow you to transfer this Option only if both you and the transferee(s) execute the forms prescribed by the Committee, which include the consent of the transferee(s) to be bound by this Agreement. This Option may not be transferred in any manner other than by will or by the laws of descent or distribution or court order and may be exercised during the lifetime of you only by you, your guardian, or legal representative, as permitted in the Plan. The terms of the Plan and this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of you.

6. Term of Option. This Option shall in any event expire on the expiration date set forth in the Notice of Grant, which date is 10 years after the grant date.

7. Tax Consequences. You should consult a tax adviser for tax consequences relating to this Option in any jurisdiction in which you are or have been subject to tax during the course of this agreement. YOU SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES. You will not be allowed to exercise this Option unless you make arrangements acceptable to the Company to pay any withholding taxes that may be due as a result of the Option exercise in all or any relevant jurisdiction.

8. Withholding Taxes and Stock Withholding. Regardless of any action the Company or your actual employer (the "***Employer***") takes with respect to any or all income tax, social insurance, payroll tax, payment on account or other tax-related withholding ("***Tax-Related Items***"), you acknowledge that the ultimate liability for all Tax-Related Items legally due by you is and remains your responsibility and that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option grant, including the grant, vesting or exercise of the Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (2) do not commit to structure the terms of the grant or any aspect of the Option to reduce or eliminate your liability for Tax-Related Items. You acknowledge that if you are subject to Tax-Related Items in more than one jurisdiction, the Company and/or the Employer may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to exercise of the Option, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all withholding and payment on account obligations of the Company and/or the Employer. In this regard, you authorize the Company and/or the Employer to withhold all applicable Tax-Related Items legally payable by you from your wages or other cash compensation paid to you by the Company and/or the Employer. With the Company's consent, these arrangements may also include, if permissible under local law, (a) withholding Shares that otherwise would be issued to you when you exercise this Option by considering up to the maximum applicable statutory withholding rates, (b) having the Company withhold taxes from the proceeds of the sale of the Shares, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf and you hereby authorize such sales by this authorization), (c) your payment of a cash amount, or (d) any other arrangement approved by the Company; all under such rules as may be established by the Committee and in compliance with the Company's Insider Trading Policy and 10b5-1 Trading Plan Policy, if applicable; provided however, that if you are a Section 16 officer of the Company under the Exchange Act, then the Committee (as constituted in accordance with Rule 16b-3 under the Exchange Act) shall establish the method of withholding from alternatives (a)-(d) above prior to the Tax-Related Items withholding event; and if no such determination is made, then the method of withholding shall be in accordance with subsection (a) hereof. The Fair Market Value of these Shares, determined as of the effective date of the Option exercise, will be applied as a credit against the withholding taxes. You shall pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold as a result of your participation in the Plan or your purchase of Shares that cannot be satisfied by the means previously described. Finally, you acknowledge that the Company has no obligation to deliver Shares to you until you have satisfied the obligations in connection with the Tax-Related Items as described in this Section. For the avoidance of doubt the above clause will also apply to any taxes or other liabilities due under the local statutes if you are or have been resident outside of the United States during the course of this agreement.

9. Insider Trading Restrictions/Market Abuse Laws. You acknowledge that, depending on your country, you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to acquire or sell the Shares or rights to Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you are advised to speak to your personal advisor on this matter.

10. Acknowledgement. The Company and you agree that the Option is granted under and governed by the Notice of Grant, this Agreement and the provisions of the Plan (incorporated herein by reference). You: (i) acknowledge receipt of a copy of the Plan prospectus, (ii) represent that you have carefully read and are familiar with their provisions, and (iii) hereby accept the Option subject to all of the terms and conditions set forth herein and those set forth in the Plan and the Notice of Grant. You hereby agree to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice of Grant and the Agreement.

11. Consent to Electronic Delivery of All Plan Documents and Disclosures. By your acceptance of this Option, you consent to the electronic delivery of the Notice of Grant, this Agreement, account statements, Plan prospectuses required by the Securities and Exchange Commission, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its security holders (including, without limitation, annual reports and proxy statements) or other communications or information related to the Option. Electronic delivery may include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. You acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost if you contact the Company by telephone, through a postal service or electronic mail at stockadmin@aegleabio.com. You further acknowledge that you will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, you understand that you must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. Also, you understand that your consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if you have provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail at stockadmin@aegleabio.com. Finally, you understand that you are not required to consent to electronic delivery.

12. Compliance with Laws and Regulations. The exercise of this Option will be subject to and conditioned upon compliance by the Company and you with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Common Stock may be listed or quoted at the time of such issuance or transfer. The Shares issued pursuant to this Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

13. **Governing Law; Severability**. If one or more provisions of this Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this Agreement, (ii) the balance of this Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this Agreement shall be enforceable in accordance with its terms. This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law. For purposes of litigating any dispute that may arise directly or indirectly from the Plan, the Notice and this Agreement, the parties hereby submit and consent to litigation in the exclusive jurisdiction of the State of California and agree that any such litigation shall be conducted only in the courts of California in San Francisco County or the federal courts of the United States for the Northern District of California and no other courts.

14. **No Rights as Employee**. Nothing in this Agreement shall affect in any manner whatsoever the right or power of the Company, or a Parent, Subsidiary or Affiliate of the Company, to terminate your Service, for any reason, with or without Cause.

15. **Adjustment**. In the event of a stock split, a stock dividend or a similar change in Company stock, the number of Shares covered by this Option and the exercise price per Share may be adjusted pursuant to the Plan.

16. **Award Subject to Company Clawback or Recoupment**. To the extent permitted by applicable law, the Option shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of your employment or other Service that is applicable to you. In addition to any other remedies available under such policy, applicable law may require the cancellation of your Option (whether vested or unvested) and the recoupment of any gains realized with respect to your Option.

17. **Entire Agreement; Enforcement of Rights.** This Agreement, the Plan and the Notice constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning this Option are superseded. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing and signed by the parties to this Agreement. The failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of any rights of such party.

BY ACCEPTING THIS OPTION, YOU AGREE TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

Exhibit 10.9

Execution Version

ASSET PURCHASE AGREEMENT

dated as of

July 27, 2023

by and between

AEGLEA BIOTHERAPEUTICS, INC.

and

IMMEDICA PHARMA AB

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ASSET PURCHASE AGREEMENT

This **ASSET PURCHASE AGREEMENT** is entered into as of July 27, 2023 (this "Agreement"), by and between Aeglea BioTherapeutics, Inc., a corporation organized and existing under the laws of Delaware ("Aeglea"), and Immedica Pharma AB, a limited company (*Aktiebolag*) organized and existing under the laws of Sweden ("Immedica"). Each of Aeglea and Immedica are sometimes referred to herein individually as a "Party" and collectively as the "Parties." Capitalized terms used herein and not otherwise defined shall have the meanings set forth in Exhibit A.

W I T N E S S E T H:

WHEREAS, Aeglea has established a research, development and manufacturing program for pegzilarginase for the treatment of Arginase-1 Deficiency as well as other therapeutic, prophylactic, palliative and diagnostic uses (the "Program");

WHEREAS, Immedica and Aeglea are parties to that certain License and Supply Agreement dated as of March 21, 2021, as amended by that certain Memorandum of Understanding dated July 1, 2021, that certain Memorandum of Understanding dated June 22, 2022, and that certain Amendment No. 2 to the Agreement dated March 28, 2023 (the "License Agreement"), pursuant to which Aeglea licenses to Immedica certain rights in and to the Product and Aeglea's Intellectual Property rights therein; and

WHEREAS, Aeglea agrees to sell to Immedica, and Immedica agrees to purchase from Aeglea, assets owned by Aeglea and related to the Product on the terms and subject to the conditions set forth herein.

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

ARTICLE I

PURCHASE PRICE

Section 1.1 Purchase Price. In consideration of the conveyance to Immedica of all right, title and interest in, under and to the Acquired Assets and the other rights granted to Immedica hereunder, and subject to the terms and conditions hereof, Immedica shall pay to Aeglea:

(a) An initial payment in cash of $15,000,000 in the aggregate (the "Initial Payment"), by wire transfer of immediately available funds in accordance with written instructions furnished to Immedica by Aeglea, payable at Closing;

(b) The Milestone Payments, if any, subject to the terms and conditions of, and payable as set forth in, Section 1.2; and

(c) The Fuji Credit, subject to the terms and conditions of, and payable as set forth in, Section 6.10.

Section 1.2 Milestone Payments.

(a) Subject to the remainder of this Section 1.2, upon the first occurrence of the applicable milestone event described in the table set forth below by Immedica (each such event, a "Milestone Event"),

Immedica shall pay an amount in cash equal to the applicable milestone payment listed next to such Milestone Event in the table below (each such payment, a "Milestone Payment"), less any Milestone Set-Offs, in accordance with Section 1.2(b). The Milestone Events and corresponding Milestone Payments are as follows:

Milestone Event	Milestone Payment
Pricing and Reimbursement Approval in France of the Product that is indicated for treatment of Arginase-1 Deficiency by the applicable Governmental Authority in France, where such Product has previously received Regulatory Approval in France for the treatment of Arginase-1 Deficiency	Reimbursement Earnout Amount for such Product in France
Pricing and Reimbursement Approval in Germany of the Product that is indicated for treatment of Arginase-1 Deficiency by the applicable Governmental Authority in Germany, where such Product has previously received Regulatory Approval in Germany for the treatment of Arginase-1 Deficiency	Reimbursement Earnout Amount for such Product in Germany
Pricing and Reimbursement Approval in the United Kingdom of the Product that is indicated for treatment of Arginase-1 Deficiency by the applicable Governmental Authority in the United Kingdom, where such Product has previously received Regulatory Approval in the United Kingdom for the treatment of Arginase-1 Deficiency	Reimbursement Earnout Amount for such Product in the United Kingdom
Regulatory Approval of the BLA of the Product for the treatment of Arginase-1 Deficiency in the United States	$30,000,000
Additional Milestone Event (as such term is defined in Schedule 1.2(a)).	Additional Milestone Amount (as such term is defined in Schedule 1.2(a)).

(b) No later than thirty (30) days after the achievement of a Milestone Event, Immedica shall provide written notice to Aeglea of the achievement of such Milestone Event and shall pay to Aeglea the corresponding Milestone Payment, less any Milestone Set-Offs.

(c) Each Milestone Payment to be paid by or on behalf of Immedica shall be paid in U.S. Dollars.

(d) Notwithstanding anything to the contrary in this Agreement, (i) the maximum aggregate amount of Milestone Payments Immedica shall be obligated to pay to Aeglea pursuant to the table set forth in this Section 1.2 shall be $100,000,000, (ii) each unique row in the table set forth in this Section 1.2 represents a separate Milestone Event, and accordingly, there are five (5) distinct Milestone Events, (iii) each Milestone Event may be achieved no more than one time, (iv) each Milestone Payment shall be payable only once, if at all, upon the first achievement of the applicable Milestone Event (regardless of (A) any subsequent or repeated achievement of a Milestone Event and (B) the number of subsequent Products achieving such Milestone Events).

(e) Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that, in addition to any other right or remedy under this Agreement, Immedica shall have the right, but not the obligation, from time to time to set off against (x) any Milestone Payment that is owed and has not yet been paid and (y) if applicable, the Specified Patents Holdback Amount if any portion of such amount continues to be held back in accordance with Section 1.2(f) (clauses (x) and (y), the "Available Remedy Amounts") (each of the following clauses (i), (ii) and (iii), a "Milestone Set-Off"): (i) any Losses for which any Immedica Indemnified Party is entitled to indemnification pursuant to, and in accordance with, Article VII, (ii) any Losses in respect of claims for intentional fraud or willful misconduct, and (iii) any Necessary IP Payments already paid or accrued or then payable by any Immedica Indemnified Party; provided that Immedica shall not be entitled to set off any Necessary IP Payment to the extent that any Immedica Indemnified Party receives an indemnification payment for such Necessary IP Payment pursuant to Article VII. Notwithstanding anything in this Agreement to the contrary, to the extent that Immedica is unable to set off any amount of any Necessary IP Payment (such amount, the "Necessary IP Payment Carryover") against any Available Remedy Amount, such Necessary IP Payment Carryover may be set off against any subsequent Available Remedy Amount. Immedica shall keep, and shall instruct any Immedica Indemnified Party to keep, reasonably complete and accurate records of any Milestone Set-Off. Any Milestone Set-Off taken by Immedica will be accompanied by a written notice including an accounting of such Milestone Set-Off ("Set-Off Notice"); provided that any failure by Immedica to provide any such Set-Off Notice to Aeglea shall not impact Immedica's rights under this Section 1.2(e). Upon reasonable written request by Aeglea, Immedica will provide reasonable documentation in support of any Milestone Set-Off, such request to be made no more than six (6) months after the date of the applicable Set-Off Notice. The Parties shall negotiate in good faith to seek to resolve any dispute regarding any Set-Off Notice before making any claim to resolve such dispute.

(f) Aeglea and Immedica agree to be bound by and comply with the terms and conditions set forth on Schedule 1.2(f) as though set forth in full herein.

(g) For purposes of this Section 1.2:

(i) The definitions of Reimbursement Earnout Amount, Actual Reimbursement Percentage, Actual Reimbursement Price, Expected Reimbursement Price and Pricing Reimbursement Approval are stated with respect to a 2 mg vial of the Product. In the event that any of the Milestone Events set forth in the first three rows of the table set forth in this Section 1.2 occurs with respect to a vial with a different amount of Product, the amounts in Euros and British Pounds Sterling will be proportionally adjusted, on a linear basis based on mg of Product, for purposes of calculating the Reimbursement Earnout Amount. By way of example, in the event that any of the Milestone Events set forth in the first three rows of the table set forth in this Section 1.2 occurs with respect to a 4 mg vial of Product, then the Expected Reimbursement Price of such 4 mg vial of Product (A) with respect to France would be [*]/4 mg vial of such Product; (B) with respect to Germany would be [*]/4 mg vial of such Product; and (C) with respect to the United Kingdom would be [*]/4 mg vial of such Product, and the Reimbursement Earnout Amount for such 4 mg vial of such Product would be determined using such amounts.

(ii) "Actual Reimbursement Percentage" means, with respect to a 2 mg vial of the Product in a given country, a number equal to the quotient of (A) the Actual Reimbursement Price for such 2 mg vial of the Product received by Immedica in such country, *divided by* (B) the Expected Reimbursement Price for such 2 mg vial of the Product in such country. By way of examples, if the Actual Reimbursement Price for a 2 mg vial of the Product received by Immedica in France is [*], then the Actual Reimbursement Percentage for such 2 mg vial of the Product in France is [*] or 93%; and if the Actual Reimbursement Price for a 2 mg vial of the Product received by Immedica in Germany is [*], then the Actual Reimbursement Percentage for such 2 mg vial of the Product is [*] or 87%.

(iii) "Actual Reimbursement Price" means, with respect to a given country, the price reimbursed by the applicable Governmental Authority, net of any mandatory rebates, for a 2 mg vial of the

Product in such country pursuant to the Pricing and Reimbursement Approval for such 2 mg vial of the Product in such country, where such reimbursed price may be the listed price or a discounted price, net of any mandatory rebates, of such 2 mg vial of the Product that is agreed and approved between Immedica and such applicable Governmental Authority.

(iv) "Expected Reimbursement Price" means, (A) with respect to France, [*]/2 mg vial of the Product; (B) with respect to Germany, [*]/2 mg vial of the Product; and (C) with respect to the United Kingdom, [*]/2 mg vial of the Product.

(v) [Reserved].

(vi) "Pricing and Reimbursement Approval" means, with respect to a 2 mg vial of the Product in a given country, following Regulatory Approval of such 2 mg vial of the Product for the treatment of Arginase-1 Deficiency in such country by the applicable Regulatory Authority in such country, the later of (A) the approval, agreement, determination or decision by (1) the Ministries of Health and Social Security in France as published in the Journal Officiel, (2) the National Institute for Health and Care Excellence in the United Kingdom as set forth in the applicable commercial access agreement and (3) Spitzenverband der Gesetzlichen Krankenkassen (GKV-Spitzenverband) in Germany as published in the Lauer Taxe establishing a price for such 2 mg vial of the Product that can be legally charged to consumers, if required or desirable, in such country in connection with the broad commercialization of such 2 mg vial of the Product for the treatment of Arginase-1 Deficiency in such country; and (B) the approval, agreement, determination or decision by the foregoing applicable Governmental Authority establishing the level of reimbursement for such 2 mg vial of the Product that will be reimbursed by such Governmental Authority, if required or desirable, in such country in connection with the broad commercialization of such 2 mg vial of the Product for the treatment of Arginase-1 Deficiency in such country.

(vii) [Reserved].

(viii) [Reserved].

(ix) [Reserved].

(x) "Reimbursement Earnout Amount" means, with respect to a 2 mg vial of the Product in a given country: (A) if the Actual Reimbursement Percentage of such 2 mg vial of the Product in such country is equal to 100% or more, $10,000,000, (B) if the Actual Reimbursement Percentage of such 2 mg vial of the Product in such country is less than 80%, zero, and (C) if the Actual Reimbursement Percentage of such 2 mg vial of the Product in such country is 80% or more but less than 100%, an amount equal to the sum of (i) $3,333,333 and (ii) the product of (A)(x) the Actual Reimbursement Percentage for such 2 mg vial of the Product in such country *minus* 80% *divided by* (y) 20% *multiplied by* (B) $6,666,666; or, in the case of the foregoing clause (C), the formula expressed as follows:

$$\$3{,}333{,}333 + \frac{\text{Actual Reimbursement Percentage minus 80\%}}{20\%} \times \$6{,}666{,}666$$

(xi) [Reserved].

(xii) [Reserved].

ARTICLE II

PURCHASE AND SALE

Section 2.1 Acquired Assets.

(a) On the terms and subject to the conditions set forth in this Agreement, at the Closing, Aeglea shall, and shall cause its Subsidiaries to, sell, assign, transfer, convey and deliver to Immedica, and Immedica shall receive, acquire and accept, all right, title and interest of Aeglea and its Subsidiaries in, to and under the Acquired Assets (including the Assigned Intellectual Property), free and clear of all Liens except for Permitted Liens.

(b) "Acquired Assets" means the following assets at the Closing:

(i) the assets listed on Schedule 2.1(b)(i)(D);

(ii) the Assigned Contracts;

(iii) all Biological Materials;

(iv) all Inventory;

(v) all Product Registrations that are (A) used in or held for use in the Program or in connection with the Product or (B) listed on Schedule 2.1(b)(v) (collectively, the "Transferred Product Registrations"); provided that Aeglea shall be entitled to retain copies of the Transferred Product Registrations solely to the extent necessary to comply with applicable Law and its internal document retention policies, subject to Aeglea's nonuse and confidentiality obligations set forth in Section 6.2;

(vi) all Documents primarily related to the Program or Product or that are otherwise related to the Product or Program and reasonably necessary and useful to the Product or the Program (collectively, the "Transferred Documents"), including all attorney-client privilege and attorney work-product protection and all Documents subject to the attorney-client privilege or work-product protection in each case that relate to the Product or the Program; provided that the Transferred Documents shall exclude all (w) personnel files for any current or former directors, officers, employees, independent contractors or consultants (collectively, "Aeglea Service Providers"), (x) Documents relating to Spyre Therapeutics, Inc. and its businesses or assets, as well as the transactions (the "Spyre Transactions") contemplated by that certain Agreement and Plan of Merger, dated June 22, 2023, by and between Aeglea, Spyre Therapeutics, Inc., Aspen Merger Sub I, Inc. and Sequoia Merger Sub II, LLC (collectively, the "Spyre Documents"), (y) Documents subject to the attorney-client privilege or work-product protection relating solely to the License Agreement (and not the Product or the Program), and (z) Documents relating to the determination by Aeglea or any of its Subsidiaries with respect to the wind-down or discontinuation of all or a portion of the Program or any study related thereto; and provided, further, that Aeglea shall be entitled to (1) redact information from any Transferred Document that if in a separate document would fall within the foregoing exceptions or that relates exclusively to something other than the Product or the Program, and (2) retain copies of the foregoing (A) to the extent necessary to comply with applicable Law and its internal document retention policies and (B) to the extent any Transferred Document relates to Excluded Assets or Excluded Liabilities, in each case, subject to Aeglea's nonuse and confidentiality obligations set forth in Section 6.2;

(vii) all claims, causes of action (including the right to sue for past infringement or misappropriation), defenses, rights of recovery and rights of set-off against third parties and all credits (including all guarantees, warranties, indemnities and similar rights) in favor of Aeglea or any of its

Subsidiaries, in each case to the extent relating to, arising out of or in connection with the Product, the Program, the Acquired Assets or the Assumed Liabilities; and

(viii) all other assets, properties and rights of a type not expressly covered in this Section 2.1(b) that are exclusively related to, exclusively used in or exclusively held for use in Program or in connection with the Product.

Section 2.2 Excluded Assets.

(a) Notwithstanding anything to the contrary in this Agreement, nothing herein contained shall be deemed to sell, transfer, assign or convey to Immedica the Excluded Assets, and Aeglea and its Subsidiaries shall retain all right, title and interest to, in and under the Excluded Assets and Immedica shall not acquire any of the Excluded Assets.

(b) "Excluded Assets" means each of the following assets at the Closing:

(i) all cash and cash equivalents, securities, negotiable instruments, accounts receivable, notes and other amounts receivable of Aeglea or its Subsidiaries;

(ii) any rights to Tax refunds, credits, deductions, allowances or other Tax benefits of Aeglea or its Subsidiaries;

(iii) the company seal, minute books, charter documents, stock or equity record books and such other books and records as pertain to the organization, existence or capitalization of Aeglea and its Subsidiaries, as well as any other records or materials relating to Aeglea or its Subsidiaries that are exclusively related to the Excluded Assets or are not related to the Acquired Assets, the Program or the Product;

(iv) the shares of capital stock, partnership interests, membership interests or other equity interests of any Person (including Aeglea or any of its Subsidiaries);

(v) other than the Assigned Intellectual Property and subject to the terms and conditions of Section 6.6 and the Specified Patent License Agreement, all right, title and interest in and to all Intellectual Property and all other intangible property of Aeglea;

(vi) all equipment and tangible personal property of Aeglea or any of its Subsidiaries;

(vii) all real property owned or leased by Aeglea or any of its Subsidiaries;

(viii) all Contracts listed on Schedule 2.2(b)(viii);

(ix) all rights which accrue or will accrue to Aeglea or any of its Subsidiaries under this Agreement;

(x) (A) all attorney-client privilege and attorney work-product protection of Aeglea or its Subsidiaries, (B) all Documents subject to the attorney-client privilege or work-product protection, in the case of the foregoing clauses (A) and (B), solely to the extent not primarily related to the Program or Product or that are otherwise not related to the Product or Program and not reasonably necessary and useful to the Product or the Program, (C) all Documents subject to the attorney-client privilege or work-product protection maintained by Aeglea or its Subsidiaries in connection with the Transaction, the License Agreement or the Spyre Transaction and (D) all Documents (including those subject to attorney-client

privilege or work-product protection) that (i) are personnel files for Aeglea Service Providers, (ii) are Spyre Documents or (iii) relate to the determination by Aeglea or any of its Subsidiaries with respect to the wind-down or discontinuation of all or a portion of the Program or any study related thereto;

(xi) Tax Returns of Aeglea and its Subsidiaries (other than Tax Returns or any portion thereof solely relating to any Acquired Asset);

(xii) all current and prior insurance policies of Aeglea and its Subsidiaries and all rights of any nature with respect thereto, including all insurance recoveries thereunder and rights to assert claims with respect to any such insurance recoveries;

(xiii) all assets with respect to any employee benefit plans, agreements or arrangements contributed to, sponsored, maintained or entered into by Aeglea or its Subsidiaries or otherwise relating to any Aeglea Service Providers;

(xiv) the ADA Assays; and

(xv) all other assets, properties, contractual rights, goodwill and other intangible assets, rights and claims of Aeglea and its Subsidiaries not included in the Acquired Assets.

Section 2.3 Assumption of Assumed Liabilities.

(a) On the terms and subject to the conditions set forth in this Agreement, as of the Closing, Immedica shall assume and be responsible for, and shall timely perform, satisfy and discharge in accordance with their terms, the Assumed Liabilities.

(b) "Assumed Liabilities" means each of the following Liabilities of Aeglea and its Subsidiaries at the Closing:

(i) all Liabilities of Aeglea arising under or in connection with the Assigned Contracts from and after the Closing, excluding for clarity the Excluded Liabilities set forth in Sections 2.4(b)(iv) and 2.4(b)(v) below, but including the amounts as set forth in Schedule 2.3(b)(i);

(ii) all Liabilities of Aeglea arising out of or relating to actions by Immedica or its Subsidiaries commenced after the Closing, irrespective of the legal theory asserted, arising from the administration, manufacture, advertising, marketing, distribution, sale or use of the Product or conduct of the Program during the period of time on or after the Closing;

(iii) without duplication of the other provisions of this Section 2.3(b), all Liabilities arising out of or in connection with an event first occurring at any time from and after the Closing to the extent relating to the Program or Product, or the use, ownership or operation of the Acquired Assets by Immedica or its Subsidiaries from and after the Closing, other than Liabilities of Aeglea or any of its Subsidiaries arising out of a breach or termination of this Agreement by Aeglea or any of its Subsidiaries.

Section 2.4 Excluded Liabilities.

(a) Notwithstanding any provision in this Agreement or any other writing to the contrary, Immedica is assuming only the Assumed Liabilities and is not assuming any other Liability of or relating to Aeglea or any of its Subsidiaries (or any of their respective predecessors or any prior owner of all or part of its or their businesses and assets) of whatever nature, whether presently in existence or arising hereafter. All such other Liabilities shall be retained by and remain Liabilities of Aeglea (or its applicable Affiliate) (all such Liabilities and

obligations not being assumed, including those specifically enumerated in Section 2.4(b), being herein referred to as the "Excluded Liabilities").

(b) "Excluded Liabilities" includes, without limitation, the following:

(i) all Liabilities to the extent not related to the Program, Product or the Acquired Assets;

(ii) all Liabilities relating to or arising out of the Excluded Assets;

(iii) (A) all Liabilities of Aeglea, its Affiliates or any consolidated, affiliated, combined or unitary group of which Aeglea or any of its Affiliates is or has been a member, for Taxes and (B) all Liabilities for Taxes with respect to the Acquired Assets for taxable periods ending on or prior to the Closing Date; provided that any Transfer Taxes incurred in connection with the Transaction and Apportioned Obligations shall be paid in the manner set forth in Article VIII;

(iv) all Liabilities relating to the Assigned Contracts to the extent such Liabilities (A) arise before the Closing, including, for the avoidance of doubt, any amounts owed under any Assigned Contract prior to the Closing pursuant to the terms thereof, regardless of whether the work to be performed, services to be rendered or goods to be provided in exchange for such amounts owed are to be provided before or after payment therefor or before or after the Closing, and regardless of whether an invoice for any such payment is rendered before or after the Closing; provided that the amounts listed on Schedule 2.3(b)(i) under the column "Expense to be Assumed by Immedica" shall be assumed by Immedica, (B) arise from or relate to any breach by Aeglea or any of its Subsidiaries of any provision of any of such Assigned Contract or (C) arise from or relate to any action or inaction by Aeglea or any of its Subsidiaries in connection with any such Assigned Contract;

(v) all Liabilities under any Contract that is not an Assigned Contract and, subject to Section 2.6, all Liabilities under any Assigned Contract that is not validly and effectively assigned to Immedica pursuant to this Agreement or any other Instrument;

(vi) all Liabilities, whether arising prior to, upon or following the Closing, with respect to any Aeglea Service Providers, including, without limitation, all Liabilities (A) under or relating to any employee benefit plan, contract, program, fund or arrangement and any trust, escrow or similar agreement related thereto, whether or not funded, in respect of any Aeglea Service Provider or with respect to which Aeglea or any of its Affiliates has made or is required to make payments, transfers or contributions, or any management, employment, severance, change in control, noncompete, confidentiality, offer letter, retention, incentive or similar Contract, and (B) the matters set forth on Schedule 2.4(b)(vi);

(vii) all Liabilities of Aeglea or any of its Affiliates in respect of Indebtedness;

(viii) all Liabilities in respect of any pending Legal Proceedings and any Legal Proceedings initiated after the Closing arising out of or relating to the administration, development, manufacture, advertising, marketing, distribution, sale or use of the Product or conduct of the Program prior to the Closing;

(ix) all Expenses of Aeglea or any of its Subsidiaries payable to Third Parties, including to any outside professionals (including any broker, finder, agent, investment banker, legal, accounting or tax adviser), incurred by Aeglea or any of its Subsidiaries before, on or after the Closing, in connection with the authorization, preparation, negotiation, execution and performance of this Agreement or the other

Instruments, or the process of selling the Acquired Assets, including any investment banking or brokerage fees, finders' fees or commissions; and

(x) all other Liabilities arising out of or relating to the Product, the Program or the Acquired Assets, to the extent such Liabilities relate to the period of time prior to Closing.

Section 2.5 Undisclosed Contracts. If any Program Contract was not set forth on Schedule 2.1(b)(i) or 2.2(b)(viii) and is identified following the Closing, Aeglea shall promptly notify Immedica in writing giving sufficient disclosure of such Program Contract and provide Immedica with a copy thereof, in which case Immedica shall thereafter be entitled to deem such Program Contract an "Assigned Contract" and the provisions of this Agreement (including Section 2.6) shall apply to such Program Contract as though it were an Assigned Contract, and Aeglea and Immedica shall take such action reasonably requested by Immedica (and consistent with the other provisions of this Agreement (including Section 2.6)) to assign such Program Contract to Immedica. Neither Aeglea nor any of its Subsidiaries shall voluntarily terminate any such nondisclosed Program Contract prior to providing Immedica with written notice of the intent to terminate and giving Immedica a reasonable period of time to review such Program Contract and determine whether to exercise its right to treat such Program Contract as an "Assigned Contract."

Section 2.6 Non-Assignable Assets. Notwithstanding anything to the contrary in this Agreement, nothing in this Agreement or the consummation of the Transaction shall be construed as an attempt or agreement to assign any Acquired Asset, including any Contract, Permit, certificate, approval, authorization or other right, which by its terms or by Law is non-assignable without the consent of a Third Party or a Governmental Authority or is terminable or cancelable by a Third Party or a Governmental Authority in the event of an assignment (any such Acquired Asset, a "Non-assignable Asset") unless and until such consent shall have been obtained. Aeglea shall and shall cause its Subsidiaries to use all commercially reasonable efforts to obtain any such consents with respect to the Acquired Assets, including all Non-assignable Assets, and including all consents set forth on Schedule 4.4(a), as promptly as practicable, and shall cooperate as reasonably requested by Immedica in any efforts made by Immedica or any of its Affiliates to obtain such consent. If any such consent or approval is not obtained, Aeglea shall, and shall cause its Subsidiaries to, provide to Immedica the benefits of such Non-assignable Asset in accordance with this Agreement and shall enforce, or cause its Subsidiaries to enforce, at the request of and for the benefit of Immedica, any rights of Aeglea or its Subsidiaries arising thereunder, including the right to seek any available remedies or to terminate in accordance with the terms thereof, in each case at Immedica's cost and expense. Aeglea shall and shall cause its Subsidiaries to promptly pay to Immedica when received all monies received by Aeglea or any of its Affiliates under any such Non-assignable Asset or any claim, right or benefit arising thereunder, except to the extent the same represents an Excluded Asset. As a condition to Aeglea providing Immedica with the benefits of any Non-assignable Asset, Immedica shall perform, in the name or on behalf of Aeglea or its applicable Subsidiary, all obligations of Aeglea or its applicable Subsidiary and shall indemnify Aeglea or its applicable Subsidiary for any Liabilities first arising thereunder following the Closing, except to the extent such Liabilities relate to the gross negligence or willful misconduct of Aeglea or any Aeglea Indemnified Party or the failure of Aeglea or any Aeglea Indemnified Party to follow the reasonable written (email being sufficient) instructions of Immedica or any of its Subsidiaries with respect to such Non-assignable Asset. To the extent that, in connection with obtaining a Third Party's consent under any Non-assignable Asset, one or more of the Parties enter into an agreement with such Third Party that provides for an allocation of liability among the Parties with respect to such Non-assignable Asset that is inconsistent with the terms of this Agreement, the Parties agree that, as among themselves, the provisions of this Agreement shall control.

Section 2.7 Designated Buyer. Notwithstanding anything to the contrary contained in this Agreement, Immedica may elect to have any or all of the Acquired Assets sold, assigned, conveyed, transferred or delivered to, or any of the Assumed Liabilities assumed by, one or more of its Subsidiaries, in each case as set forth in the Instruments to be delivered at Closing; provided, however, that no such sale, assignment, conveyance, transfer

or delivery shall (a) relieve Immedica of any of its obligations to Aeglea hereunder with respect to the Assumed Liabilities or (b) otherwise increase or expand the obligations of Aeglea hereunder.

Section 2.8 ADA Assay License. Aeglea and its Subsidiaries hereby grant to Immedica and its Affiliates a royalty-free, fully paid-up, worldwide, fully transferable, irrevocable, perpetual, non-exclusive, sublicensable (including the right to sublicense through multiple tiers) license under their respective rights in and to the ADA Assays to use and otherwise Exploit the ADA Assays for any and all purposes.

ARTICLE III

CLOSING

Section 3.1 Closing. The closing of the Transaction (the "Closing") shall take place on the date hereof (the "Closing Date") remotely by exchange of documents and signatures (or their electronic counterparts), simultaneously with the execution and delivery of this Agreement.

Section 3.2 Deliveries by Aeglea.

(a) At the Closing, Aeglea shall pay an amount in cash equal to the Fuji Credit to Fujifilm by wire transfer of immediately available funds, and, at or prior to the Closing, shall provide to Immedica proof of such payment that is reasonably satisfactory to Immedica.

(b) At the Closing, Aeglea shall deliver, or cause to be delivered, to Immedica, as applicable, the following:

(i) an assignment and assumption agreement and bill of sale, in a form reasonably agreed among the Parties (the "Assignment and Assumption and Bill of Sale"), executed by a duly authorized officer of Aeglea;

(ii) the agreements listed on Schedule 3.2(b); and

(iii) the IP Assignment Agreement, executed by a duly authorized officer of Aeglea.

(iv) [Reserved].

Section 3.3 Deliveries by Immedica at the Closing. At the Closing, Immedica shall deliver, or cause to be delivered, to Aeglea, as applicable, the following:

(a) the Initial Payment by wire transfer of immediately available funds, in accordance with Section 1.1(a);

(b) the Assignment and Assumption and Bill of Sale, executed by a duly authorized officer of Immedica;

(c) the agreements listed on Schedule 3.3; and

(d) the IP Assignment Agreement, executed by a duly authorized officer of Immedica.

(e) [Reserved].

Section 3.4 Additional Closing Deliveries. From time to time following the Closing, at the reasonable request of Aeglea or Immedica, such other Party shall execute, acknowledge and deliver all such further

conveyances, notices, assumptions, releases and acquittances and such other instruments, and shall take such further actions, as may be necessary to assure (a) to Immedica and its successors and assigns, all of the properties, rights, titles, interests, estates, remedies, powers and privileges intended to be conveyed to Immedica under this Agreement and the other Instruments, and (b) to the Parties and their respective Affiliates, and their respective successors and assigns, the assumption of the Liabilities intended to be assumed by Immedica under this Agreement and the other Instruments, and to otherwise make effective the Transaction.

Section 3.5 Appointment. Aeglea hereby constitutes and appoints, effective as of the Closing, Immedica and its successors and assigns as the true and lawful attorney of Aeglea with full power of substitution in the name of Immedica, or in the name of Aeglea but for the benefit of Immedica, to collect for the account of Immedica any items of Acquired Assets. Immedica shall be entitled to retain for its own account any amounts collected pursuant to the foregoing powers, including any amounts payable as interest in respect thereof and shall promptly remit to Aeglea without any set-off any amounts collected that are not Acquired Assets.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF AEGLEA

Aeglea hereby represents and warrants to Immedica as of the Closing Date as follows:

Section 4.1 Organization and Good Standing. Aeglea is an entity duly organized, validly existing and in good standing under the applicable Laws of the state of its organization and has all requisite corporate or other similar organizational powers required to carry on its business as now conducted. Aeglea is duly qualified to do business as a foreign entity and, to the extent legally applicable, in good standing as a foreign entity in each jurisdiction where such qualification is necessary, except for those jurisdictions where failure to be so qualified or in good standing would not, individually or in the aggregate, reasonably be expected to be material to the Acquired Assets, the Product (which term "Product," solely for purposes of this Article IV, shall refer to the Product in accordance with good manufacturing practices, as defined under the applicable sections of the United States Code of Federal Regulations, and the specifications contained in the Transferred Product Registrations) or the Program (which term "Program," solely for purposes of this Article IV, shall refer to the research, development and manufacturing program for pegzilarginase solely with respect to the treatment of Arginase-1 Deficiency), or materially impede or materially delay the consummation by Aeglea of the Transactions or the performance of its obligations under this Agreement or any Instrument to which it is a party.

Section 4.2 Authorization of Agreement. Aeglea and each of its applicable Subsidiaries has all requisite power and authority to execute and deliver this Agreement and each other agreement, document or instrument contemplated by this Agreement to which it is a party (collectively, the "Instruments"), to perform its respective obligations hereunder and thereunder and to consummate the Transaction and the other transactions contemplated hereby and thereby. The execution, delivery and performance by Aeglea and each of its applicable Subsidiaries of each of this Agreement and each other Instrument and the consummation of the Transaction and the other transactions contemplated hereby and thereby have been duly authorized and approved by all requisite corporate or similar action on the part of Aeglea and each of its applicable Subsidiaries. Each of the Instruments has been, or will be at or prior to the Closing, duly and validly executed and delivered by Aeglea and each of its Subsidiaries party thereto and (assuming the due authorization, execution and delivery by the other parties thereto) each of the Instruments, when so executed and delivered, will constitute the legal, valid and binding obligations of Aeglea and each such Subsidiary, enforceable against it in accordance with its terms, subject to the effect of any applicable Laws relating to bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance or preferential transfers, or similar Laws relating to or affecting creditors' rights generally and subject, as to enforceability, to the effect of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at Law).

Section 4.3 Subsidiaries. Each Subsidiary of Aeglea which has title to any Acquired Assets is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization and has all requisite corporate or similar power and authority to carry on its portion of the Program as currently conducted and is duly qualified to do business and is in good standing as a foreign corporation or other entity in each jurisdiction where the ownership or operation of the Acquired Assets or the conduct of the Program requires such qualification, except for failures to be so duly organized, validly existing, qualified or in good standing that would not, individually or in the aggregate, be material to the Acquired Assets, the Product or the Program or materially impede or materially delay the consummation by such Subsidiary of the Transactions or the performance of its obligations under this Agreement or any Instrument to which it is a party.

Section 4.4 Conflicts; Consents of Third Parties.

(a) Assuming the receipt of the consents identified on Schedule 4.4(a), none of the execution and delivery of this Agreement or the Instruments by Aeglea or any of its Subsidiaries, or the consummation of the Transaction or the other transactions contemplated hereby and thereby, will conflict with, or result in any violation of, or constitute a breach of, or conflict with or constitute a default (with or without notice or lapse of time, or both) under any provision of, or require any consent or other action by any Person under, or give rise to any right of termination, cancellation or acceleration under: (i) the certificate of incorporation and by-laws or comparable organizational documents of Aeglea or any of its Subsidiaries party to any Instrument; (ii) any Contract to which Aeglea or any such Subsidiary is a party or by which any of the properties or assets of Aeglea or any of its Subsidiaries used or held for use in the Program or in connection with the Product, or any Acquired Asset, is bound; (iii) any Order of any Governmental Authority applicable to Aeglea or any of its Subsidiaries or by which any of the properties or assets of Aeglea used or held for use in the Program or in connection with the Product, or any Acquired Asset, is bound; or (iv) any applicable Law, except, in the case of clauses (ii), (iii) and (iv) above, where such conflict, violation or default would not be material to the Acquired Assets, the Product or the Program or materially impede or materially delay the consummation by Aeglea or any such Subsidiary of the Transactions or the performance of its obligations under this Agreement or any Instrument to which it is a party. None of the execution and delivery of this Agreement or the Instruments by Aeglea or any of its Subsidiaries, or the consummation of the Transaction or the other transactions contemplated hereby and thereby, will result in the creation or imposition of any Lien on any Acquired Asset, except for Permitted Liens.

(b) Assuming the receipt of the consents from a Governmental Authority identified on Schedule 4.4(a), and except for any such filings, notices, Permits, authorizations, registrations, consents or approvals, the failure to make or obtain would not be material to the Acquired Assets, the Product or the Program and would not materially impede or materially delay the consummation by Aeglea of the Transactions or the performance of its obligations under this Agreement or any Instrument to which it is a party, no consent, waiver, approval, Order, Permit or authorization of, or declaration or filing with, or notification to, any Governmental Authority is required for Aeglea in connection with the execution and delivery of this Agreement or the Instruments, or the consummation of the Transaction.

Section 4.5 Acquired Assets.

(a) Except as set forth on Schedule 4.5(a), prior to the transfer of the Acquired Assets to Immedica at the Closing in accordance with this Agreement, Aeglea owns and has good title to the Acquired Assets, free and clear of all Liens other than Permitted Liens. Other than any Permitted Liens, neither Aeglea nor any of its Subsidiaries has granted to any Third Party any interest, right to use, license or entered into any covenants not to sue, releases for infringement, or waivers of claims for infringement, in, of or with respect to the Acquired Assets. Neither Aeglea nor any of its Subsidiaries has received any written notice from any other Person challenging its ownership or rights to use any Acquired Assets and there are no pending Legal Proceedings against Aeglea or any of its Subsidiaries challenging such ownership or rights.

(b) There are no existing Contracts to which Aeglea or any of its Subsidiaries is a party, pursuant to which a Third Party is granted an option to acquire any interest in any of the Acquired Assets.

(c) Schedule 4.5(c) sets forth a true and complete list of all Non-assignable Assets.

(d) All Inventory has been manufactured (i) in accordance with good manufacturing practices, as defined under the applicable sections of the United States Code of Federal Regulations, (ii) in compliance with all applicable Law, (iii) in accordance with the Inventory Specifications and (iv) in accordance with the specifications and standards contained in the Transferred Product Registrations.

Section 4.6 Transferred Product Registrations.

(a) The Transferred Product Registrations constitute all material registrations, applications, approvals, licenses or permits granted by any Governmental Authority to develop and market the Product, other than any Product Registrations held by Immedica or its Subsidiaries.

(b) Except as set forth in Schedule 4.6(b), prior to the transfer of any Transferred Product Registration in accordance with this Agreement, Aeglea is the sole and exclusive owner of such Transferred Product Registration other than any Product Registrations held by Immedica or its Subsidiaries, and has not granted any right of reference with respect thereto.

Section 4.7 Assigned Contracts.

(a) Other than the Assigned Contracts and the Contracts listed on Schedule 2.2(b)(viii), neither Aeglea nor any of its Subsidiaries is party to any Contract that is primarily related to, or otherwise material to, the Product or the Program. Each Assigned Contract is a valid, binding and enforceable agreement of Aeglea or its applicable Subsidiaries party thereto and, to the Knowledge of Aeglea, of each other party to such Assigned Contract, and each such Assigned Contract is in full force and effect. In respect of each Assigned Contract, neither Aeglea nor any of its applicable Subsidiaries party thereto is, nor, to the Knowledge of Aeglea, any other counterparty thereto is, in default or breach under the terms of any such Assigned Contract, and, to the Knowledge of Aeglea, no event has occurred that, with or without the lapse of time or the giving of notice or both, would constitute a breach thereof or default thereunder by Aeglea or its applicable Subsidiaries party thereto or, to the Knowledge of Aeglea, any other party thereto, except for any such defaults or breaches that, individually or in the aggregate, would not reasonably be expected to be material to the Acquired Assets, the Product or the Program. There are no disputes pending, or to Aeglea's Knowledge, threatened, with respect to any of the Assigned Contracts and neither Aeglea nor any of its Subsidiaries has received any written notice of the intention of any other party to any Assigned Contract to terminate or not renew or reduce any commitment under any Assigned Contract, nor to the Knowledge of Aeglea is any such party intending to do so, in each case, except where such dispute, or such termination or nonrenewal or commitment reduction would not be material to the Product or the Program.

(b) No Assigned Contract (i) contains a covenant not to compete or other covenants that purport to limit or restrict the business activity of Aeglea or any of its Subsidiaries or limit the freedom of Aeglea or any of its Subsidiaries to use the Acquired Assets, or (ii) grants a Third Party a license, or a covenant not to be sued under, any Assigned Intellectual Property, excluding nonexclusive licenses granted in the ordinary course of business.

(c) There are no obligations to make any payments or any amounts owed under any Assigned Contract, including under the Fuji Scope of Work, that have not been paid by Aeglea or any of its Subsidiaries at or prior to Closing, regardless of whether the work to be performed, services to be rendered or goods to be provided in exchange for such payments are to be provided before or after payment therefor or before or after the Closing, and regardless of whether an invoice for any such payment is rendered before or after the Closing.

Section 4.8 Sufficiency of the Assets; Title to Acquired Assets.

(a) The Acquired Assets, together with the license to the ADA Assays granted pursuant to Section 2.8, comprise all of the property, assets and rights, tangible and intangible, of any nature whatsoever, used or held for use in the Program or with the Product, except for any and all such assets or rights for the general operation of an entity, all personnel, all contracts in support of clinical trials and the Excluded Assets (provided that for purposes of this Section 4.8(a), the definition of "Excluded Assets" shall be deemed not to include clause (xv) thereof), and (subject to the foregoing exceptions) are sufficient to conduct the Program, *provided* that this Section 4.8(a) shall not be construed as a representation or warranty with respect to not infringing, misappropriating or otherwise violating Intellectual Property of a Third Party.

(b) Aeglea hereby represents and warrants to Immedica as of the Closing Date as set forth on Schedule 4.8 as though set forth in full herein.

Section 4.9 Compliance with Laws; Litigation.

(a) Except as would not reasonably be expected to be material to the Program, the Acquired Assets or the Product, (i) neither Aeglea nor any of its Subsidiaries is in violation of any applicable Law relating to the Program, the Product, the Acquired Assets or the Assumed Liabilities, (ii) except as set forth on Schedule 4.9, all governmental licenses, permits, approvals and authorizations employed in, or necessary to the ongoing operation of the Program as currently conducted, are in full force and effect and (iii) neither Aeglea nor any of its Subsidiaries has received any communication from any Governmental Authority relating to any violation of any applicable Law in connection with the Acquired Assets, Assumed Liabilities, the Product or the operation of the Program.

(b) The Program has been conducted and developed, and the Product been manufactured, processed, tested and stored, in accordance with all applicable Laws, rules and regulations, in all material respects.

(c) There is no Legal Proceeding pending against, or to the knowledge of Aeglea or any of its Subsidiaries, threatened against or affecting, the Acquired Assets or relating to the Acquired Assets or the Program before any arbitrator or any Governmental Authority, and there are no outstanding Orders, injunctions or decrees of any Governmental Authority that apply to or otherwise relate to the Acquired Assets or the Program (or that will apply to Immedica after Closing) that restrict the ownership, disposition or use of the Acquired Assets or the Product, or the conduct of the Program.

Section 4.10 Regulatory Compliance.

(a) Except as would not reasonably be expected to be material to the Program, the Acquired Assets or the Product, Aeglea and each of its Subsidiaries is in compliance with all applicable legal requirements of the U.S. Centers for Medicare & Medicaid Services, U.S. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, U.S. Drug Enforcement Agency, U.S. Food and Drug Administration, U.S. Federal Trade Commission (the "FTC"), U.S. Department of Agriculture, U.S. Department of Commerce, and similar federal, state and local Governmental Authorities, and comparable non-U.S. Governmental Authorities (collectively, the "Regulatory Bodies"), as well as all applicable healthcare-related legal requirements of the U.S. Department of Justice and healthcare-related Presidential Executive Orders, including with respect to the maintenance, compilation and filing of reports and the sale, labeling, storing, testing, development, distribution, marketing, promotion and advertising of the Product, including all anti-kickback laws.

(b) Since January 1, 2020, neither Aeglea nor any of its Subsidiaries (i) has received any written notice or warning letter from any Regulatory Body or any other Governmental Authority alleging any violation of any requirements under applicable Law by Aeglea or any of its Subsidiaries, (ii) has received notice of nor is subject to any adverse inspection, finding of deficiency, finding of noncompliance, compelled or voluntary recall, product

seizure, investigation, penalty for corrective or remedial action or other compliance or enforcement action by any Governmental Authority, in each case relating to the Product or to the facilities in which the Product is manufactured, produced, processed, packaged, labeled, collected, stored or handled. There is no corporate integrity agreement in effect with respect to Aeglea or otherwise with respect to the Program or the Product.

(c) Neither Aeglea nor any of its Subsidiaries has received (i) any FDA Form 483 "Inspectional Observations," or similar notice from any Governmental Authority, relating to the Product or the facilities in which the Product is manufactured; or (ii) any "warning letters," or "untitled letters," or other similar Governmental Authority notice of inspectional observations or legal deficiencies or other written correspondence from the FDA or any other Governmental Authority asserting a violation of applicable Law concerning the Acquired Assets, the Program or the Product. There has not been a recall or market withdrawal or replacement of any Product by, or on behalf of, Aeglea or any of its Subsidiaries, whether voluntary or involuntary. Aeglea and its Subsidiaries have complied at all times with all adverse event reporting requirements applicable to the Product.

(d) Neither Aeglea nor any of its Subsidiaries has made any false statements on, or omissions from, the applications, reports and other submissions or communications (written or oral) to the FDA or any other Governmental Authority with respect to the Program, the Product or its manufacture or any other records, reports and documentation prepared or maintained to comply with the requirements of applicable Law, and all such applications, reports, submissions and communications were true, correct and complete in all material respects. Neither Aeglea nor any of its Subsidiaries is the subject of any pending or, to Aeglea's Knowledge, threatened investigation by any Governmental Authority with respect to the Program, or the Product, including by (i) the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto; (ii) the FTC; or (iii) any other Governmental Authority that has jurisdiction over the Program under any similar policy.

Section 4.11 Intellectual Property; Data Privacy and Security.

(a) Schedule 4.11(a) contains a true and complete list of each of the issuances, registrations and applications for issuance or registration included in the Assigned Intellectual Property, specifying as to each such item, as applicable (i) the owner of such item, (ii) the title of such item, (iii) each jurisdiction in which such item is issued or registered or in which any application for issuance or registration has been filed, (iv) the respective issuance, registration, or application number of such item and (v) the date of application and issuance or registration of such item (all such Assigned Intellectual Property required to be listed on Schedule 4.11(a), the "Registered IP").

(b) Aeglea or one of its Subsidiaries is the sole and exclusive owner of the Assigned Intellectual Property.

(c) Except as set forth in Schedule 4.11(c), there exist no restrictions on the disclosure, use, license or transfer of the Assigned Intellectual Property. The consummation of the transactions contemplated by this Agreement will not (i) alter, encumber, impair or extinguish any Assigned Intellectual Property or Aeglea's or its applicable Subsidiary's rights under any Intellectual Property licensed to Aeglea or its Subsidiaries pursuant to an Assigned Contract ("Licensed Intellectual Property"); or (ii) impair the right of Immedica or any of its Affiliates to develop, use, sell, license or otherwise dispose of, or to bring any action for the infringement, misappropriation or other violation of, any Assigned Intellectual Property.

(d) The Assigned Intellectual Property (including the Specified Patents and CPRIT Technology), Licensed Intellectual Property and the ADA Assays constitute all of the Intellectual Property (i) used or held for use by Aeglea and its Subsidiaries in, or (ii) owned or licensed by Aeglea or its Subsidiaries and otherwise necessary for, the conduct of the Program and the Exploitation of the Product.

(e) (i) None of the Assigned Intellectual Property has ever been found invalid or unenforceable, in whole or in part, for any reason in any administrative, arbitration, judicial or other Legal Proceeding (other than in proceedings before a patent office in connection with the prosecution of any Assigned Patent) or been the subject of a final and nonappealable finding of unpatentability, (ii) Aeglea has not received any written notice from any other Person that any issued Assigned Patent is not valid and enforceable, (iii) all Assigned Intellectual Property is, to Aeglea's Knowledge, valid, enforceable, in full force and effect and subsisting, (iv) all registration, maintenance and renewal fees applicable to the Registered IP that are currently due have been paid and all documents and certificates related to such items that are currently required to be filed have been filed with the relevant Governmental Authority or other authorities in the applicable jurisdictions for the purposes of maintaining such items, (v) effective written assignments constituting an unbroken, complete chain-of-title from each original owner or inventor to Aeglea or its applicable Subsidiary have been obtained with respect to all the Registered IP and have been duly recorded with the appropriate Governmental Authorities and (vi) to the Aeglea's Knowledge, there is no relevant prior art revealed, disclosed or discovered after the issuance of any Assigned Patent that was not cited during the prosecution of such Assigned Patent.

(f) There is no Legal Proceeding pending against, or, to Aeglea's Knowledge, threatened against, Aeglea or any of its Subsidiaries or any of their respective present or, to Aeglea's Knowledge, former, officers, directors or employees (i) based upon, or challenging or seeking to deny or restrict, the rights of Aeglea or any of its Subsidiaries in any of the Assigned Intellectual Property or, to Aeglea's Knowledge, Licensed Intellectual Property or (ii) alleging that any Assigned Intellectual Property or, to Aeglea's Knowledge, Licensed Intellectual Property is invalid or unenforceable (including in any reexamination, reissue, opposition proceeding, or any similar proceeding).

(g) The Exploitation of the Product and the conduct of the Program has not infringed upon (including inducing or contributing to the infringement of), misappropriated or otherwise violated, and, to Aeglea's Knowledge, will not infringe upon (including inducing or contributing to the infringement of), misappropriate or otherwise violate, any Intellectual Property rights of any Third Party. There is no Legal Proceeding pending against, or, to Aeglea's Knowledge, threatened against, Aeglea or any of its Subsidiaries or any of their respective present or, to Aeglea's Knowledge, former, officers, directors or employees alleging that the use of any of the Assigned Intellectual Property or Licensed Intellectual Property or the conduct of the Program conflicts with, misappropriates, infringes or otherwise violates any Intellectual Property of any Person.

(h) None of Aeglea nor its respective agents and advisors, has (i) put a Third Party on notice of actual or potential infringement, misappropriation or other violation of any of the Assigned Intellectual Property or (ii) initiated any enforcement action with respect to any of the Assigned Intellectual Property, and, to Aeglea's Knowledge, no Person has infringed, misappropriated or otherwise violated any Assigned Intellectual Property or Aeglea's or its applicable Subsidiary's rights under any Licensed Intellectual Property.

(i) Aeglea has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of all Assigned Intellectual Property and Licensed Intellectual Property, the value of which to Aeglea is contingent upon maintaining the confidentiality thereof, and no such Intellectual Property has been disclosed other than pursuant to written confidentiality agreements or enforceable confidentiality obligations.

(j) Aeglea and its Subsidiaries have appropriate procedures in place designed to provide that all Intellectual Property related to the Product or Program and conceived or developed by employees performing their duties for Aeglea and its Subsidiaries, and by Third Parties performing research and development for Aeglea or its Subsidiaries, has been assigned to Aeglea or its Subsidiaries, as applicable, and to the extent that any such Intellectual Property has been developed or created by any Third Party (including any current or former employee), Aeglea or one of its Subsidiaries has a written agreement with such Third Party with respect thereto, which provides that Aeglea or its applicable Subsidiary either (i) has obtained ownership of and is the sole and exclusive owner of

or (ii) has obtained a valid and unrestricted right to exploit, sufficient for the conduct of its business, as currently conducted or proposed to be conducted, such Intellectual Property.

(k) Schedule 4.11(k) contains a true and complete list of any and all Assigned Intellectual Property that was created, developed or reduced to practice, or is being created, developed or reduced to practice, (i) pursuant to, or in connection with, any contract with any Governmental Authority or Governmental Authority-affiliated entity, or university, college or other educational institution, or (ii) using any funding or facilities of any Governmental Authority or Governmental Authority-affiliated entity, or university, college or other educational institution (collectively, "Government Funded IP"). Except as set forth in Schedule 4.11(k), Aeglea and its Subsidiaries have taken any and all actions necessary to obtain, secure, maintain, enforce and protect Aeglea's or its applicable Subsidiary's right, title and interest in, to and under all Government Funded IP, and Aeglea and its Subsidiaries have complied with any and all Intellectual Property disclosure and/or licensing obligations under any applicable contract referenced in clause (i) above.

(l) In connection with the conduct of the Program, Aeglea and each of its Subsidiaries have complied in all material respects with (i) all applicable Laws, rules and regulations pertaining to data privacy, data security, security breach notification and the collection, storage and use of personally identifiable information and user information gathered or accessed in the course of the conduct of the Program, (ii) all rules, policies and procedures established by any of Aeglea or its Subsidiaries with respect to the foregoing and (iii) all restrictions and requirements with respect to the foregoing contained in any contractual obligations to which Aeglea or any of its Subsidiaries is bound. To Aeglea's Knowledge, there has been no (A) losses or thefts of, or security breaches relating to, personally identifiable information in the possession, custody or control of Aeglea or any of its Subsidiaries and held in connection with the conduct of the Program; (B) unauthorized access or unauthorized use of any such personally identifiable information; or (C) improper disclosure of any such personally identifiable information by Aeglea or any of its Subsidiaries or any Person acting on their behalf. No Legal Proceedings are pending or, to Aeglea's Knowledge, threatened against Aeglea or any of its Subsidiaries by any Person alleging a violation of any Person's privacy, personal or confidentiality rights under any such applicable Laws, contractual obligations, or the rules, policies or procedures established by any of Aeglea or its Subsidiaries relating to privacy, data protection and the collection and use of personal information gathered or accessed in the conduct of the Program.

Section 4.12 Taxes.

(a) Aeglea has filed all material Tax Returns and paid all material Taxes (whether or not shown on any Tax Return), the failure of which could result in a Lien on any Acquired Asset.

(b) There are no Liens on any Acquired Asset that arose in connection with any failure or alleged failure to pay any Tax.

(c) No Taxing Authority has proposed or is threatening in writing to propose any adjustment to any item with respect to material Taxes, the nonpayment of which could result in a Lien on any Acquired Asset.

(d) There is no Legal Proceeding now pending or, to Aeglea's Knowledge, threatened against or with respect to Aeglea in respect of any material Tax, the nonpayment of which could result in a Lien on any Acquired Asset.

(e) None of the Acquired Assets being transferred to Immedica hereunder is a "United States real property interest" within the meaning of Section 897(c) of the Code.

Section 4.13 Employee Matters.

(a) Neither Aeglea nor any of its Subsidiaries (nor any predecessor of the foregoing or any prior owner of all or part of the business or assets of any of the foregoing) has had, at any time during the six (6) year period prior to the date of this Agreement, any direct or indirect Liability with respect to any plan subject to Title IV of the Employee Retirement Income Security Act of 1974, as amended, including any "multiemployer plan" as defined in Section 3(37) of such act.

(b) Aeglea and its Subsidiaries are and have been in compliance with all applicable Laws relating to the Worker Adjustment and Retraining Notification Act and any comparable foreign, state or local Law, except for any failures to comply that would not result in any direct or indirect Liability to Immedica or any of its Affiliates.

Section 4.14 Environmental Compliance. Except as to matters that would not reasonably be expected to be material to the Program, the Acquired Assets or the Product:

(a) (i) no written notice, Order, request for information, complaint or penalty has been received by Aeglea or any of its Subsidiaries, and (ii) there are no Legal Proceedings pending or threatened, in the case of each of (i) and (ii), which allege a violation of any Environmental Law and relate to the Acquired Assets;

(b) Aeglea has obtained or caused to be obtained all environmental permits necessary for the current operation and use of the Acquired Assets to comply with all applicable Environmental Laws and Aeglea and each of its Subsidiaries is in compliance with the terms of such permits and, with respect to the current operation and use of the Acquired Assets, with all other applicable Environmental Laws; and

(c) there is no written environmental audit that has been conducted within the past five years by Aeglea or any of its Subsidiaries of any Acquired Asset.

Section 4.15 Finders Fees. There is no investment banker, broker, finder or other intermediary which has been retained by or is authorized to act on behalf of Aeglea or any of its Affiliates who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.16 No Other Representations or Warranties. **Except for the representations and warranties contained in this Article IV and the representations and warranties contained in any other Instrument, Immedica acknowledges that neither Aeglea nor any other Person on behalf of Aeglea has made, and Immedica has not relied upon, any representation or warranty, whether express or implied, with respect to the Program, Product, Acquired Assets, Aeglea or its Subsidiaries, or Aeglea's or its Subsidiaries' businesses, affairs, assets, Liabilities, financial condition, results of operations, future operating or financial results, estimates, projections, forecasts, plans or prospects (including the reasonableness of the assumptions underlying such estimates, projections, forecasts, plans or prospects) or with respect to the accuracy or completeness of any other information provided or made available to Immedica by or on behalf of Aeglea in connection with the Transaction.**

ARTICLE V

REPRESENTATIONS AND WARRANTIES OF IMMEDICA

Immedica hereby represents and warrants to Aeglea as of the Closing Date as follows:

Section 5.1 Organization and Good Standing. Immedica is an entity duly organized, validly existing and, to the extent legally applicable, in good standing under the applicable Laws of the country of its organization and has all requisite corporate or other similar organizational powers required to carry on its business as now conducted. Immedica is duly qualified to do business as a foreign entity and, to the extent legally applicable,

in good standing as a foreign entity in each jurisdiction where such qualification is necessary, except for those jurisdictions where the failure to be so qualified or in good standing would not, individually or in the aggregate, reasonably be expected to materially impede or materially delay the consummation by Immedica of the Transactions or the performance of its obligations under this Agreement or any Instrument to which it is a party.

Section 5.2 Authorization of Agreement. Immedica has all requisite power and authority to execute and deliver this Agreement and each Instrument to which it is a party, to perform its respective obligations hereunder and thereunder and to consummate the Transaction and the other transactions contemplated hereby and thereby. The execution, delivery and performance by Immedica of each of this Agreement and each other Instrument to which it is a party and the consummation of the Transaction and the other transactions contemplated hereby and thereby have been duly authorized and approved by all requisite corporate or similar action on the part of Immedica. Each of the Instruments to which Immedica is a party has been, or will be at or prior to the Closing, duly and validly executed and delivered by Immedica and (assuming the due authorization, execution and delivery by the other parties thereto) each of such Instruments, when so executed and delivered, will constitute the legal, valid and binding obligations of Immedica, enforceable against it in accordance with its terms, subject to the effect of any applicable Laws relating to bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance or preferential transfers, or similar Laws relating to or affecting creditors' rights generally and subject, as to enforceability, to the effect of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at Law).

Section 5.3 Conflicts; Consents of Third Parties. None of the execution and delivery of this Agreement or the Instruments to which Immedica is a party by Immedica, or the consummation of the Transaction or the other transactions contemplated hereby and thereby, will conflict with, or result in any violation of, or constitute a breach of, or conflict with or constitute a default (with or without notice or lapse of time, or both) under any provision of, or require any consent or other action by any Person under, or give rise to any right of termination, cancellation or acceleration under: (i) the certificate of incorporation and by-laws or comparable organizational documents of Immedica; (ii) any Order of any Governmental Authority applicable to Immedica; or (iii) any applicable Law, except, in the case of clauses (ii) and (iii) above, where such conflict, violation or default would not reasonably be expected to materially impede or materially delay the consummation by Immedica of the Transactions or the performance of its obligations under this Agreement or any Instrument to which it is a party.

ARTICLE VI

COVENANTS

Section 6.1 Cooperation. Each of the Parties shall use commercially reasonable efforts to take, or cause to be taken, all actions and do, or cause to be done, all things necessary, proper or advisable to, in the most expeditious manner practicable, carry out the intent of this Agreement.

Section 6.2 Confidentiality. For a period of ten (10) years from and after the Closing Date, each Party shall not, and shall cause its Affiliates and Representatives not to, directly or indirectly, disclose, reveal, divulge or communicate to any Person other than the other Party or any of their respective Affiliates or Representatives, or, subject to the provisos set forth herein, use or otherwise exploit for the benefit of any Person other than the other Party or any of their respective Affiliates or Representatives, any Confidential Information of the other Party without the prior written consent of such other Party; provided, that, with respect to any Confidential Information that constitutes a trade secret under applicable Law, the obligations under this Section 6.2 shall remain in effect until such Confidential Information is no longer maintained as a trade secret under applicable Law. Neither Party shall have any obligation to keep confidential any Confidential Information if and to the extent disclosure thereof is specifically required by applicable Law; provided, that in the event disclosure is required by applicable Law, the disclosing Party shall, to the extent permissible under applicable Law, notify the other Party of such requirement prior to making any disclosure so that the other Party may seek an appropriate protective order. For

purposes of this Agreement, "Confidential Information" means all confidential and proprietary information of such Party; provided, that Confidential Information of a Party shall not include, and there shall be no obligation hereunder with respect to, information that (i) is generally available to the public on the date of this Agreement, (ii) becomes generally available to the public other than as a result of a disclosure by the receiving Party or any of its Affiliates or Representatives in breach of this Section 6.2, (iii) is or becomes available to the receiving Party or any of its respective Affiliates from a source that is not known, after reasonable inquiry, by such Person to be bound by an obligation of confidentiality (provided that the provisions of this clause (iii) shall only apply to Confidential Information relating to the Acquired Assets and Assumed Liabilities to the extent that such information first becomes available after the Closing) or (iv) is independently developed by the receiving Party or any of its respective Affiliates after Closing without the use of, or reference to, the disclosing Party's Confidential Information. For clarity, from and after Closing, Confidential Information relating to the Acquired Assets and Assumed Liabilities shall be the Confidential Information of Immedica, and Confidential Information relating to the Excluded Assets and Excluded Liabilities shall remain the Confidential Information of Aeglea. Notwithstanding anything in the foregoing to the contrary, nothing shall prevent a Party from disclosing Confidential Information that is reasonably required to be disclosed in connection with the enforcement of this Agreement or any other Instrument.

Section 6.3 Publicity. Neither Party nor their respective Affiliates shall issue any press release or public announcement concerning this Agreement or the Transaction or make any other public disclosure containing the terms of this Agreement without obtaining the prior written approval of the other Party (not to be unreasonably withheld, conditioned or delayed) unless, in the judgment of the disclosing Party, disclosure is otherwise required by applicable Law; provided, however, that if disclosure is required by applicable Law, the Parties shall, to the extent reasonably possible, provide the other Party with prompt notice of such requirements prior to making any disclosure and confer with the other Party concerning the timing and content of such required public statement before the same is made; provided, further, that Immedica may provide general information regarding this Agreement, the other Instruments and the transactions contemplated hereby and thereby to its existing or prospective investors on a confidential basis without consulting with or obtaining the consent of Aeglea. Notwithstanding the foregoing, the Parties agree that (a) Immedica may issue a press release regarding the Transaction in the form mutually agreed by the Parties prior to the date hereof, and (b) Aeglea may file a Form 8-K with the United States Securities and Exchange Commission regarding the Transaction, which 8-K may include a copy of this Agreement, *provided* that Immedica shall be afforded a reasonable opportunity to review and comment on such 8-K prior to the filing thereof, which comments Aeglea shall consider in good faith.

Section 6.4 Transfer of Acquired Assets; Transfer and Maintenance of Product Registrations; Cooperation.

(a) On or as promptly as practicable after the Closing, Aeglea shall and shall cause its Subsidiaries to (i) transfer or cause to be transferred (or implement arrangements for the transfer and delivery of physical possession of) all tangible assets included in the Acquired Assets that are in the possession of Aeglea or any of its Affiliates (including, if applicable, all Inventory, Biological Materials and Transferred Documents, whether electronic or otherwise) to Immedica or its designated Representatives, and (ii) notify all of its agents and any other third parties that hold files or other tangible assets included in the Acquired Assets that, effective as of the Closing, Immedica owns such Acquired Assets, with directions to transfer such Acquired Assets to Immedica in accordance with Immedica's reasonable instructions; provided that Aeglea shall not, at Closing, be required to deliver to Immedica any information, data or files that is commingled with information, data or files pertaining to the Excluded Assets that is not reasonably practicable to identify and extract prior to Closing, in which case, as promptly as practicable following Closing, Aeglea shall deliver to Immedica such information, data or files in accordance with this Section 6.4(a), and until such delivery, Aeglea shall provide Immedica and its Affiliates reasonable access to such materials.

(b) On or as promptly as practicable after the Closing, Aeglea shall and shall cause its Subsidiaries to transfer to Immedica or its designated Representatives the Transferred Product Registrations.

(c) Without limiting Section 6.4(b), Aeglea shall (or shall cause one of its Subsidiaries to) provide to Immedica a copy of the most recent sequence submitted to the FDA with respect to the IND related to Product set forth on Schedule 6.4(c) (the "Product IND") as promptly as possible following the Closing, and in any event within five (5) days of the Closing. As soon as practicable following receipt by Immedica of such copy, on a date to be mutually agreed by Aeglea and Immedica that is no more than twenty (20) days following the Closing, (i) Aeglea shall (or shall cause one of its Subsidiaries to) file with the FDA a letter authorizing the transfer of ownership from Aeglea (or its applicable Subsidiary) to Immedica of such Product IND and (ii) Immedica shall (or shall cause one of its Subsidiaries to) execute and submit to the FDA a letter, accompanied by the transfer letter referred to in clause (i), acknowledging Immedica's commitment to assume ownership of the Product IND and commitment to the obligations and agreements therein. The parties shall use commercially reasonable efforts to take such additional actions, and execute and deliver, and file with the FDA, such additional documents, as are reasonably necessary to effect the transfer and assignment to Immedica of the Product IND as contemplated by this Section 6.4(c).

(d) With respect to the Product, from and after the Closing Date, until the later of (x) the date on which Immedica (or its applicable Affiliate) receives an assignment or transfer of the Transferred Product Registration for the Product or a replacement thereof naming Immedica (or its applicable Affiliate) as the Product Registration holder for the Product, and (y) such other date on which regulatory responsibilities are assumed by Immedica in accordance with applicable Law, Aeglea shall, with respect to the Product, operate in compliance with the terms of the relevant Transferred Product Registration, and with all applicable Law and all requirements of relevant Governmental Authorities. Until the completion of the transfer of the Transferred Product Registrations to Immedica: (i) Aeglea shall use commercially reasonable efforts to maintain the Transferred Product Registration and (ii) if and to the extent reasonably requested by Immedica, Aeglea shall use commercially reasonable efforts to pursue, in such manner as may be reasonably directed by Immedica, those ongoing variations, amendments and renewals which are pending at the Closing Date and shall not withdraw them.

(e) Immedica shall, and shall cause its Subsidiaries to, cooperate with Aeglea to deliver to Aeglea any additional documentation and materials that may be reasonably requested by Aeglea to affect the transfer of the Transferred Product Registrations to Immedica. Each of Aeglea and Immedica shall bear 50% of the cost of all fees levied by the relevant Governmental Authority in connection with the transfer of the Transferred Product Registrations pursuant to this Section 6.4 .

Section 6.5 Batch Disposition. Prior to the later of (i) thirty (30) days after Closing and (ii) ten (10) days following the date on which Aeglea or its applicable Affiliate receives analysis results and batch documentation reasonably necessary to affect the following batch release, Aeglea shall, or shall cause one or more of its Subsidiaries to, perform batch disposition and release of 2 mg vials of batch number B23020012 of the Inventory produced by Aeglea or one or more of its Subsidiaries to Immedica for secondary packaging.

Section 6.6 Specified Patents.

(a) Aeglea and Immedica agree to be bound by and comply with the terms and conditions set forth on Schedule 6.6 as though set forth in full herein.

Section 6.7 Misallocated Assets. If, following the Closing, any right, property or asset not forming part of the Acquired Assets is found to have been transferred to Immedica in error, either directly or indirectly, Immedica shall (a) transfer at no cost to Aeglea, such right, property or asset (and any related Liability) as soon as practicable to one or more of Aeglea and its Subsidiaries designated by Aeglea and (b) prior to such transfer, ensure that Immedica shall, where permitted by the terms on which it has the right to such asset, hold the asset (or part

thereof), and any monies, goods or other benefits arising after the Closing by virtue of it, as agent of and trustee for Aeglea and its Subsidiaries and allow Aeglea and its Subsidiaries from and after the Closing to have full enjoyment and use of such asset and Aeglea and its Subsidiaries shall bear all burdens relating to such asset. If, following the Closing, any right, property or asset forming part of the Acquired Assets is found to have been retained by Aeglea in error, either directly or indirectly, Aeglea shall (i) transfer, at no cost to Immedica, such right, property or asset (and any related Liability) as soon as practicable to Immedica and (ii) prior to such transfer, ensure that Aeglea shall where permitted by the terms on which Aeglea or its applicable Affiliate has the right to such asset, hold the asset (or part thereof), and any monies, goods or other benefits arising after the Closing by virtue of it, as agent of and trustee for Immedica and allow Immedica from and after the Closing to have full enjoyment and use of such asset and Immedica shall bear all burdens relating to such asset. For the avoidance of doubt, the Parties understand and agree that (x) the Excluded Assets are not intended to, and shall not, be transferred to Immedica and Aeglea shall retain such rights, properties and assets, and (y) the Acquired Assets are intended to, and shall, be transferred to Immedica and Immedica shall acquire such rights, properties and assets.

Section 6.8 Lien Releases. Aeglea shall provide, and shall cause its Subsidiaries to provide, all assistance reasonably requested by Immedica in connection with obtaining, effective at or as soon as possible following the Closing, appropriate termination statements under the Uniform Commercial Code (or equivalent documents pursuant to applicable Law), payoff letters and other instruments, in connection with the release of security interests or other Liens against or relating to any of the Acquired Assets.

Section 6.9 Certain Matters.

(a) Aeglea and Immedica agree to be bound by and comply with the terms and conditions set forth on Schedule 6.9 as if set forth in full herein.

Section 6.10 Reimbursement. Following the Closing, promptly following the earlier of (a) receipt by Immedica of a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use recommending the granting of a marketing authorization with respect to the Product and (b) the date of vial thaw by the applicable manufacturer to Immedica of the first drug substance batch of the Product initiated by Immedica pursuant to the Fuji Scope of Work, Immedica shall, within thirty (30) days thereof, pay an amount equal to the Fuji Credit to Aeglea in cash by wire transfer of immediately available funds in accordance with written instructions furnished to Immedica by Aeglea.

Section 6.11 Delivery of Post-Closing Correspondence. Following the Closing, Aeglea shall promptly forward to Immedica any mail (including electronic mail) and other correspondence that Aeglea or any of its Subsidiaries receives after the Closing Date that is intended for the owner of the Acquired Assets, Assumed Liabilities, the Program or the Product. Following the Closing, Immedica shall promptly forward to Aeglea any mail (including electronic mail) and other correspondence that Immedica or any of its Subsidiaries receives after the Closing Date that relates to the Excluded Assets, the Excluded Liabilities or is otherwise intended for the owner of the Excluded Assets.

ARTICLE VII

INDEMNIFICATION

Section 7.1 Survival. The representations and warranties of the Parties contained in this Agreement or in any certificate or other writing delivered pursuant hereto shall survive until 5:00 p.m. Eastern Time on the twelve (12)-month anniversary of the Closing Date; provided, that (a) the representations and warranties of Aeglea contained in Sections 4.1, 4.2, 4.3, 4.4(a)(i), 4.8(b) and 4.15 and the first two sentences of Section 4.5(a) (collectively, the "Fundamental Representations") shall survive the Closing until 5:00 p.m. Eastern Time on May 22, 2026 and (b) the representations and warranties of Aeglea contained in Section 4.11 (the "IP Representations")

and the representations and warranties of Aeglea contained in Section 4.8(a) shall survive the Closing until 5:00 p.m. Eastern Time on May 22, 2026 (as applicable, the "Survival Period"). The covenants and agreements of the Parties contained in this Agreement or in any certificate or other writing delivered pursuant hereto shall survive indefinitely or for such shorter period explicitly specified therein. Upon termination and expiration of any representation and warranty, covenant or agreement for the purposes of indemnification, all indemnification obligations with respect to such representation and warranty, covenant or agreement shall likewise terminate and expire, except to the extent that the Person to be indemnified pursuant to this Article VII (the "Indemnified Party") shall have (in good faith) given written notice a claim to the indemnifying party pursuant to this Article VII (the "Indemnifying Party") before termination of the applicable Survival Period, in which event the representation and warranty, covenant or agreement alleged in the claim to have been breached and any associated right to indemnification shall continue until such claim for indemnification is resolved. For the avoidance of doubt, it is the intention of the Parties that the foregoing respective Survival Periods and termination dates supersede any applicable statutes of limitations that would otherwise apply to such matters.

Section 7.2 Indemnification by Aeglea. From and after the Closing Date and subject to the provisions of this Article VII, Aeglea shall reimburse, defend, indemnify and hold Immedica and its directors, officers, employees, Affiliates, agents, attorneys and Representatives, and each of their respective successors and permitted assigns (collectively, the "Immedica Indemnified Parties") harmless from and against any and all Losses incurred, resulting or arising from or relating to:

(a) the failure of any representation or warranty of Aeglea contained in this Agreement to be true and correct as of the Closing Date (except for any such representation and warranty that addresses matters only as of a specific date, which representation and warranty shall be true and correct as of such specific date); provided that for purposes of (i) determining whether any failure of a representation or warranty to be true and correct has occurred and (ii) calculating the amount of any Losses relating thereto, in each case, the representations and warranties shall be considered and applied without regard to any reference to materiality, Material Adverse Effect or similar materiality qualification set forth therein; and provided, further, that if the absence of an asset has resulted in a failure of a representation or warranty set forth in Section 4.8(a) to be so true and correct, to the extent that such failure may be cured (in whole or in part) by the delivery of such asset to Immedica after the Closing (including by the grant of a license if such absent asset was a license), Aeglea's indemnification obligations hereunder may (but without limiting any obligation set forth in this Agreement) be cured to such extent (and only such extent) by delivery of such asset, and the remaining indemnification obligations with respect to such failure (if any) shall be satisfied in accordance with the other provisions of this Article VII;

(b) any breach of or failure to perform any covenant or obligation made or to be performed by Aeglea in this Agreement or in any certificate or other writing delivered pursuant hereto;

(c) any Excluded Asset or Excluded Liability (including, for the avoidance of doubt, in respect of any Person seeking to impose any Excluded Liability on any of the Immedica Indemnified Parties based upon any theory of successor liability or based upon any claim of fraudulent transfer or any other claim alleging that the consideration paid in connection with the consummation of the transactions contemplated hereby is insufficient for any reason); and

(d) the matters set forth on Schedule 7.2(d).

Section 7.3 Indemnification by Immedica. From and after the Closing Date and subject to the provisions of this Article VII, Immedica shall reimburse, defend, indemnify and hold each of Aeglea and its respective directors, officers, employees, Affiliates, agents, attorneys, Representatives, successors and permitted

assigns (the "Aeglea Indemnified Parties") harmless from and against any and all Losses incurred, resulting or arising from or relating to:

(a) the failure of any representation or warranty of Immedica contained in this Agreement to be true and correct as of the Closing Date (except for any such representation and warranty that addresses matters only as of a specific date, which representation and warranty shall be true and correct as of such specific date);

(b) any breach of or failure to perform any covenant or obligation made by Immedica in this Agreement; and

(c) the Assumed Liabilities, except (notwithstanding anything to the contrary herein) to the extent due to the breach by Aeglea of this Agreement.

Section 7.4 Indemnification Procedures.

(a) A claim for indemnification for any matter not involving a Third-Party Claim may be asserted by prompt written notice to the Indemnifying Party, including, to the extent known, the amount of the claim or an estimate thereof, to such Indemnifying Party; provided that the failure to so notify the Indemnifying Party shall not relieve the Indemnifying Party of any indemnification obligation hereunder unless (and then solely to the extent that) the Indemnifying Party is materially prejudiced as a result of such failure.

(b) In the event that any Legal Proceedings shall be instituted, or that any claim or demand shall be asserted or threatened in writing, by any Person not party to this Agreement in respect of which an Indemnification Claim may be made under this Agreement (a "Third-Party Claim"), the Indemnified Party shall promptly cause written notice of the assertion or written threat of any Third-Party Claim of which it has knowledge that is or may be covered by this indemnity to be delivered to the Indemnifying Party; provided that the failure to so notify the Indemnifying Party shall not relieve the Indemnifying Party of any indemnification obligation hereunder unless (and then solely to the extent that) the Indemnifying Party is materially prejudiced as a result of such failure. The Indemnifying Party shall have the right, at its sole option and expense, to be represented by counsel of its choice, which must be reasonably satisfactory to the Indemnified Party, and to defend against, negotiate, settle or otherwise address any Third-Party Claim; provided, however, that prior to assuming control of such defense, the Indemnifying Party must acknowledge that it would have an indemnity obligation for the Losses resulting from such Third-Party Claim as provided under this Article VII if the material facts alleged in such Third-Party Claim at the time of its assumption of the defense are ultimately determined to be accurate; and provided, further, that the Indemnifying Party shall not be entitled to assume or maintain control of the defense of any Third-Party Claim and shall pay the fees and expenses of counsel retained by the Indemnified Party if (1) the Indemnifying Party does not deliver the acknowledgment referred to in the preceding proviso within 30 days of receipt of notice of the Third-Party Claim pursuant to this Section 7.4, (2) the Third-Party Claim is made by a Governmental Authority or relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation, (3) the Third-Party Claim seeks an injunction or equitable relief against the Indemnified Party or any of its Affiliates, (4) the Indemnifying Party has failed or is failing to prosecute or defend vigorously the Third-Party Claim (after reasonable notice and opportunity to cure) or (5) the Third-Party Claim relates to Taxes. If the Indemnifying Party is entitled to and elects to defend against, negotiate, settle or otherwise address any Third-Party Claim, it shall within twenty (20) Business Days (or sooner, to the extent that the nature of the Third-Party Claim so requires) ("Dispute Period") notify the Indemnified Party of its intent to do so. If the Indemnifying Party shall assume the defense of any Third-Party Claim, then the Indemnified Party may participate, at his or its own expense, in the defense of such Third-Party Claim; provided, that such Indemnified Party shall be entitled to participate in any such defense with separate counsel at the expense of the Indemnifying Party if (i) requested by the Indemnifying Party to participate, (ii) the named parties to any such Third-Party Claim (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party or (iii) representation of both the Indemnifying Party and the Indemnified Party by the same counsel would be inappropriate due to a conflict of interest between the

Indemnified Party and the Indemnifying Party; provided, further, that the Indemnifying Party shall not be required to pay for more than one such counsel for all Indemnified Parties in connection with any Third-Party Claim. If the Indemnifying Party does not elect (if so entitled) within the Dispute Period to defend against, negotiate, settle or otherwise address any Third-Party Claim or fails to notify the Indemnified Party of its election during the Dispute Period, the Indemnified Party shall have the right, but not the obligation, to defend against such Third-Party Claim; provided that the Indemnifying Party may nonetheless participate in the defense of such Third-Party Claim (but not control or make decisions related thereto) with its own counsel and at its own expense.

(c) If the Indemnifying Party elects to defend against, negotiate, settle or otherwise address any Third-Party Claim, the Indemnifying Party shall (i) conduct the defense of such Third-Party Claim with reasonable diligence and keep the Indemnified Party reasonably informed of material developments in the Third-Party Claim at all stages thereof; (ii) promptly submit to the Indemnified Party copies of all pleadings, responsive pleadings, motions and other similar legal documents and papers received or filed in connection therewith; (iii) permit the Indemnified Party and its counsel to confer on the conduct of the defense thereof; and (iv) permit the Indemnified Party and its counsel an opportunity to review all legal papers to be submitted prior to their submission (to the extent practical).

(d) The Parties agree to provide reasonable access to each other Party to such documents and information as may reasonably be requested in connection with the defense, negotiation or settlement of any such Third-Party Claim. The Indemnified Party shall have the right to negotiate, compromise and settle any Third-Party Claim for which the Indemnifying Party may have any Liability under this Agreement but only with the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party may not enter into any compromise or settlement of, or cease to defend against, a Third-Party Claim unless the Indemnifying Party (i) has assumed the defense of such claim pursuant to this Section 7.4 and (ii)has received the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing, the Indemnifying Party may enter into any compromise or settlement of any Third-Party Claim if (x) pursuant to or as a result of such compromise or settlement, (A) injunctive or other equitable relief would not be imposed against the Indemnified Party, (B) each claimant or plaintiff in such Third-Party Claim has given to the Indemnified Party an unconditional release from all Liability with respect to such Third-Party Claim, (C) a finding or admission of a violation of Law would not be made against the Indemnified Party, and (D) the Indemnified Party would not have a monetary Liability that will not be paid or reimbursed by the Indemnifying Party in full; (y) such Third-Party Claim would not reasonably be expected to have a material impact on the ongoing business of the Indemnified Party; and (z) such Third-Party Claim is not brought by a Governmental Authority.

(e) After any final non-appealable decision, judgment or award shall have been rendered by a Governmental Authority of competent jurisdiction and the expiration of the time in which to appeal therefrom, or a settlement or arbitration shall have been consummated, or the Indemnified Party and the Indemnifying Party shall have arrived at a mutually binding agreement with respect to an Indemnification Claim hereunder, the Indemnified Party shall forward to the Indemnifying Party notice of any sums due and owing by the Indemnifying Party pursuant to this Agreement with respect to such matter and the Indemnifying Party shall make prompt payment thereof by wire transfer in immediately available funds within thirty (30) days after the date of such notice or, if applicable, pursuant to the terms of the agreement reached with respect to the Indemnification Claim.

Section 7.5 Limitations on Indemnified Costs.

(a) Notwithstanding anything to the contrary in this Agreement, with the exception of intentional fraud and willful misconduct, no Indemnifying Party shall have any Liability for any Loss under Section 7.2(a) (other than in respect of the Fundamental Representations or the IP Representations) or Section 7.3(a) (other than in respect of the representations and warranties contained in Section 5.1, Section 5.2 and Section 5.3(i)), as applicable, (i) unless and until such Loss (or series of related Losses) equals or exceeds $15,000 (the "De Minimis Amount"), it being understood that if such Loss (or series of related Losses) does not exceed the De Minimis

Amount, such Loss (or series of related Losses) shall not be applied to or considered for purposes of calculating the aggregate amount of Losses incurred by any Indemnified Parties pursuant to the immediately following clause (ii); and (ii) unless the aggregate amount of all Losses incurred by the Immedica Indemnified Parties under Section 7.2(a) (other than in respect of the Fundamental Representations or the IP Representations) or the Aeglea Indemnified Parties under Section 7.3(a) (other than in respect of the representations and warranties contained in Section 5.1, Section 5.2 and Section 5.3(i)), as applicable, exceeds $300,000 (the "Basket"), it being understood that if such Losses exceed the Basket, the applicable Indemnifying Party shall be obligated for only the Losses of the applicable Indemnified Parties in excess of the Basket.

(b) Notwithstanding anything to the contrary in this Agreement, with the exception of intentional fraud and willful misconduct, (i) Aeglea's maximum aggregate Liability to the Immedica Indemnified Parties for any Loss under Section 7.2 (except for Sections 7.2(b) and 7.2(d), and except for Section 7.2(a) with respect to Fundamental Representations, IP Representations and the representations and warranties contained in Section 4.8(a)) shall not exceed $1,800,000 *plus* 15% of the aggregate Milestone Payments received or that become payable to Aeglea (calculated prior to giving effect to any Milestone Set-Off); (ii) Aeglea's maximum aggregate Liability to the Immedica Indemnified Parties for any Loss under Section 7.2(a) with respect to the representations and warranties contained in Section 4.8(a) shall not exceed $2,400,000 *plus* 20% of the aggregate Milestone Payments that become payable to Aeglea (calculated prior to giving effect to any Milestone Set-Off); (iii) Aeglea's maximum aggregate Liability to the Immedica Indemnified Parties for any Loss under Section 7.2(a) with respect to IP Representations shall not exceed $3,600,000 *plus* 30% of the aggregate Milestone Payments that become payable to Aeglea (calculated prior to giving effect to any Milestone Set-Off); (iv) Aeglea's maximum aggregate Liability to the Immedica Indemnified Parties for all Losses under Section 7.2(a) with respect to Fundamental Representations, Section 7.2(b) and Section 7.2(d) shall not exceed the Initial Payment *plus* 100% of the aggregate Milestone Payments that become payable to Aeglea (calculated prior to giving effect to any Milestone Set-Off.

(c) Aeglea agrees that if a Third-Party Claim is made against an Immedica Indemnified Party concerning an Excluded Asset or Excluded Liability, Aeglea shall, at its sole cost and expense, (i) communicate to the Person making such Third-Party Claim that Aeglea (rather than such Immedica Indemnified Party) is responsible for or otherwise liable in respect of such Excluded Asset or Excluded Liability (and otherwise acknowledge that Aeglea rather than such Immedica Indemnified Party is the appropriate party in interest) and (ii) use commercially reasonable efforts to cause such Immedica Indemnified Party to be released or otherwise dismissed from such Third-Party Claim and any related Legal Proceeding.

(d) With respect to any Milestone Set-Off pursuant to Section 1.2(e) (and subject to the limitations set forth in Sections 7.5(a) and 7.5(b) and the terms of Section 1.2(e)), if at the time any Milestone Payment is due and payable (or any portion of the Specified Patents Holdback Amount continues to be held back in accordance with Section 1.2(f)), there shall be any outstanding Indemnification Claim delivered in accordance with Section 7.4, the amount of Losses with respect to which shall not have been finally determined in accordance with this Article VII, then Immedica shall be entitled, but shall not be required, to withhold from such Available Remedy Amount, the amount of Losses the applicable Immedica Indemnified Party reasonably estimates to be subject to such Indemnification Claim. If the final amount of Losses for such Indemnification Claim is determined in accordance with this Article VII to be less than the amount withheld from such Available Remedy Amount, then Immedica shall promptly, and in any event within five (5) Business Days following the final determination of the amount of such Losses, deliver the difference to Aeglea by wire transfer of immediately available funds to an account designated in writing by Aeglea (provided that no amount set off against the Specified Patents Holdback Amount shall be required to be so delivered to Aeglea unless, prior to such time, the Specified Patents Holdback Amount was required to be released to Aeglea in accordance with the last sentence of Section 1.2(f)). If the final amount of Losses for such Indemnification Claim is determined in accordance with this Article VII to exceed the amount by which such Available Remedy Amount was reduced for such claim, then Immedica shall continue to be entitled to indemnification for the amount of such excess subject to the terms and conditions of this Article VII.

(e) **In no event shall any Indemnifying Party have Liability to any Indemnified Party for any consequential, special, incidental, indirect, punitive or exemplary damages**, except, in each case of the foregoing damages, to the extent (i) any of the foregoing are payable to a Third Party pursuant to a Third-Party Claim, (ii) in the case of consequential or indirect damages, to the extent such damages are the reasonably foreseeable result of the event that gave rise thereto or the matter for which indemnification is sought hereunder, (iii) arising under Section 7.2(d) or (iv) any of the foregoing arise as a result of intentional fraud or willful misconduct by the Indemnifying Party. No Indemnified Party shall be entitled to recover from an Indemnifying Party more than once in respect of Losses resulting from a single or series of related claims. Any Liability for indemnification hereunder shall be determined without duplication of recovery by reason of state of facts giving rise to such Liability constituting a breach of more than one representation, warranty, covenant or agreement.

(f) The amount of any and all Losses under this Article VII shall be determined net of (i) any Tax benefit actually realized by the applicable Indemnified Parties in the form of Tax refunds received or a reduction of Taxes otherwise owed in the taxable year of such Losses, and (ii) any insurance proceeds actually received by the applicable Indemnified Parties in connection with the facts giving rise to the right of indemnification (net of any costs of recovery, deductibles or increased premiums as a result of paying such insurance claims), it being agreed that if third-party insurance or indemnification proceeds in respect of such facts are recovered by the Indemnified Party subsequent to the Indemnifying Party's making of an indemnification payment in satisfaction of its applicable indemnification obligation, such proceeds shall be promptly remitted to the Indemnifying Party to the extent of the indemnification payment made. The Parties shall make commercially reasonable efforts to mitigate any Losses subject to an Indemnification Claim in accordance with applicable Law; provided, that (A) no Party is required to bring any suit, action or proceeding in connection with such mitigation and (B) any Liability of any Indemnifying Party under this Agreement for Losses suffered or incurred by the Indemnified Party shall include the reasonable costs and expenses suffered or incurred by the Indemnified Party in performing its mitigation obligations hereunder.

Section 7.6 Sources of Recovery. The Milestone Set-off shall be the sole and exclusive recourse for any and all payments that may become owing to the Immedica Indemnified Parties pursuant to a claim for indemnification under this Article VII (other than (A) pursuant to Section 7.2(d), (B) pursuant to Section 7.2(b) with respect to any breach of or failure to perform any covenant or obligation contained in this Agreement that by its terms contemplates performance thereof following the Closing and such breach remains uncured for a period greater than sixty (60) days after Immedica provides written notice of such breach, and (C) with respect to willful misconduct or intentional fraud (collectively, the "Excluded Indemnity Matters")); provided that (i) the Immedica Indemnified Parties shall not be entitled to recover any Loss (or series of related Losses) against Aeglea or any of its Subsidiaries (other than by means of a Milestone-Setoff) with respect to an Excluded Indemnity Matter referred to in the foregoing clause (B) unless and until such Loss (or series of related Losses) equals or exceeds $100,000 and (ii) following May 22, 2026, the Immedica Indemnified Parties shall not be entitled to recover any Loss against Aeglea or any of its Subsidiaries (other than by means of a Milestone-Setoff) with respect to an Excluded Indemnity Matter referred to in the foregoing clause (A), except to the extent an Indemnification Claim in respect of such Loss was first made prior May 22, 2026 (it being understood, for the avoidance of doubt, that nothing in this proviso shall limit or otherwise affect an Immedica Indemnified Party's rights to recover Losses at any time with respect to an Excluded Indemnity Matter by means of a Milestone-Setoff). No claim for indemnification under this Article VII by the Immedica Indemnified Parties shall be asserted against, and the Immedica Indemnified Parties shall not be entitled to indemnification from, Aeglea or any of its Subsidiaries for a claim for indemnification under Article VII (other than in respect of the Excluded Indemnity Matters, but subject to the proviso in this Section 7.6) except to the extent such recourse is limited to Milestone Set-Offs. For the avoidance of doubt, nothing in this Section 7.6 shall limit or otherwise affect Immedica's right to specific performance as provided in Section 9.3.

Section 7.7 Exclusive Remedy. Following the Closing Date, the sole and exclusive remedy of any Indemnified Parties for any Losses (including any Losses from claims for breach of contract, warranty, tortious conduct (including negligence) or otherwise and whether predicated on common Law, statute, strict liability or otherwise) that each Party may at any time suffer or incur, or become subject to, as a result of, or in connection with

this Agreement, including any inaccuracy or breach of any representation and warranty contained in this Agreement by any Party, or any failure by any Party to perform or comply with any covenant or agreement that, by its terms, was to have been performed, or complied with, under this Agreement, shall be indemnification in accordance with this Article VII and any Milestone Set-Off pursuant to Section 1.2(e), except with respect to any claim based on intentional fraud or willful misconduct or claims for specific performance pursuant to Section 9.3, injunction or other equitable relief. For the avoidance of doubt, the limitations set forth in this Article VII shall not apply to claims for intentional fraud or willful misconduct.

ARTICLE VIII

TAX MATTERS

Section 8.1 Tax Matters; Cooperation. Each Party shall cooperate fully, as and to the extent reasonably requested by the other Party, in connection with the filing of Tax Returns, making of elections and any audit or other Legal Proceeding with respect to Taxes attributable to the Acquired Assets. Such cooperation shall include the retention and (upon any other Party's request) the provision of records and information that are reasonably relevant to any such audit or other Legal Proceeding for a period of at least six (6) years following the Closing Date. On or after the end of such period, each Party shall provide the other with at least ten (10) days' prior written notice before destroying any such books and records, during which period the Party receiving such notice can elect to take possession, at its own expense, of such books and records. Each Party shall make employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. Each Party agrees, upon reasonable request, to use their commercially reasonable efforts to obtain any certificate or other document from any Governmental Authority or any other Person as may be necessary to mitigate, reduce or eliminate any Tax that could be imposed (including with respect to the Transaction). The Parties shall cooperate with each other in the conduct of any audit or other proceeding relating to Taxes involving the Acquired Assets.

Section 8.2 Allocation of Purchase Price; Treatment of Milestone Payments. The Initial Payment, and any Milestone Payments, for the Acquired Assets shall be allocated as determined by the mutual agreement of the Parties. The Parties shall provide such information as any of them shall reasonably request. The Parties shall (a) prepare each report relating to the federal, state and local and other tax consequences of the purchase and sale contemplated hereby in a manner consistent herewith and (b) not take any position in any tax filing, return, proceeding, audit or otherwise which is inconsistent with the position of the other parties unless permitted to do so by Law. The Parties agree and acknowledge that any Milestone Payments shall be treated for all applicable Tax purposes as additional purchase price for the Acquired Assets, except as otherwise required by applicable Law (including Section 483 of the Code)

Section 8.3 Transfer Taxes. Aeglea and Immedica shall be each responsible for 50% of any Transfer Taxes in connection with the sale and purchase of the Acquired Assets, regardless of the Person liable for such Transfer Taxes under applicable Law, and the Parties shall work together to timely file or caused to be filed all necessary documents (including all Tax Returns) with respect to such Transfer Taxes.

Section 8.4 Apportioned Obligations.

(a) All personal property Taxes and similar ad valorem obligations levied with respect to the Acquired Assets for a taxable period which includes (but does not end on) the Closing Date (collectively, the "Apportioned Obligations") shall be apportioned between Aeglea and Immedica based on the number of days of such taxable period up to and including the Closing Date (any such portion of such taxable period, the "Pre-Closing Tax Period") and the number of days of such taxable period after the Closing Date (any such portion of such taxable period, the "Post-Closing Tax Period"). Aeglea shall be liable for the proportionate amount of such Taxes that is

attributable to the Pre-Closing Tax Period, and Immedica shall be liable for the proportionate amount of such Taxes that is attributable to the Post-Closing Tax Period.

(b) Apportioned Obligations shall be timely paid, and all applicable filings, reports and returns shall be filed, as provided by applicable Law.

(c) The paying party of any Transfer Tax or Apportioned Obligation shall be entitled to reimbursement from the non-paying party in accordance with Section 8.3 and Section 8.4(a), respectively. Upon payment of any such Transfer Tax or Apportioned Obligation, the paying party shall present a statement to the non-paying party setting forth the amount of reimbursement to which the paying party is entitled under Section 8.3 and Section 8.4(a), respectively, together with such supporting evidence as is reasonably necessary to calculate the amount to be reimbursed. The non-paying party shall make such reimbursement promptly but in no event later than ten (10) days after the presentation of such statement.

Section 8.5 Withholding. Immedica and its Affiliates shall be entitled to deduct and withhold from any consideration payable hereunder, or other payment otherwise payable pursuant to this Agreement, the amounts required to be deducted and withheld under applicable Law. Immedica shall use commercially reasonable efforts (a) to provide prompt notice to Aeglea if Immedica determines that any payment required to be made by Immedica or any of its Affiliates is subject to any such deduction or withholding, and (b) to cooperate with Aeglea to reduce or eliminate such deduction or withholding. Any amounts so withheld shall be paid over to the appropriate Governmental Authority, and shall be treated for all purposes of this Agreement as having been paid to the applicable Person in respect to which such deduction and withholding was made.

ARTICLE IX

MISCELLANEOUS

Section 9.1 Expenses. Except as specifically provided to the contrary in this Agreement, all costs and expenses incurred in connection with the negotiation and execution of this Agreement, and the other Instruments, and the consummation of the Transaction shall be paid by the Party incurring such costs and expenses, whether or not the Transaction is consummated.

Section 9.2 Governing Law. This Agreement and all Legal Proceedings relating to, arising out of or under or in connection with this Agreement and the Transaction, including the negotiation, execution and performance hereunder, shall be governed by, and construed in accordance with, the Laws of the State of New York, regardless of the Laws that might otherwise govern under applicable principles of choice of Law or conflicts of Law rules or provisions thereof to the extent they would result in the application of the Laws of another jurisdiction.

Section 9.3 Specific Performance. Each of Aeglea and Immedica acknowledges and agrees that any breach of this Agreement may give rise to irreparable harm for which monetary damages would not be an adequate remedy. Each Party accordingly agrees that, in addition to any other remedies available under applicable Law or this Agreement, each of Immedica and Aeglea shall be entitled to seek enforcement of the terms of this Agreement by decree of specific performance without the necessity of proving the inadequacy of monetary damages as a remedy and to obtain injunctive relief against any breach or threatened breach of this Agreement. Any Party seeking an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement shall not be required to provide any bond or other security in connection with such order or injunction. The rights and remedies provided for pursuant to this Section 9.3 are cumulative to, and not exclusive of, any rights or remedies otherwise available hereunder.

Section 9.4 Jurisdiction. The Parties agree that any Legal Proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the Transaction shall be brought exclusively in the United States District Court for the Southern District of New York or any New York State court sitting in New York City, Borough of Manhattan, so long as one of such courts shall have subject matter jurisdiction over such Legal Proceeding, and that any cause of action arising out of this Agreement shall be deemed to have arisen from a transaction of business in the State of New York, and each of the Parties hereby irrevocably consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such Legal Proceeding and irrevocably waives, to the fullest extent permitted by Law, any objection that it may now or hereafter have to the laying of the venue of any such Legal Proceeding in any such court or that any such Legal Proceeding brought in any such court has been brought in an inconvenient forum. Process in any such Legal Proceeding may be served on any Party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each Party agrees that service of process on such party as provided in Section 9.9 shall be deemed effective service of process on such party.

Section 9.5 *WAIVER OF JURY TRIAL*. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

Section 9.6 Entire Agreement. This Agreement (including all Exhibits and Schedules hereto) and other documents and instruments delivered pursuant hereto constitute the entire agreement and supersede all prior representations, agreements, understandings and undertakings, both written and oral, between the Parties, with respect to the subject matter hereof, including the License Agreement, and no Party is relying on any prior oral or written representations, agreements, understandings or undertakings with respect to the subject matter hereof and thereof.

Section 9.7 License Agreement. The Parties hereby agree that, as of Closing, (i) the License Agreement is hereby terminated in full, (ii) no rights or obligations (including any rights or obligations that purport to survive termination of the License Agreement) of either Party under the License Agreement shall survive such termination, (provided, that Immedica shall remain responsible for the payment of the invoices set forth in Schedule 9.7), and (iii) the License Agreement shall have no further force or effect. For clarity, nothing in this Section 9.7 will be construed to limit or modify a Party's rights or obligations pursuant to this Agreement or any other Instrument.

(a) Aeglea, on behalf of itself, its Affiliates and its and their current and former officers, employees, stockholders, agents, representatives, attorneys, successors and assigns (collectively, the "Aeglea Releasing Parties"), hereby irrevocably and unconditionally releases and forever discharges Immedica and its Affiliates and their current and former officers, directors, stockholders, employees, agents, representatives and attorneys (collectively, the "Immedica Releasees"), or any of them, from any and all Losses of any nature whatsoever, known or unknown, liquidated or unliquidated, suspected or unsuspected, fixed or contingent, in law or in equity, arising under or in connection with the License Agreement that the Aeglea Releasing Parties now have, own or hold, or at any time heretofore ever had, owned or held or could have had, owned or held against the Immedica Releasees, except for the payment of the invoices set forth in Schedule 9.7 and for any and all Losses arising from intentional fraud or willful misconduct of the Immedica Releasees.

(b) Immedica, on behalf of itself, its Affiliates and its and their current and former officers, employees, stockholders, agents, representatives, attorneys, successors and assigns (collectively, the "Immedica Releasing Parties"), hereby irrevocably and unconditionally releases and forever discharges Aeglea and its Affiliates and their current and former officers, directors, stockholders, employees, agents, representatives and attorneys (collectively, the "Aeglea Releasees"), or any of them, from any and all Losses of any nature whatsoever, known or unknown, liquidated or unliquidated, suspected or unsuspected, fixed or contingent, in law or in equity,

arising under or in connection with the License Agreement that the Immedica Releasing Parties now have, own or hold, or at any time heretofore ever had, owned or held or could have had, owned or held against the Aeglea Releasees, except for any and all Losses arising from intentional fraud or willful misconduct by the Aeglea Releasees.

Section 9.8 Amendments and Waivers. This Agreement can be amended, supplemented or changed, and any provision hereof can be waived, only by written instrument making specific reference to this Agreement signed by the Party against whom enforcement of any such amendment, supplement, modification or waiver is sought. The waiver by any Party of a breach of any provision of this Agreement shall not operate or be construed as a further or continuing waiver of such breach or as a waiver of any other or subsequent breach. No failure on the part of any Party to exercise, and no delay in exercising, any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of such right, power or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right, power or remedy.

Section 9.9 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally or sent by nationally recognized overnight courier or by registered or certified mail, postage prepaid, return receipt requested, or by email, as follows:

If to Aeglea, to:

Aeglea BioTherapeutics, Inc.
221 Crescent Street
Building 17, Suite 102B
Waltham, MA 02453
Attn: Jonathan Alspaugh
Email: [*]

and by email to:

Aeglea BioTherapeutics, Inc.
Attn: General Counsel
Email: bd@aeglea.com

If to Immedica, to:

Immedica Pharma AB
Solnavägen 3H, 116 63
Stockholm, Sweden
Attention: Chief Executive Officer; General Counsel
Email: corporate@immedica.com; legal@immedica.com

With a copy (which shall not constitute notice) to:

Davis Polk & Wardwell LLP
450 Lexington Ave.
New York, New York 10017
Attention: William Chudd
Email: william.chudd@davispolk.com

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. All such notices and other communications required or permitted by this Agreement shall

be deemed to have been duly given (a) if sent to a recipient at the proper address as determined pursuant to this Section 9.9, by registered or certified mail, return receipt requested, five calendar days after being deposited in the United States mail, postage prepaid; (b) if sent by Express Mail, Federal Express or similar reputable overnight delivery service that maintains records of receipt for next Business Day delivery, the next Business Day after being entrusted to such service, with delivery charges prepaid or charged to the sender's account; (c) if sent by email, on the date of transmission with electronic confirmation of transmission; and (d) if delivered by hand, on the date of delivery.

Section 9.10 Severability. If any term or other provision of this Agreement is held by a court of competent jurisdiction or other Governmental Authority to be invalid, illegal or incapable of being enforced under any applicable Law or public policy, all other terms or provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the Transaction is not affected in any manner materially adverse to any Party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to affect the original intent of the Parties as closely as possible in an acceptable manner in order that the Transaction is consummated as originally contemplated to the greatest extent possible.

Section 9.11 No Third-Party Beneficiaries. Nothing in this Agreement shall create or be deemed to create any third-party beneficiary rights in any Person that is not a Party (or its permitted successors and assigns) except with respect to indemnification as contemplated by Section 7.2 and Section 7.3.

Section 9.12 Bulk Sales Laws. Immedica and Aeglea each hereby waive compliance by Aeglea with the provisions of the "bulk sales," "bulk transfer" or similar laws of any state. Aeglea agrees to indemnify and hold the Immedica Indemnified Parties harmless against any and all Losses (including any Taxes) incurred or suffered by any Immedica Indemnified Party as a result of any failure to comply with any such "bulk sales," "bulk transfer" or similar laws.

Section 9.13 Assignment. The provisions of this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. No Party may assign or transfer this Agreement or any rights or obligations hereunder, directly or indirectly (by operation of Law or otherwise), without the prior written approval of the other Parties and any attempted assignment without such required approval shall be null, void and of no effect; provided, that (a) Aeglea may assign its rights, interests, and obligations hereunder to an Affiliate of Aeglea or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of its business, in each case without Immedica's prior written approval, and (b) Immedica may assign its rights, interests, and obligations hereunder (in whole and not in part) to a wholly owned Affiliate of Immedica without Aeglea' prior written approval; provided that any such assignment or designation pursuant to the foregoing clause (a) or (b) shall not relieve the assigning Party of any of its obligations hereunder or otherwise adversely affect the other Party or any of its Affiliates. Upon any permitted assignment, the references in this Agreement to a Party shall also apply to any such assignee unless the context otherwise requires.

Section 9.14 Neutral Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

Section 9.15 Counterparts; Effectiveness. This Agreement may be executed and delivered in one or more counterparts, and by the different Parties in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement, with the same effect as if the signatures thereto were upon the same instrument. Counterparts may be delivered via electronic mail (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., www.docusign.com)) or other transmission method and any counterpart so delivered shall be

deemed to have been duly and validly delivered and be valid and effective as delivery of a manually executed counterpart of this Agreement. Each of the Parties represents that it has undertaken commercially reasonable steps to verify the identity of each individual person executing any such counterparts via electronic signature on behalf of such Party and has and will maintain sufficient records of the same. This Agreement shall become effective when each Party shall have received a counterpart hereof signed by all of the other Parties. Until and unless each Party has received a counterpart hereof signed by each other Party, this Agreement shall have no effect and no Party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication).

[Signature Pages Follow]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective officers thereunto duly authorized, as of the date first written above.

IMMEDICA PHARMA AB

By: _____
Name:
Title:

AEGLEA BIOTHERAPEUTICS, INC.

By: _____
Name:
Title:

Exhibit A

Definitions; Interpretations

(a) For purposes of this Agreement, the following terms shall have the meanings specified in this Exhibit A, and the terms defined in Schedule 1.2 shall have the meanings specified in such Schedule. Further, those additional capitalized terms not defined in this Exhibit A or Schedule 1.2 shall have the meaning as set forth in the Agreement.

"ADA Assays" means the assays used in connection with the Program for anti-drug antibody testing developed pursuant to that certain Master Services Agreement by and between Aeglea and BioAgilytix Labs, LLC, dated as of October 16, 2015.

"Affiliate" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such Person. For purposes of this definition, "control" when used with respect to any Person means the power to direct the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise, and the terms "controlling" and "controlled" have correlative meanings.

"Assigned Contracts" means the Contracts set forth on Schedule 2.1(b)(ii), including all amendments and supplements thereto and all Statements of Work and Purchase Orders thereunder.

"Assigned Intellectual Property" means, any and all Intellectual Property that is owned by Aeglea or any of its Subsidiaries and used or held for use in, or otherwise related to, the conduct of the Program or any Exploitation of the Product as of the Closing, including the Intellectual Property listed on Schedule 2.1(b)(i)(A), but excluding the ADA Assays.

"Assigned Patents" means any and all Patents included in the Assigned Intellectual Property.

"Biological Materials" means any biological substances and materials, including any tissues, cells, cell lines, organisms, blood samples, genetic material, antibodies, and plasmids, in each case relating exclusively to the Product or held for exclusive use in the Program. For the sake of clarity, human tissue samples taken from a human patient in the context of a Clinical Study with respect to a Product or a Program do not relate exclusively to such Product or such Program.

"Bayh Dole Act" means the Bayh-Dole Act, 35 U.S.C. § 200-211 together with all regulations implementing the same, including 37 CFR 401, as each may be amended from time to time.

"BLA" means a Biologics License Application (as defined in 21 C.F.R. 600 et. seq.) filed with the FDA, and any amendments thereto.

"Business Day" means any day of the year on which national banking institutions in New York, U.S. and Stockholm, Sweden are open to the public for conducting business and are not required or authorized by applicable Law to close.

"Clinical Study" means any investigation in human subjects intended to determine the clinical pharmacological, pharmacokinetic, and/or other pharmacodynamic effects of an investigational agent, and/or to identify any adverse reactions to an investigational agent to assess the agent's safety and efficacy.

"Code" means the Internal Revenue Code of 1986, as amended.

"Contract" means any written or oral agreement, contract, indenture, note, mortgage, loan, instrument, license, guarantee, bond, lease, commitment, understanding or undertaking.

"CPRIT Technology" means (i) all Patents set forth on Schedule 2.1(b)(i)(C) and (ii) any and all data generated pursuant to that certain Cancer Research Grant Contract between AERase, Inc. and Cancer Prevention and Research Institute of Texas dated as of June 1, 2014.

"Documents" means all files, documents (including all documents related to past or present preclinical and clinical trials, nonclinical studies and stability studies, in each case in both raw data and processed data (i.e., JMP file) form), instruments, papers, books, reports (including clinical, preclinical and nonclinical reports, and all data sets associated with such reports), records, budgets, forecasts, ledgers, journals, supplier lists, customer data, operating data and plans (including all launch preparation documentation), technical documentation, and other similar materials, and specifically including the label components with respect to the Product, the safety database for the Product (including all source data, related correspondence with the FDA and any similar information), all information, reports, records, data or materials relating to quality assurance matters with respect to the Product, in each case whether in hard copy or electronic format; provided, that "Documents" does not include Product Registrations or Permits.

"Environmental Law" means any applicable Law relating to the protection of the environment or the handling, treatment, storage, disposal or release of hazardous substances, wastes or materials.

"Expenses" means any and all expenses, costs, claims, demands, assessments, judgments, penalties and fees (including reasonable attorneys' and other professionals' fees and disbursements).

"Exploit" means to research, have researched, develop, have developed, use, have used, make, have made, sell, have sold, offer for sale, have offered for sale, commercialize, have commercialized, import, have imported, export, have exported, register, have registered, and otherwise exploit or have exploited. "Exploitation" has a correlative meaning.

"FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

"FDA" means the United States Food and Drug Administration or any successor agency thereto.

"Fuji Credit" means [*] to be paid by Aeglea to Fujifilm pursuant to the Fuji Scope of Work for services not yet rendered.

"Fuji Scope of Work" means that certain Scope of Work 7 entitled "Manufacturing Pre-Production, cGMP Production, Testing and Disposition for AEB1101," with Program Reference R2841.03, by and between Fujifilm and Aeglea dated as of November 27, 2022.

"Fujifilm" means Fujifilm Diosynth Biotechnologies U.S.A., Inc.

"Governmental Authority" means any nation or government or governmental or regulatory body thereof, or political subdivision thereof, whether federal, state, local or foreign, or any agency, instrumentality or authority thereof, or any court or arbitrator (public or private) or any other entity exercising executive, judicial, legislative, regulatory or administrative functions of or pertaining to regulation or to government.

"IND" means an Investigational New Drug Application submitted under Section 505(i) of the FD&C Act, or an analogous application or submission with any analogous agency or Regulatory Authority outside of the United States for the purposes of obtaining permission to conduct clinical trials.

"Indebtedness" means any amount owed by Aeglea or any of its Subsidiaries (including (i) unpaid principal, (ii) unpaid interest, (iii) premium thereon (including make-whole premiums) and (iv) prepayment penalties, breakage costs, fees, expenses or similar charges arising as a result of the discharge of such amount owed), without duplication, in respect of: (a) obligations of Aeglea or any of its Subsidiaries for borrowed money (including the current portion thereof) and related accrued interest payable in respect of such borrowed money, (b) obligations of Aeglea or any of its Subsidiaries evidenced by bonds, notes, debentures or other similar instruments (including a purchase money obligation), (c) all reimbursement obligations of Aeglea or any of its Subsidiaries relating to letters of credit, bankers' acceptances, surety, performance bonds or other bonds or similar instruments to the extent called, drawn or otherwise due, (d) capitalized lease obligations of Aeglea or any of its Subsidiaries (including the current portion thereof) and related accrued interest payable in respect of such obligations, (e) all guarantees, including guarantees of any items set forth in clauses (a) through (d) and (f) obligations of Aeglea or any of its Subsidiaries that are secured in whole or in part by the assets of Aeglea or any of its Subsidiaries.

"Indemnification Claim" means any claim in respect of which payment may be sought under Article VII of this Agreement.

"Intellectual Property" means any and all intellectual property rights or similar proprietary rights throughout the world, including all (i) Patents, (ii) Trademarks, (iii) copyrights and moral rights, including registrations or applications for registrations thereof and all renewals, extensions, restorations and reversions of the foregoing ("Copyrights"), (iv) Know-How, (v) database rights, industrial designs, industrial property rights, publicity rights and privacy rights and (vi) rights to assert, claim or sue and collect damages for the past, present or future infringement, misappropriation or other violation of any of the foregoing.

"Inventory" means all inventory of the Product owned by Aeglea or its Subsidiaries as of the Closing Date, wherever located, including all finished goods, work in process, raw materials, cell banks, vials and other reagents, starting materials, and intermediates from the synthesis of Product.

"Inventory Specifications" means the applicable specifications and standards set forth in the Marketing Authorization Application (EMEA/H/C/005484) submitted by Immedica to the European Medicines Agency with respect to the Product.

"IP Assignment Agreement" means the Intellectual Property Assignment Agreement to be entered into between Aeglea (or an Affiliate thereof) and Immedica (or an Affiliate thereof) at the Closing in substantially the form attached hereto as Exhibit B.

"Know-How" means any and all know-how, trade secrets, data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including practices, techniques, methods, assays, techniques, processes, protocols, inventions, discoveries, improvements, developments, specifications, formulations, formulae, algorithms, marketing reports, business plans, expertise, technology, software, test data (including pharmacological, biological, chemical, biochemical, medical, toxicological, preclinical, and clinical test data and any other research or development data), standard operating procedures, manufacturing records, stability data and other study data and procedures.

"Knowledge" means the actual knowledge of each of Jonathan Alspaugh, Cortney Caudill and Jim Kastenmayer, after reasonable inquiry of each such individual's direct reports.

"Law" means any foreign, federal, state and local law (including common law), statute, code, ordinance, rule, regulation (including zoning and building code), permit, legislation, injunction, judgment, decree, ruling, Order or other requirement of any Governmental Authority or any securities exchange upon which a Party is listed or becomes listed.

"Legal Proceeding" means any judicial, administrative or arbitral actions, suits, mediations, audits, investigations, inquiries, hearings, proceedings (public or private), litigation, complaints, allegations, demands, charges, grievances, prosecutions or claims (including counterclaims).

"Liability" means any debt, liability or obligation (whether direct or indirect, absolute or contingent, accrued or unaccrued, known or unknown, liquidated or unliquidated, or due or to become due) and including all costs and expenses relating thereto.

"Lien" means any lien, encumbrance, pledge, mortgage, deed of trust, security interest, charge, condition, restriction, covenant, license, purchase option, lease, sublease or other third-party right, right of first refusal, easement, right of way, servitude, transfer restriction, encroachment, reservation or title defect of any kind or nature.

"Losses" means all damages, losses, claims, Liabilities, charges, fines, penalties, diminution in value, lost profits, judgments, amounts paid in settlement, costs and Expenses (including reasonable expenses of investigation and reasonable attorneys' fees and expenses in connection with any Legal Proceeding, whether involving a Third-Party Claim or a claim solely between the parties hereto to enforce the provisions hereof).

"Material Adverse Effect" means any fact, event, change, development, condition, circumstance or effect that, individually or in the aggregate, (A) has, or would reasonably be expected to have, a material adverse effect on the Program, the Product and the Acquired Assets taken as a whole, or (B) prevents or materially impairs or delays, would be reasonably expected to prevent or materially impair or delay, the ability of Aeglea to perform its obligations hereunder, including the consummation of the Transaction; provided that, in the case of clause (A) above, "Material Adverse Effect" shall not include any such fact, event, change, development, condition, circumstance or effect to the extent it results from (i) global or national political conditions, including the outbreak or escalation of war or terrorist activities, (ii) global or national economic, monetary, or financial conditions, including changes in prevailing interest rates, credit markets, or financial market conditions in or affecting the United States, (iii) changes in applicable Law (or the interpretations thereof) or GAAP (or the interpretations of), (iv) the taking of any action specifically required to be taken by this Agreement or taken by any Party or any of its Affiliates or any of their respective Affiliates with the prior written consent or at the written request of the other Party, (v) earthquakes, hurricanes, tsunamis, typhoons, lightning, hailstorms, blizzards, tornadoes, droughts, floods, cyclones, arctic frosts, mudslides, wildfires and other natural disasters and weather conditions, (vi) impacts on relationships with suppliers, employees, labor organizations, or Governmental Authorities, in each case attributable to the execution, announcement or pendency of this Agreement or the Transaction, or (vii) changes generally in the life sciences and healthcare industries; except to the extent, in the case of clauses (i), (ii), (iii), (v) and (vii), such fact, event, change, development, condition, circumstance or effect disproportionately affects the Program, the Product or the Acquired Assets, relative to other participants in the industry or industries in which the Program operates.

"Order" means any order, injunction, judgment, decree, determination, ruling, writ, assessment or arbitration or other award of a Governmental Authority.

"Ordinary Course of Business" means, with respect to any Person or business, the ordinary course of business of such Person and its Affiliates or such business, in each case, consistent with past practices.

"Patents" means any and all patents (which shall include invention patents, utility models, design patents, industrial designs, and priority rights), applications for patents, invention disclosures, provisional applications, substitutions, supplementary protection certificates, reissues, reexaminations, renewals, revisions, extensions, divisionals, continuations, continuations-in-part, inventors' certificates, utility certificates, patents or certificates of addition, inventors' certificates of addition, and utility certificates of addition and other indices of invention ownership and the right to claim priority to any part of the foregoing.

"Permits" means any approvals, authorizations, consents, licenses, permits or certificates (including certificates of occupancy) of a Governmental Authority.

"Permitted Liens" means (i) Liens for Taxes, assessments or other governmental charges or levies not yet due or payable or that are being contested in good faith by appropriate Legal Proceedings and for which adequate reserves have been set aside in the relevant financial statements in accordance with generally applicable accounting principles; (ii) statutory Liens of landlords and mechanics', carriers', warehousemen's, workers', repairers' and similar Liens imposed by applicable Law or arising or incurred in the Ordinary Course of Business with respect to amounts not yet due and payable or being contested in good faith by appropriate Legal Proceedings; (iii) Liens incurred or deposits made in the Ordinary Course of Business in connection with workers' compensation, unemployment insurance or other types of social security; (iv) rights under the Specified Patents licensed to the U.S. Federal Government on a non-exclusive basis pursuant to the Bayh Dole Act; (v) rights under the CPRIT Technology licensed to the Cancer Prevention and Research Institute of Texas on a non-exclusive basis pursuant to that certain Cancer Research Grant Contract between AERase, Inc. and Cancer Prevention and Research Institute of Texas dated as of June 1, 2014; and (vi) non-exclusive licenses that were entered into by Aeglea or any of its Subsidiaries in the Ordinary Course of Business and where the grant of rights to use any Intellectual Property is solely for any performance of services under each such agreement.

"Person" means any individual, corporation, limited liability company, partnership, firm, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Authority or other entity.

"Product" means any pharmaceutical product containing, incorporating or comprising pegzilarginase (CAS Registry Number: 1659310-95-8) whether as the sole pharmaceutical ingredient, or in combination with other active pharmaceutical ingredients, in any form, formulation, mode of administration, presentation or dosage form.

"Product Registrations" means (i) any approvals, clearances, registrations, licenses, listings, permits, investigational new drug exemptions, orphan drug designations, rare pediatric disease designations, clinical trial authorizations or marketing authorizations, together with any supplements or amendments thereto (collectively, "Approvals"), whether existing, pending or issued or in draft form, to Aeglea or an Affiliate of Aeglea by the relevant Governmental Authority prior to the Closing Date related to the research, development, manufacture, importation, distribution, marketing and/or sale of the Product, (ii) any rights that Aeglea or a Subsidiary of Aeglea has in any Approval referred to in clause (i) of this definition under any agreement pursuant to which any such Approval is held in the name of a third person, (iii) any regulatory applications, submissions, dossiers, notifications, registrations, decisions, correspondence or other filings made to or with a Regulatory Authority with respect to the Product or the Program, (iv) supporting documentation in Aeglea's or an Affiliate of Aeglea's files with respect to any of the foregoing clauses (i)-(iii), including annual reports and adverse event reports and (v) as applicable, complete and accurate electronic copies of all items referred to in the foregoing clauses (i)-(iv). The Product Registrations shall include INDs, Regulatory Approvals and the pricing and reimbursement approval (if applicable or available) and all national drug code numbers (if any) assigned to the Product.

"Program Contract" means any Contract that is primarily related to, or otherwise material to, the Product or the Program.

"Regulatory Approvals" means, with respect to the Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Governmental Authority to market and sell the Product in such country or jurisdiction.

"Regulatory Authority" means, with respect to a country, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval or, to the extent required in such country, price approval, for biological or pharmaceutical Product in such country.

"Representatives" means, with respect to any Person, such Person's directors, officers, employees, attorneys, counsel, consultants, advisors, financing sources, accountants, auditors, authorized representatives, agents or Affiliates.

"Subsidiary" means, with respect to any Person, any entity of which securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions are at the time directly or indirectly owned by such first Person.

"Tax Return" means any return (including any information return), report, statement, schedule, notice, form or other document or information filed with or submitted to, or required to be filed with or submitted to, any Taxing Authority in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

"Taxes" means (I) any and all federal, state, local or foreign taxes, charges, fees, imposts, levies or other assessments, including all net income, gross receipts, capital, sales, use, ad valorem, value added, transfer, franchise, profits, inventory, capital stock, license, withholding, payroll, employment, social security, unemployment, excise, severance, stamp, occupation, property and estimated taxes, customs duties, fees, assessments and charges of any kind whatsoever, together with any such Liabilities for any other Person, whether arising by reason of consolidated, combined, or similar Tax Returns, as a transferee, by contract, by operation of Law, or otherwise; and (ii) all interest, penalties, fines, additions to tax or additional amounts imposed by any Taxing Authority in connection with any item described in clause (i) above.

"Taxing Authority" means any Governmental Authority responsible for the administration of any Tax.

"Third Party" means any Person other than the Parties or any of their respective Affiliates.

"Trademarks" means any and all trademarks, service marks, logos, slogans, trade names, trade dress, internet domain names, social media handles, and any other indicator of the source of origin of goods or services, including all applications and registrations of, and all goodwill associated with, the foregoing.

"Transaction" means the purchase and sale of the Acquired Assets and the assumption of the Assumed Liabilities as contemplated by this Agreement.

"Transfer Taxes" means any and all sale, use, stamp, documentary, filing, recording, transfer, gross receipts, registration, duty or similar fees or Taxes or governmental charges (together with any interest or penalty, addition to tax or additional amount imposed) as levied by any Taxing Authority on the purchase and sale of the Acquired Assets.

"United States" or "U.S." means the United States of America and its territories, possessions and commonwealths.

(b) Other Definitional and Interpretive Matters. Unless otherwise expressly provided, for purposes of this Agreement, the following rules of interpretation shall apply:

(i) Calculation of Time Periods. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded. If the last day of such period is a non-Business Day, the period in question shall end on the next succeeding Business Day.

(ii) Currency. Unless otherwise specified in this Agreement, all references to "$" and dollars set forth herein shall mean United States (U.S.) dollars.

(iii) Exhibits/Schedules. The Exhibits and Schedules to this Agreement are an integral part of this Agreement and are hereby incorporated herein and made a part hereof as if set forth herein. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein shall be defined as set forth in this Agreement. The representations and warranties contained in Article IV are qualified by reference to the Schedules attached hereto and referred to in Article IV (collectively, the "Disclosure Schedule"). The Parties acknowledge and agree that (i) the Disclosure Schedule may include items or information that Aeglea is not required to disclose under this Agreement, (ii) disclosure of such items or information shall not be deemed to expand the scope of the representations and warranties of Aeglea under this Agreement, (iii) inclusion of information in the Disclosure Schedule shall not be construed as an admission that such information is necessarily material in any respect and (iv) reference in a particular Section of the Disclosure Schedule shall only be deemed to be an exception to (or, as applicable, a disclosure for purposes of) (A) the representations and warranties (or covenants and agreements, as applicable) of Aeglea that are contained in the corresponding Section of this Agreement and (B) any other representation and warranty (or covenant and agreement, as applicable) of Aeglea that is contained in this Agreement, but only if the relevance of that reference as an exception to (or a disclosure for purposes of) such representation and warranty (or covenant and agreement, as applicable) would be reasonably apparent to a reasonable person without any independent knowledge regarding the matter(s) so disclosed.

(iv) Gender and Number. Any reference in this Agreement to gender shall include all genders, and words imparting the singular number only shall include the plural and vice versa.

(v) Headings. The provision of the Table of Contents, the division of this Agreement into Articles, Sections and other subdivisions and the insertion of headings are for convenience of reference only and shall not affect or be utilized in construing or interpreting this Agreement. All references in this Agreement to any "Article," "Section" or other subdivision are to the corresponding Article, Section or other subdivision of this Agreement unless otherwise specified.

(vi) Herein. Words such as "herein," "hereinafter," "hereof," "hereunder" and "hereto" refer to this Agreement as a whole and not merely to a subdivision in which such words appear unless the context otherwise requires.

(vii) Including. The word "including" or any variation thereof means "including without limitation," unless otherwise specified and shall not be construed to limit any general statement that it follows to the specific or similar items or matters immediately following it.

(viii) Other. The word "or" shall be exclusive; references to "written" or "in writing" include in electronic form (including email); any reference to "days" means calendar days unless Business Days are expressly specified; and references to any statute, rule, regulation, law or applicable Law shall be deemed to refer to all applicable Laws as amended or supplemented from time to time and to any rules, regulations and interpretations promulgated thereunder.

Exhibit B

IP Assignment Agreement

Exhibit C

Specified Patent Assignment Agreement

Exhibit D

Specified Patent License Agreement

Exhibit 31.1

Certification of Periodic Report under Section 302 of the Sarbanes-Oxley Act of 2002

I, Jonathan Alspaugh, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aeglea BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a 15(f) and 15d 15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2023

/s/ Jonathan Alspaugh

Jonathan Alspaugh

President and Chief Financial Officer

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

Certification Of
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

In connection with the Quarterly Report on Form 10-Q of Aeglea BioTherapeutics, Inc. (the "Company") for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Alspaugh, President and Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2023

/s/ Jonathan Alspaugh

Jonathan Alspaugh

President and Chief Financial Officer

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)