UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from_____ to_____

Commission File Number: 001-35966

bluebird bio, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-3680878**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
455 Grand Union Boulevard Somerville , Massachusetts	**02145**
(Address of Principal Executive Offices)	**(Zip Code)**

(339) 499-9300

(Registrant's Telephone Number, Including Area Code)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	BLUE	The NASDAQ Stock Market LLC

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

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

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

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

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

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

As of November 12, 2024, there were 194,444,345 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans and expectations regarding our commercialization activities for SKYSONA, ZYNTEGLO, and LYFGENIA, as well as any future approved products and the timing or success thereof, including expectations regarding our network of qualified treatment centers;
- the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical studies;
- our ability to obtain adequate financing to fund our operations and to execute on our strategy;
- our expectations and projections regarding the sufficiency of our cash and cash equivalents to fund our operations;
- our ability to establish and scale commercial viral vector and drug product manufacturing capabilities, and to ensure adequate supply of our viral vectors and drug products, and our plans and expectations regarding our manufacturing activities;
- the timing or likelihood of regulatory filings and marketing approvals for our product candidates and our plans and expectations relating thereto;
- our ability to obtain adequate pricing and reimbursement of any approved products;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations and licenses;
- developments relating to our competitors and our industry;
- the impact of the general economic conditions and uncertainties;
- our ability to mitigate the commercial, reputational and regulatory risks to our business that may arise as a consequence of the restatement of our financial statements;
- the estimated charges and expenses related to, and anticipated benefits from, our restructuring action;
- our ability to comply with Nasdaq continued listing rules;
- our ability to retain key personnel;
- our ability to comply with covenants in our loan agreement;
- our ability to remediate the material weakness in our internal control over financial reporting; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these

forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Summary of the Material and Other Risks Associated with Our Business

Below is a summary of the material risks to our business, operations and the investment in our common stock. This summary does not address all of the risks that we face. Risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q in its entirety before making investment decisions regarding our common stock.

- We have incurred significant losses since our inception and we may not achieve our goal of becoming profitable in the timeframe we expect, or at all.
- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our commercial programs, product development efforts or other operations.
- Among other potential adverse events, insertional oncogenesis is a significant risk of gene therapies using viral vectors that can integrate into the genome. Any such adverse events may require us to halt or delay further clinical development of our products or any future product candidates or to suspend or cease commercialization, and the commercial potential of our products and any such future product candidates may be materially and negatively impacted.
- We rely on complex, single-source supply chains for SKYSONA, ZYNTEGLO, and LYFGENIA, respectively. The manufacture, testing and delivery of LVV and drug products present significant challenges for us, and we may not be able to produce our vector and drug products at the quality, quantities, or timing needed to support our clinical programs and commercialization.
- We have limited experience as a commercial company and the marketing and sale of ZYNTEGLO, SKYSONA and LYFGENIA may be unsuccessful or less successful than anticipated.
- The commercial success of ZYNTEGLO, SKYSONA and LYFGENIA will depend upon the degree of market acceptance by physicians, patients, payers and other stakeholders.
- If the market opportunities for our commercial products or any future product candidates are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.
- The insurance coverage and reimbursement status of newly-approved products in the United States is uncertain. Due to the novel nature of our technology and the potential for our products to offer lifetime therapeutic benefit in a single administration, we face unique and additional challenges in obtaining adequate coverage and reimbursement for our products. Failure to obtain or maintain adequate coverage and reimbursement for any new or current product, including to the extent that payers 'non-prefer' any or all of our therapies to our competitors, could limit our ability to market those products and decrease our ability to generate revenue.
- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced, safer or more effective than ours, which may adversely affect our financial condition and our ability to successfully develop and commercialize ZYNTEGLO, SKYSONA and LYFGENIA.
- The restatement of our consolidated financial statements for the year ended December 31, 2022 and the quarterly periods in the years ended December 31, 2022 and 2023 has subjected us to a number of additional risks and uncertainties, including increased possibility of legal proceedings.
- Our existing and any future indebtedness could adversely affect our ability to operate our business.
- Our restructuring and reduction in force undertaken to optimize our cost structure may not achieve our intended outcome.

- We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls.

bluebird bio, Inc.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

bluebird bio, Inc.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except par value amounts)

	As of September 30, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 70,651	$ 221,755
Prepaid expenses	7,553	14,800
Inventory	53,944	22,919
Due from factor	1,062	560
Receivables and other current assets	17,601	21,651
Total current assets	150,811	281,685
Property, plant and equipment, net	62,593	65,936
Goodwill	5,646	5,646
Intangible assets, net	9,780	10,438
Operating lease right-of-use assets	183,098	201,113
Restricted cash and other non-current assets	53,128	54,343
Total assets	$ 465,056	$ 619,161
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 24,481	$ 18,498
Due to factor	10,080	2,520
Accrued expenses and other current liabilities	70,179	73,188
Operating lease liability, current portion	24,511	21,202
Financing lease liability, current portion	96,181	84,705
Term loan debt	70,600	—
Total current liabilities	296,032	200,113
Operating lease liability, net of current portion	168,056	186,687
Financing lease liability, net of current portion	5,675	37,732
Other non-current liabilities	1,079	92
Total liabilities	470,842	424,624
Commitments and contingencies *(Note 10)*		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000 shares authorized; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value, 250,000 shares authorized; 193,917 and 192,772 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1,917	1,905
Additional paid-in capital	4,466,141	4,454,756
Accumulated other comprehensive loss	(1,511)	(1,796)
Accumulated deficit	(4,472,333)	(4,260,328)
Total stockholders' equity	(5,786)	194,537
Total liabilities and stockholders' equity	$ 465,056	$ 619,161

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
		(As Restated)		(As Restated)
Revenue:				
Product revenue, net	$ 10,612	$ 12,281	$ 45,274	$ 21,414
Other revenue	—	111	12	249
Total revenues	10,612	12,392	45,286	21,663
Cost of product revenue	11,781	9,126	66,591	21,335
Gross margin	(1,169)	3,266	(21,305)	328
Operating expenses:				
Selling, general and administrative	39,765	40,771	136,479	118,700
Research and development	23,174	58,501	73,408	131,536
Restructuring expenses	2,811	—	2,811	—
Total operating expenses	65,750	99,272	212,698	250,236
Gain from sale of priority review voucher, net	—	—	—	92,930
Loss from operations	(66,919)	(96,006)	(234,003)	(156,978)
Interest income	1,640	2,454	7,056	7,961
Interest expense	(5,778)	(4,311)	(16,875)	(12,331)
Other income, net	10,191	10,631	31,782	30,177
Loss before income taxes	(60,866)	(87,232)	(212,040)	(131,171)
Income tax (expense) benefit	58	—	37	80
Net loss	$ (60,808)	$ (87,232)	$ (212,003)	$ (131,091)
Net loss per share - basic	$ (0.31)	$ (0.80)	$ (1.10)	$ (1.23)
Net loss per share - diluted	$ (0.31)	$ (0.80)	$ (1.10)	$ (1.23)
Weighted-average number of common shares used in computing net loss per share - basic:	193,893	109,098	193,588	106,924
Weighted-average number of common shares used in computing net loss per share - diluted:	193,893	109,098	193,588	106,924
Other comprehensive income (loss):				
Other comprehensive income (loss), net of tax benefit (expense) of $0.0 million for the three and nine months ended September 30, 2024 and 2023	611	137	285	1,843
Total other comprehensive income (loss)	611	137	285	1,843
Comprehensive loss	$ (60,197)	$ (87,095)	$ (211,718)	$ (129,248)

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(in thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2023	192,772	$ 1,905	$ 4,454,756	$ (1,796)	$ (4,260,328)	$ 194,537
Vesting of restricted stock units	811	8	(8)	—	—	—
Issuance of warrants	—	—	2,571	—	—	2,571
Stock-based compensation expense	—	—	4,054	—	—	4,054
Other comprehensive loss	—	—	—	(312)	—	(312)
Net loss	—	—	—	—	(69,804)	(69,804)
Balances at March 31, 2024	193,583	$ 1,913	$ 4,461,373	$ (2,108)	$ (4,330,132)	$ 131,046
Vesting of restricted stock units	185	$ 2	$ (2)	$ —	$ —	$ —
Purchase of common stock under employee stock purchase plan (ESPP)	88	1	80	—	—	81
Stock-based compensation expense	—	—	3,261	—	—	3,261
Other comprehensive loss	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(81,393)	(81,393)
Balances at June 30, 2024	193,856	$ 1,916	$ 4,464,712	$ (2,122)	$ (4,411,525)	$ 52,981
Vesting of restricted stock units	61	$ 1	$ (1)	$ —	$ —	$ —
Reclassification of warrants to liability upon modification	—	—	(1,945)	—	—	(1,945)
Stock-based compensation expense	—	—	3,375	—	—	3,375
Other comprehensive income (loss)	—	—	—	611	—	611
Net loss	—	—	—	—	(60,808)	(60,808)
Balances at September 30, 2024	193,917	$ 1,917	$ 4,466,141	$ (1,511)	$ (4,472,333)	$ (5,786)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2022 (As Restated)	82,923	$ 830	$ 4,185,988	$ (4,070)	$ (4,048,415)	$ 134,333
Vesting of restricted stock units	382	3	(198)	—	—	(195)
Exercise of stock options	3	—	7	—	—	7
Purchase of common stock under ESPP	62	1	226	—	—	227
Issuance of common stock	23,000	230	130,061	—	—	130,291
Stock-based compensation expense	—	—	5,843	—	—	5,843
Other comprehensive income	—	—	—	984	—	984
Net income	—	—	—	—	18,930	18,930
Balances at March 31, 2023 (As Restated)	106,370	$ 1,064	$ 4,321,927	$ (3,086)	$ (4,029,485)	$ 290,420
Vesting of restricted stock units	65	1	(1)	—	—	—
Exercise of stock options	19	—	77	—	—	77
Stock-based compensation expense	—	—	6,388	—	—	6,388
Other comprehensive income	—	—	—	722	—	722
Net loss	—	—	—	—	(62,789)	(62,789)
Balances at June 30, 2023 (As Restated)	106,454	$ 1,065	$ 4,328,391	$ (2,364)	$ (4,092,274)	$ 234,818
Vesting of restricted stock	566	6	(6)	—	—	—
Exercise of stock options	2	—	8	—	—	8
Issuance of common stock	—	—	(50)	—	—	(50)
Stock-based compensation	—	—	5,153	—	—	5,153
Other comprehensive income	—	—	—	137	—	137
Net loss	—	—	—	—	(87,232)	(87,232)
Balances at September 30, 2023 (As Restated)	107,022	$ 1,071	$ 4,333,496	$ (2,227)	$ (4,179,506)	$ 152,834

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	For the nine months ended September 30,	
	2024	**2023**
		(As Restated)
Cash flows from operating activities:		
Net loss	$ (212,003)	$ (131,091)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	47,339	19,660
Stock-based compensation expense	9,669	16,013
Noncash research and development expense (finance lease)	—	22,223
Noncash operating lease expense	18,015	23,965
Gain from sale of priority review voucher	—	(92,930)
Change in excess inventory reserve	8,035	9,202
Noncash interest related to debt	1,916	—
Other non-cash items	(14)	100
Gain on foreign currency exchange rates	(86)	(1,062)
Changes in operating assets and liabilities:		
Accounts receivable	—	(14,600)
Prepaid expenses and other assets	(47,022)	2,117
Inventory	(38,038)	(26,197)
Accounts payable	6,660	1,712
Accrued expenses and other liabilities	2,986	5,709
Accrued interest payable under finance lease	8,010	3,203
Operating lease liabilities	(15,323)	(18,686)
Deferred revenue	—	(248)
Net cash used in operating activities	(209,856)	(180,910)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(2,114)	(2,975)
Purchases of marketable securities	—	(43,297)
Proceeds from previously transferred invoices, net of fees	3,546	—
Proceeds from maturities of marketable securities	—	99,521
Proceeds from sales of marketable securities	—	5,853
Purchase of intangible assets	—	(868)
Proceeds from sale of priority review voucher	—	92,930
Net cash provided by investing activities	1,432	151,164
Cash flows from financing activities:		
Proceeds from the issuance of debt, net of fees paid to lender	71,316	—
Proceeds allocated to detachable warrants issued in conjunction with debt	2,669	—
Payments of debt issuance costs	(2,576)	—
Proceeds from exercise of stock options and ESPP contributions	—	93
Proceeds from the transfer of invoices, net of fees	50,646	—
Proceeds from vesting of restricted stock	—	(196)
Principal payments on finance leases	(69,576)	(40,299)
Proceeds from the secondary public offering, net of issuance costs	—	130,072
Net cash provided by financing activities	52,479	89,670
(Decrease) increase in cash, cash equivalents and restricted cash	(155,945)	59,924
Cash, cash equivalents and restricted cash at beginning of period	274,597	158,445
Cash, cash equivalents and restricted cash at end of period	$ 118,652	$ 218,369
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 70,651	$ 165,347

Restricted cash included in other current assets	4,360	8,885
Restricted cash included in restricted cash and other non-current assets	43,641	44,137
Total cash, cash equivalents and restricted cash	$ 118,652	$ 218,369
Supplemental cash flow disclosures from investing and financing activities:		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	31	941
Offering expenses included in accounts payable and accrued expenses	—	248
Right-of-use assets obtained in exchange for operating lease liabilities	—	(708)
Right-of-use assets obtained in exchange for finance lease liabilities	41,893	21,508
Cash paid (refund received) during the period for income taxes	(10)	5
Beneficiary interest obtained in transferred invoices	4,850	—
Derecognition of due to factor liabilities	43,650	—

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of the business

bluebird bio, Inc. (the “Company” or “bluebird”) was incorporated in Delaware on April 16, 1992, and is headquartered in Somerville, Massachusetts. The Company is a biotechnology company committed to researching, developing and commercializing potentially curative gene therapies for severe genetic diseases based on its proprietary lentiviral vector ("LVV") gene addition platform. Since its inception, the Company has devoted substantially all of its resources to its research and development efforts relating to its product candidates, and commercialization of its approved products, including activities to manufacture product candidates, conduct clinical studies of its product candidates, perform preclinical research to identify new product candidates, provide selling, general and administrative support for these operations and market and commercially manufacture and distribute its approved products.

The Company’s programs in severe genetic diseases include ZYNTEGLO (betibeglogene autotemcel, also known as beti-cel) as a treatment for β-thalassemia; LYFGENIA (lovotibeglogene autotemcel, also known as lovo-cel) as a treatment for sickle cell disease ("SCD"); and SKYSONA (elivaldogene autotemcel, also known as eli-cel) as a treatment for cerebral adrenoleukodystrophy ("CALD"). On August 17, 2022, ZYNTEGLO was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adult and pediatric patients with ß-thalassemia who require regular red blood cell transfusions. On September 16, 2022, the FDA granted Accelerated Approval of SKYSONA to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active CALD. On December 8, 2023, LYFGENIA was approved by the FDA for the treatment of patients 12 years of age or older with sickle cell disease and with a history of vaso-occlusive-events.

In August 2023, the Company entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") to sell shares of the Company’s common stock up to $125.0 million, from time to time, through an “at the market” equity offering program under which Jefferies will act as sales agent. As of September 30, 2024, the Company has made no sales pursuant to the Sales Agreement.

In December 2023, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Goldman Sachs & Co. LLC ("Goldman") and J.P. Morgan Securities LLC, to sell 83.3 million shares of the Company's common stock. The Company received net proceeds of approximately $118.1 million.

In March 2024, the Company entered into a five-year term loan facility agreement with Hercules Capital, Inc. to secure debt financing for up to $175.0 million, available in four tranches. This is described in Note 8, *Term Loan Debt*, in the Notes to Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q.

In September 2024, the Company's board of directors approved a restructuring action (the "Restructuring") following a comprehensive review of the Company's operations, which resulted in a reduction of the Company's workforce by 94 employees, or approximately 25% of employees. The Restructuring is designed to support the Company's commercial focus and reduce its cash operating expenses. Refer to Note 15, *Reduction in workforce,* for more information on the Restructuring.

Since its inception, the Company has incurred significant operating losses and negative operating cash flows. As of September 30, 2024, the Company had an accumulated deficit of $4.5 billion. During the nine months ended September 30, 2024, the Company incurred a net loss of $212.0 million and used $209.9 million of cash in operations. As of September 30, 2024, the Company had cash and cash equivalents of $70.7 million.

In accordance with Accounting Standards Codification (“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.

This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

The Company's history of recurring operating losses and negative operating cash flows, its expectation to generate operating losses and negative operating cash flows, its projection that it may not maintain the minimum cash coverage related to

the Loan and Security Agreement (the “LSA”), and the need for additional funding to support its planned operations raise substantial doubt regarding the Company’s ability to continue as a going concern for a period of one year after the date that these consolidated financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include controlling spending, executing on commercial launch plans, and exploring additional financing options. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources, or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company’s ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

The Company has based the estimated cash needs on assumptions that may prove to be wrong, and its operating plan may change as a result of many factors currently unknown to it. As a result, the Company could deplete its capital resources sooner than it currently expects. Along with the Company's revenue from product sales, the Company expects to finance its future cash needs through the issuance of equity, or debt, or other alternative means. If the Company is unable to obtain funding on a timely basis, or if revenues from product sales are less than it has projected, the Company may be required to further revise its business plan and strategy, which may result in the Company significantly curtailing, delaying or discontinuing one or more of its research or development programs or the commercialization of any products or may result in the Company being unable to continue or expand its operations or otherwise capitalize on its business opportunities. As a result, the Company's business, financial condition and results of operations could be materially affected.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

2. Basis of presentation, principles of consolidation and significant accounting policies

Basis of presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as included in the Accounting Standard Codification (“ASC”) and Accounting Standards Updates (“ASUs”) of the Financial Accounting Standards Board (“FASB”). Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. These condensed consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company’s financial position and results of operations for the interim periods ended September 30, 2024 and 2023.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2023, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the Securities and Exchange Commission (the “SEC”) on September 13, 2024 (the "2023 Annual Report on Form 10-K").

Amounts reported are computed based on thousands, except percentages, per share amounts, or as otherwise noted. As a result, certain totals may not sum due to rounding.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company views its operations and manages its business in one operating segment.

Restatement of Previously Issued Financial Statements

As previously disclosed in the Company's 2023 Annual Report Form 10-K filed with the SEC on September 13, 2024, the Company is restating its previously issued unaudited condensed consolidated financial information for the three and nine month periods ending September 30, 2023 due to multiple prior period misstatements. The accompanying condensed consolidated financial information as of and for the quarter ended September 30, 2023 have been restated in this Quarterly Report on Form 10-Q (see Note 16: Restatement of Previously Issued Financial Statements). In addition, the Company has corrected the accompanying footnotes in connection with the restatement.

Significant accounting policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2024 are consistent with those discussed in Note 3 to the consolidated financial statements included in the Company's 2023 Annual Report on Form 10-K.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified to conform to the current year presentation. Specifically, interest expense has been reclassified from interest income to interest expense in the consolidated statement of operations and comprehensive loss. These reclassifications had no effect on the reported results of operations.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Estimates and judgments are used in the following areas, among others: the alternative future use of assets used in research and development activities, realizability of inventories, future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including goodwill and intangible assets, and the measurement of right-of-use assets and lease liabilities, gross-to-net revenue calculations, stock-based compensation expense, accrued expenses, income taxes, the assessment of the Company's ability to fund its operations for at least the next twelve months from the date of issuance of these financial statements, and the assessment of the likelihood and magnitude of losses that may be sustained upon resolution of contingencies.

Inventory

Inventories are stated at the lower of cost or net realizable value under the first-expired, first-out ("FEFO") methodology. Given human gene therapy products are a new and novel category of therapeutics and future economic benefit is not probable until regulatory approval for the product has been obtained, the Company has only considered inventory for capitalization upon regulatory approval. Manufacturing costs incurred prior to regulatory approval for pre-launch inventory that did not qualify for capitalization and clinical manufacturing costs are charged to research and development expense in the Company's consolidated statements of operations and comprehensive loss as costs are incurred. Additionally, inventory that initially qualifies for capitalization but that may ultimately be used to produce clinical drug product is expensed as research and development expense when it has been designated for the manufacture of clinical drug product.

Inventory consists of cell banks, plasmids, LVV, other materials and compounds sourced from third party suppliers and utilized in the manufacturing process, and drug product which has been produced for the treatment of specific patients, that are owned by the Company until infusion.

Management periodically reviews inventories for excess or obsolescence, considering factors such as sales forecasts compared to quantities on-hand and firm purchase commitments as well as remaining shelf life of on-hand inventories. The Company writes down its inventory that is in excess, obsolete or otherwise unmarketable to its estimated net realizable value in the period in which the impairment is first identified. Any such adjustments are included as a component of cost of goods sold within cost of product revenue in the Company's consolidated statements of operations and comprehensive loss.

Revenue recognition

Under ASC Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii)

identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

The Company assesses whether each promised good or service is distinct to identify the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the adjustment period.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue generating arrangements to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

Product revenue

In 2022, the Company received approval of ZYNTEGLO and SKYSONA from the FDA. In 2023, the Company received approval of LYFGENIA from the FDA. The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers. The Company uses Specialty Distributors ("SD") and Specialty Pharmacies ("SP") to deliver product to the Qualified Treatment Centers ("QTC"). Revenue is only recognized when the performance obligation is satisfied. The Company recognizes revenue upon infusion to the patient. To determine whether a significant reversal will occur in future periods, the Company will assess both the likelihood and magnitude of any such potential reversal of revenue. Gross product revenue is reduced by outcomes-based rebates, other rebates and distributor fees.

Rebates expense

Rebates are based on contractual arrangements or statutory requirements and include amounts due to Medicaid agencies and third-party payers. These amounts may vary by product and payer. Rebates are estimated primarily based on product sales, including product mix and pricing, historical and estimated payer mix and discount rates, among other inputs, which require

significant estimates and judgment. The Company assesses and updates estimates each reporting period to reflect actual claims and other current information.

Rebates that are payable to Medicaid agencies and third-party payers are recorded in accrued expenses and other current liabilities on the Company's consolidated balance sheets.

Distributor fees

The Company pays distribution fees to SDs and SPs in connection with the sales of our product. These distributor fees are based on a contractually determined fixed percentage of sales.

Other revenue

In 2021, the Company entered into a grant agreement with the Bill and Melinda Gates Foundation. The Company recognizes grant revenue in accordance with ASC 958-605, *Revenue Recognition Not-for-Profit Entities*, when qualifying costs are incurred and barriers to restriction have been overcome. When grant funds are received after costs have been incurred, the Company records revenue and a corresponding grant receivable. Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. In 2023, the Company ceased further research work.

Recent accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures* to update reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance and requires companies to disclose all annual disclosures about segments in interim periods. The ASU also requires companies with a single reportable segment to provide all disclosures required by Topic 280 – Segment Reporting. This update is effective beginning with the Company’s 2024 fiscal year annual reporting period and interim periods beginning thereafter. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This ASU expands disclosures in an entity’s income tax rate reconciliation table and disclosures regarding taxes paid both in the U.S. and foreign jurisdictions. This update is effective beginning with the Company’s 2025 fiscal year annual reporting period. The Company is currently evaluating the impact to its income tax disclosures.

In March 2024, the FASB issued ASU 2024-01, *Compensation-Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards*. This update clarifies the scope of "Profit Interest" and similar awards and adds an illustrative example to the existing ASC 718 standard that includes four fact patterns to demonstrate how an entity should apply the scope guidance in paragraph 718-10-15-3 to determine whether a profits interest award should be accounted for in accordance with Topic 718. The amendments in this ASU are effective for annual periods beginning after December 15, 2024, and interim periods within those annual periods. Early adoption is permitted for interim and annual financial statements not yet issued or made available for issuance. The amendments in this ASU should be applied either (1) retrospectively to all prior periods presented in the financial statements or (2) prospectively to profits interest and similar awards granted or modified on or after the date at which the entity first applies the amendments. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements and disclosures.

In March 2024, the FASB issued ASU 2024-02 "*Codification Improvements—Amendments to Remove References to the Concepts Statements"*, which removes various references to concepts statements from the FASB Accounting Standards Codification. This ASU is effective for the Company beginning in the first quarter of fiscal year 2026, with early adoption permitted. The Company expects the new guidance will have an immaterial impact on its consolidated financial statements and intends to adopt the guidance when it becomes effective in the first quarter of fiscal year 2026.

In November 2024, the FASB issued ASU 2024-03 *"Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses"*. This ASU requires expanded disclosures of specific income statement expense categories such as cost of product revenue, selling, general, and administrative expenses, and research and development expenses. This update is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted.

3. Product revenue and reserves

For the three months ended September 30, 2024 and 2023, the Company recorded $10.6 million and $12.3 million, respectively, of product revenue. For the nine months ended September 30, 2024 and 2023, the Company recorded $45.3 million and $21.4 million, respectively, of product revenue. Product revenue by therapy represents:

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
ZYNTEGLO	$ 5,493	$ 4,851	$ 35,212	$ 9,031
LYFGENIA	2,632	—	2,632	—
SKYSONA	2,487	7,430	7,430	12,383
Total product revenue, net	$ 10,612	$ 12,281	$ 45,274	$ 21,414

Six individual customers accounted for 84% of product revenue for the nine months ended September 30, 2024 and two individual customer accounted for 89% of product revenue for the nine months ended September 30, 2023.

The Company considers there to be revenue concentration risks for customers that represent product revenues that exceed 10% of total product revenue. The concentration of the Company's product revenue within a particular customer may have a material adverse effect on the Company's revenue and results of operations if sales with the respective customer experience difficulties. All product revenue during the nine months ended September 30, 2024 and 2023 were within the United States.

The following table summarizes an analysis of the change in reserves for gross to net deductions for the periods indicated:

	Total
Balance at December 31, 2023	$ 5,365
Provision for rebates	8,506
Payments/credits	—
Balance at September 30, 2024	$ 13,871

4. Fair value measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2024 and December 31, 2023 (in thousands):

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2024				
Assets:				
Cash and cash equivalents	$ 70,651	$ 70,651	$ —	$ -
Due from factor:				
Beneficiary interest in factored invoices	1,062	—	—	1,06
Other non-current liabilities				
Warrant liability	987	—	—	98
Total	$ 72,700	$ 70,651	$ —	$ 2,04
December 31, 2023				
Assets:				
Cash and cash equivalents	$ 221,755	$ 221,755	$ —	$ -
Due from factor:				
Beneficiary interest in factored invoices	560	—	—	56
Total	$ 222,315	$ 221,755	$ —	$ 56

Cash and cash equivalents

The Company considers all highly liquid securities with original final maturities of 90 days or less from the date of purchase to be cash equivalents. As of September 30, 2024 and December 31, 2023, cash and cash equivalents comprise funds in cash and money market accounts held at multiple banking and asset management institutions.

Factoring agreement

Due from factor classified as Level 3 within the valuation hierarchy consists of beneficiary interest in transferred invoices. The Company estimates the fair value of the beneficiary interest based on the estimated cash flows after applying counterparty and credit risk adjustments associated with the factoring agent and distributors, respectively. As of September 30, 2024, no adjustment to the beneficiary interest in invoices sold was deemed an unobservable input and was determined based from ongoing credit evaluations and historical experience with aging of such invoices, among other factors. A significant change to this input could result in a significantly lower fair value measurement.

The following table shows a reconciliation of the beginning and ending balances for due from factor Level 3 financial liabilities measured at fair value on a recurring basis for the nine months ended September 30, 2024:

	For the nine months ended September 30, 2024
Balance at December 31, 2023	$ 560
Beneficiary interest obtained in transferred invoices	4,850
Gross proceeds from previously transferred invoices	(4,240)
Accrual for factor reserve deficiency	(26)
Accrual for anticipated loss on sale of invoices	(82)
Balance at September 30, 2024	$ 1,062

Common stock warrants

On March 15, 2024, in connection with its debt issuance (see Note 8, *Term loan debt*), the Company issued warrants to a lender to purchase shares of the Company's common stock at an exercise price of $1.45 per share. On August 13, 2024, the Company amended the exercise price of the warrants to be the lesser of $1.03 per share and the price per share of the Company's first financing event within six months of August 13, 2024 or February 13, 2025. As a result of the modification, the warrants were reclassified from additional paid-in-capital within stockholders' equity to other non-current liabilities on the condensed consolidated balance sheet at their fair value as of the modification date. The warrants are adjusted to fair value at period end through "other income (expense)" on the condensed consolidated statements of operations and comprehensive loss.

The warrants have been recorded at their fair value using the Black-Scholes option-pricing model and the following assumptions: no dividend yield, probability-weighted exercise price ranging between $0.50 and $1.03, stock price of $0.52 per share, expected volatility of 85.7%, risk free rate of 3.7%, and expected term of 7 years, equal to the life of the warrant.

The following table shows a reconciliation of the beginning and ending balances for other non-current liabilities due from factor Level 3 financial liabilities measured at fair value on a recurring basis for the nine months ended September 30, 2024:

	For the nine months ended September 30, 2024
Balance at December 31, 2023	$ —
Warrant modification and reclassification to liabilities	2,100
Change in fair value	(1,113)
Balance at September 30, 2024	$ 987

5. Inventory

Inventory, net, consists of the following (in thousands):

	As of September 30, 2024	As of December 31, 2023
Raw materials	$ 2,965	$ 2,329
Work in progress	48,649	17,375
Finished goods	2,330	3,215
Inventory	$ 53,944	$ 22,919

Raw materials inventory consists of completed materials purchased directly from third party suppliers. Work in progress inventory consists of materials manufactured at contract manufacturing organizations ("CMOs") that are either partially completed, fully manufactured but are pending quality acceptance, or completed meeting quality acceptance standards to be used in the manufacture of drug product and drug products that are either partially completed or fully manufactured but are pending quality acceptance. Finished goods are completed and quality approved drug products that are either awaiting shipment, in-transit or delivered to a qualified treatment center, but have not yet been infused in a patient.

6. Factoring agreement

The Company sells rights to future revenues associated with invoices issued upon delivery of drug product to QTCs. The Company sells 100% of the invoice, and the upfront purchase price is 90% of the invoice amount. The remaining 10% less applicable fees is payable when the factor receives full payment from the customer. The upfront payments are treated as a short-term liability, presented as due to factor on the Company's consolidated balance sheets until the right to consideration from the customer is deemed unconditional. The remaining invoice amount payable to the Company at infusion is considered a beneficial interest in the factored invoice and represents the extent of our continued involvement in the sale of invoices.

Due to Factor

For the three and nine months ending September 30, 2024, the Company collected $15.2 million and $50.6 million, respectively, in cash receipts prior to an unconditional right to consideration and derecognized $10.6 million and $43.7 million, respectively, of due to factor amounts as a result of patient drug product infusions. Amounts presented as due to factor on the condensed consolidated balance sheets would be subject to payment based on the repurchase requirements that exist prior to the infusion date in the factoring agreement.

Due from Factor

For the three and nine months ending September 30, 2024, the company obtained $1.2 million and $4.9 million, respectively, of beneficiary interest in invoices and collected $0.7 million and $3.5 million, respectively, in cash receipts. Uncollected amounts presented as due from factor on the consolidated balance sheets are net of accrued fees of $0.1 million. The maximum loss exposure is $1.2 million at September 30, 2024.

The total loss from the sale of customer invoices is estimated on the patient infusion date of the drug product and was $0.5 million and $1.4 million, respectively, for the three and nine months ending September 30, 2024. In addition to the loss from the sale of invoices, the Company has incurred $0.3 million and $0.8 million, respectively, in servicing fees for the three and nine months ending September 30, 2024.

7. Accrued expenses and other current liabilities

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

	As of September 30, 2024	As of December 31, 2023
Accrued CMO and CRO costs	$ 21,735	$ 24,824
Accrued employee compensation	15,375	19,972
Accrued rebates	13,998	5,365
Accrued goods and services	1,814	8,391
Accrued professional fees	10,070	2,531
Other sublease rent liability	3,379	3,310
Accrued refund liability	—	5,600
Other	3,808	3,195
Total accrued expenses and other current liabilities	$ 70,179	$ 73,188

8. Term loan debt

2024 Term Loan

On March 15, 2024 (the "Effective Date"), the Company entered into the LSA and a Warrant Agreement (the "Warrant Agreement") with Hercules Capital and funds managed by Hercules Capital (collectively, "Hercules" or "the lenders"). Under the terms of the LSA, the Company may borrow up to an aggregate principal amount of $175.0 million over the term of the agreement, in four separate tranches (the "Term Loans") dependent on the achievement of certain milestones. On the Effective Date, the Company drew down the initial $75.0 million of gross proceeds ("Initial Loan"), and paid initial debt issuance costs of $3.5 million, inclusive of legal fees of approximately $2.7 million and the original issuance discount ("OID") of $0.8 million, or 1% of the drawn amount, in accordance with the terms of the LSA.

On August 13, 2024, the Company and Hercules entered into an amendment to the LSA (the "Third Amendment"), pursuant to which the parties agreed to, among other things, revised terms for the availability of the second and third tranches of funding under the LSA and an increase to the minimum cash coverage requirement. In accordance with the Third Amendment, the Company may draw the second tranche of $25.0 million during the period commencing on the date the Company has (x) received at least $75.0 million in gross cash proceeds from qualified financing transactions by December 20, 2024 and (y) completed patient starts (cell collections) for at least 50 LYFGENIA patients by March 31, 2025 or 70 LYFGENIA patients by June 30, 2025 (collectively, the "Tranche 2 Milestone") and ending on the earlier of (i) the date that is 30 days immediately following achievement of the Tranche 2 Milestone and (ii) July 31, 2025. The Company may draw the third tranche of $25.0 million during the period commencing on the date the Company has (x) received at least $100.0 million in gross cash proceeds from qualified financing transactions by December 20, 2024 or at least $125.0 million by June 30, 2025 and (y) completed 70 drug product deliveries within a given six-month period ending no later than December 31, 2025, at least 40 of which are for LYFGENIA (collectively, the "Tranche 3 Milestone") and ending on the earlier of (i) the date that is 30 days immediately following the date the Company achieves the Tranche 3 Milestone and (ii) December 31, 2025. The Company may request up to an additional $50.0 million through December 15, 2026 from Hercules ("Tranche 4"). The lenders have no obligation to fund any amounts under Tranche 4 as funding is conditioned on approval by the lenders' investment committee.

The 2024 Term Loan is collateralized by substantially all the Company's assets. In addition to other covenants, the 2024 Term Loan contains affirmative covenants as well as certain financial covenants, including a minimum cash coverage requirement of 45% of the outstanding principal of the term loan. The Company was in compliance with the minimum cash coverage covenant as of September 30, 2024, but the Company projects that it may not maintain its minimum cash coverage requirement within the next 12 months (see the Company's going concern assessment in Note 1, *Description of the business*). As such, the term loan is presented as a current liability as of September 30, 2024.

The Term Loans bear both cash interest and paid-in-kind interest ("PIK"). The cash interest is due on the first business day of each month ("Payment Date") and will be equal to the WSJ prime rate ("prime rate") plus 1.45% (floored at 9.95%). The PIK interest is fixed at 2.45% and is to be capitalized and added to the outstanding principal on each Payment Date. Unless prepaid by the Company at their discretion, subject to certain prepayment penalties and conditions, the Term Loans are repayable in monthly interest-only payments until April 1, 2027, or April 1, 2028, if the Company has achieved, no later than December 31, 2026, certain financial metrics (the "Performance Milestone"). After the expiration of the interest-only payment period, the Term Loans are repayable in equal monthly payments of principal and accrued interest until maturity. The Term Loans will mature on April 1, 2029.

The Company also issued warrants under the Warrant Agreement for the right to purchase shares of the Company's common stock to Hercules, with the number of shares to be based on the amounts borrowed under the LSA (the "Warrants"). The Warrants are exercisable for a number of shares of common stock equal to the quotient of (i.) 5% times the aggregate original principal of amounts drawn under the LSA divided by (ii.) the exercise price of $1.45 per share.

Upon issuance, during the period ended March 31, 2024, the Warrants were recorded at their relative fair value using the Black-Scholes option-pricing model and the following assumptions: no dividend yield, expected volatility of 81.1%, risk free rate of 4.3%, and expected term of 7 years, equal to the life of the warrant. The relative fair value allocated to the initial warrants was $2.7 million, which was classified as additional-paid-in-capital and recorded as a debt discount which will be amortized, together with debt issuance costs, to interest expense using the effective interest method over the life of the loan at an effective interest rate of 15.7%.

In connection with the Third Amendment, the Company agreed to amend the exercise price of the Warrants to purchase shares of the Company's common stock from $1.45 per share to the lesser of the volume weighted average price ("VWAP") of the Company's common stock for the ten-day period preceding August 13, 2024 (determined to be $1.03), and the price per share of the Company's first financing event within six months of the Third Amendment date, or February 13, 2025. As the modification only impacts the exercise price, the amendment does not impact the number of shares the lenders may purchase pursuant to the Warrants. As of September 30, 2024, the Company had issued 2.6 million warrants associated with the Initial Loan ("Initial Warrants") to purchase common stock and a contractual life of 7 years from the Effective Date.

As a result of the Third Amendment, the price adjustment feature on the warrant exercise price is affected by variables that are extraneous to the pricing of a fixed-for-fixed option or forward contract on common shares, and therefore, the Initial Warrants were reclassified from additional paid-in-capital within stockholders' equity to other non-current liabilities on the Condensed Consolidated Balance Sheet (see Note 4, *Fair value measurements*). Upon modification of the warrants at the Third Amendment date, the Company recorded the incremental increase in fair value of $0.2 million as debt discount which will be amortized over the life of the Initial Loan at an effective interest rate of 16%. The fair value of the Initial Warrants was then remeasured to $1.0 million at the reporting date of September 30, 2024, resulting in a gain in the amount of $1.1 million recorded within other income, net, on the Condensed Consolidated Statement of Operations.

For the three and nine months ended September 30, 2024, the Company recorded approximately $2.8 million and $6.1 million in interest expense associated with the Term Loans, respectively, inclusive of amounts related to the debt discount.

9. Leases

The Company leases certain office and laboratory space, primarily located in Somerville, Massachusetts. Additionally, the Company has embedded leases through its agreements with CMOs and a contract testing organization ("CTO") in both the United States and internationally. Except as described below, there have been no material changes in lease obligations from those disclosed in Note 11 to the consolidated financial statements included in the Company's 2023 Annual Report on Form 10-K.

Embedded leases

Periodically, throughout the three and nine months ended September 30, 2024, the Company amended several of its embedded contract manufacturing leases, some of which were accounted for as lease modifications under ASC 842. The lease modifications primarily relate to the execution of new statements of work with the vendors or the extension of contractual terms.

As it relates to embedded leases related to drug product manufacturing and quality testing, due to lease modification adjustments and amortization, the Company increased its finance lease right-of-use assets in the amount of $10.3 million during the nine months ended September 30, 2024.

As it relates to embedded leases related to drug substance manufacturing, due to lease modification adjustments and amortization, the Company decreased its finance lease right-of-use assets in the amount of $12.1 million during the nine months ended September 30, 2024.

The following paragraphs describe significant lease modifications to the Company's embedded drug substance manufacturing leases that were executed during the three months ended September 30, 2024.

In August 2024, the Company provided its lessor with 12-months' written notice of its intent to terminate one of its embedded leases effective August 31, 2025. The termination, which relates to an embedded drug vector manufacturing lease, resulted in the reduction to the lease term and the corresponding reduction in fixed lease payments.

In September 2024, the Company extended one of its embedded lease for the manufacturing of vector for five years, resulting in a lease term extending through September 2029. The extension resulted in additional fixed lease payments.

Summary of all lease costs recognized under ASC 842

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating and finance leases for the three months and nine months ended September 30, 2024 and 2023 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
		(As Restated)		(As Restated)
Finance leases				
Interest expense	$ 2,364	$ 4,311	$ 9,421	$ 12,327
Amortization expense	14,193	6,459	43,896	16,903
Total fixed finance lease cost	$ 16,557	$ 10,770	$ 53,317	$ 29,230
Operating leases				
Fixed lease cost	$ 9,486	$ 11,470	$ 28,459	$ 34,411
Total fixed operating lease cost	$ 9,486	$ 11,470	$ 28,459	$ 34,411
Variable lease cost	9,129	4,186	22,128	16,140
Short-term lease cost	98	43	265	140
Total lease cost	$ 35,270	$ 26,469	$ 104,169	$ 79,921
Operating sublease income	$ 10,219	$ 9,742	$ 30,825	$ 30,223
Cash paid in the measurement of lease liabilities				
Operating cash flows used for operating leases			$ 15,323	$ 18,686
Operating cash flows used for finance leases			$ 1,411	$ 9,125
Financing cash flows for finance leases			$ 69,576	$ 40,299

Supplemental balance sheet information related to leases was as follows:

	As of September 30, 2024	As of September 30, 2023
Weighted average remaining lease term - finance leases	1.92 years	1.72 years
Weighted average discount rate - finance leases	12.56 %	14.49 %
Weighted average remaining lease term - operating leases	6.32 years	7.21 years
Weighted average discount rate - operating leases	6.97 %	7.02 %

As of September 30, 2024, future minimum commitments under ASC 842 under the Company's leases were as follows (in thousands):

	Operating Leases	Financing Leases
Remaining Lease Payments		
Remainder of 2024	$ 9,151	$ 57,718
2025	37,084	43,068
2026	35,719	2,738
2027	36,742	1,673
2028	37,795	685
2029 and thereafter	81,986	—
Total	$ 238,477	$ 105,882
Less: Imputed Interest	(45,910)	(4,036)
Present Value of Lease Liabilities	$ 192,567	$ 101,846

10. Commitments and contingencies

Lease commitments

The Company leases certain office and laboratory space and has embedded leases at CMOs and a CTO. As of September 30, 2024, the Company has commitments arising from forward starting leases that have not yet commenced related to an embedded equipment lease with a CMO. These forward starting leases are expected to commence in the fourth quarter of 2024 and the first quarter of 2025 with an initial term of approximately three and four years, respectively. Fixed commitments under these contracts approximate $60.5 million. The following table presents the non-cancelable contractual obligations arising from this arrangement as of September 30, 2024 (in thousands):

	Future commitment
Remainder of 2024	$ 294
2025	15,047
2026	18,733
2027	18,733
2028	7,668
2029 and thereafter	—
Total purchase commitments	$ 60,475

Litigation

From time to time, the Company is party to various claims and complaints arising in the ordinary course of business, including securities class action litigation and intellectual property litigation. The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company’s business partners. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is generally unlimited. Accruals for loss contingencies are recognized when a loss is probable, and the amount of such loss can be reasonably estimated. The Company has not accrued for a loss for any matter as a loss is not probable and a loss, or a range of loss, is not reasonably estimable.

On April 27, 2023, San Rocco Therapeutics, LLC ("SRT") filed another complaint against the Company (as well as against Mr. Nick Leschly, Mr. Mitchell Finer, Mr. Philip Reilly, Third Rock Ventures LLC, and 2Seventy Bio, Inc.) in the United States District Court for the District of Massachusetts. This complaint alleges civil violations of the Federal Racketeer Influenced and Corrupt Organizations Act, violations of Mass. Gen. Laws ch. 93A, § 11, and fraudulent inducement of SRT into a release provision in a November 2020 confidential settlement agreement we executed with, inter alia, SRT. The allegations relate to the Company's use of the BB305 lentiviral vector, including in connection with the beti-cel program, and SRT seeks declaratory relief and money damages. On July 3, 2023, the Company (in conjunction with the other defendants) moved to dismiss all claims with prejudice brought by SRT in its Complaint for failure to state a claim upon which relief may

be granted. On August 7, 2023, SRT filed an amended complaint, adding Craig Thompson as a defendant, and adding additional claims of alleged antitrust violations under federal and state law. The case is now captioned San Rocco Therapeutics, LLC v. Nick Leschly, Mitchell Finer, Philip Reilly, Craig Thompson, Third Rock Ventures LLC, bluebird bio, Inc. and 2Seventy Bio, Inc., C.A. No. 1:23-cv-10919-ADB. On September 18, 2023, the Company (in conjunction with the non-Thompson defendants), moved to dismiss with prejudice once again. SRT filed an opposition to that motion on October 12, 2023. On October 24, 2023, the Company filed a motion for leave to file a reply brief, which was granted on October 30, 2023. SRT filed a sur-reply brief on November 2, 2023. On September 30, 2024, the court issued a Memorandum and Opinion granting the motion to dismiss filed by the non-Thompson defendants as well as a motion to dismiss filed by Mr. Thompson. On October 2, 2024, the court issued an Order dismissing SRT's amended complaint, and closing the case. SRT's time to file any notice of appeal has expired, rendering the court's ruling a final non-appealable decision.

On April 15, 2024, SRT filed a Demand for Arbitration with the American Arbitration Association, accusing the Company of breaching a November 2020 confidential settlement agreement by initiating a proceeding before the Patent Trial & Appeal Board (PTAB) of the United States Patent & Trademark Office in October 2022, asserting invalidity of two patents licensed to SRT. SRT seeks reimbursement of its costs and fees, including attorney's fees, incurred in the PTAB proceeding, totaling approximately $1.5 million. On August 26, 2024, the parties submitted their respective opening dispositive briefs. The Company filed its response on September 24, 2024, when SRT also filed its opposition to our dispositive motion. The parties' respective replies were due on October 8, 2024. On October 29, 2024, the arbitrator granted the Company's early dispositive motion and dismissed SRT's claim in its entirety.

On March 28, 2024, a class action lawsuit captioned Garry Gill v. bluebird bio, Inc. et al., Case No. 1:24-cv-10803-PBS (the "*Gill* Action"), was filed against the Company in the United States District Court for the District of Massachusetts. An amended complaint was filed on August 15, 2024. The amended complaint purports to assert claims against the Company and certain of its current and former officers pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, on behalf of a putative class of investors who purchased or otherwise acquired the Company's shares between April 24, 2023 and December 8, 2023 (the "class period"). Plaintiff seeks to recover damages allegedly caused by purported misstatements and omissions regarding (i) whether the Company could obtain FDA approval for the lovo-cel BLA without a black box warning for hematologic malignancies; and (ii) whether the Company would be granted a priority review voucher by the FDA in connection with the BLA, which it could sell in order to strengthen its financial position. The amended complaint claims these alleged statements and omissions operated to artificially inflate the price paid for the Company's common stock during the class period. On September 2, 2024, the Court entered the parties' stipulated schedule for briefing a motion to dismiss the amended complaint. The Company's opening brief in support of a motion to dismiss was filed on October 11, 2024; the opposition brief is due December 5, 2024; and a reply brief in further support of a motion to dismiss is due December 20, 2024. The Company intends to vigorously defend against the claims in this action.

Apart from the above, there have been no other material changes in claims and complaints from those disclosed in Note 12 to the consolidated financial statements included in the Company's 2023 Annual Report on Form 10-K.

The Company also indemnifies each of its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and by-laws. The term of the indemnification period lasts as long as such officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations.

11. Equity

On January 18, 2023, the Company entered into an underwriting agreement (the "January Underwriting Agreement") with Goldman and J.P. Morgan Securities LLC in connection with the public offering, issuance, and sale by the Company of 20.0 million shares of the Company's common stock at a public offering price of $6.00 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 and a related prospectus supplement filed with the Securities and Exchange Commission. Under the terms of the January Underwriting Agreement, the Company also granted the underwriters an option exercisable for 30 days to purchase up to an additional 3.0 million shares of common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. The offering closed on January 23, 2023. The Company received aggregate net proceeds of $130.5 million.

In August 2023, the Company entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") to sell shares of the Company's common stock up to $125.0 million, from time to time, through an "at the market" equity offering program under which Jefferies will act as sales agent. As of September 30, 2024, the Company has made no sales pursuant to the Sales Agreement.

On December 19, 2023, the Company entered into an underwriting agreement (the "December Underwriting Agreement") with Goldman and J.P. Morgan Securities LLC, in connection with the public offering, issuance, and sale by the Company of 83.3 million shares of the Company's common stock at a public offering price of $1.50 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 and a related prospectus supplement filed with the Securities and Exchange Commission. Under the terms of the December Underwriting Agreement, the Company also granted the underwriters an option exercisable for 30 days to purchase up to an additional 12.5 million shares of common stock at the public offering price, less underwriting discounts and commissions, which option was not exercised. The offering closed on December 22, 2023. The Company received aggregate net proceeds of $118.1 million.

12. Stock-based compensation

In June 2023, the Company's stockholders approved the bluebird bio, Inc. 2023 Incentive Award Plan (the "2023 Plan"), which replaced the 2013 Stock Option and Incentive Plan ("2013 Plan"). Following approval of the 2023 Plan, no further awards will be granted under the 2013 Plan. The Company also maintains the 2021 Inducement Plan (the "2021 Plan"), pursuant to which equity-based awards may be granted to new hires. As of September 30, 2024, the total number of shares of common stock available for issuance under the 2023 Plan was approximately 1.5 million, and the total number of shares of common stock available for issuance under the 2021 Plan was approximately 0.6 million.

Stock-based compensation expense

The Company recognized stock-based compensation expense totaling $2.7 million and $4.9 million during the three months ended September 30, 2024 and 2023, respectively. The Company recognized stock-based compensation expense totaling $9.7 million and $16.0 million during the nine months ended September 30, 2024 and 2023, respectively. Stock-based compensation expense recognized by award type is included within the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
Stock options	$ 920	$ 1,758	$ 3,343	$ 5,19
Restricted stock units	1,755	2,916	6,217	10,55
Employee stock purchase plan and other	26	194	109	26
	$ 2,701	$ 4,868	$ 9,669	$ 16,0

Stock-based compensation expense by classification included within the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
Cost of product revenue	102	342	882	435
Selling, general and administrative	1,650	2,461	5,783	7,503
Research and development	681	2,065	2,736	8,075
Restructuring Expenses	268	—	268	—
	$ 2,701	$ 4,868	$ 9,669	$ 16,013

During the nine months ended September 30, 2024 and 2023, the Company had $1.0 million and $1.4 million of stock compensation expense that was capitalized into inventory.

Stock options

The following table summarizes the stock option activity under the Company's equity award plans excluding awards held by employees of 2seventy bio:

	Shares (in thousands)	Weighted-average exercise price per share
Outstanding at December 31, 2023	4,227	$ 14.16
Granted	3,010	$ 1.47
Exercised	—	$ —
Canceled, forfeited, or expired	(905)	$ 10.52
Outstanding at September 30, 2024	6,332	$ 8.66
Exercisable at September 30, 2024	2,290	$ 18.54
Vested and expected to vest at September 30, 2024	6,332	$ 8.66

During the nine months ended September 30, 2024, no stock options were exercised.

Restricted stock units

The following table summarizes the restricted stock unit activity under the Company's equity award plans excluding awards held by employees of 2seventy bio:

	Shares (in thousands)	Weighted-average grant date fair value
Unvested at December 31, 2023	4,207	$ 6.08
Granted	3,357	$ 1.23
Vested	(1,083)	$ 7.08
Forfeited	(907)	$ 4.05
Unvested at September 30, 2024	5,574	$ 3.29

Employee stock purchase plan

In June 2013, the Company's board of directors adopted its 2013 Employee Stock Purchase Plan ("2013 ESPP"), which authorized the initial issuance of up to a total of 0.2 million shares of the Company's common stock to participating employees. In June 2021, the Company amended the 2013 ESPP to authorize an additional 1.4 million shares of the Company's common stock available to participating employees. During each of the nine months ended September 30, 2024 and 2023, 0.1 million shares and 0.1 million shares, respectively, of common stock were issued under the 2013 ESPP.

13. Income taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. The tax benefit recognized during the three and nine months ended September 30, 2024 was $0.1 million and $0.0 million, respectively, due to the full valuation allowance.

14. Net loss per share

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	For the three and nine months ended September 30,	
	2024	2023
Outstanding stock options[(1)]	7,473	5,875
Restricted stock units[(1)]	5,574	4,194
Warrants	2,586	—
ESPP shares and other	61	—
	15,694	10,069

[(1)] Outstanding stock options and restricted stock units include awards outstanding to employees of 2seventy bio.

Net loss per share for the three and nine months ended September 30, 2024 was $0.31 and $1.10, respectively. Net loss per share for the three and nine months ended September 30, 2023 was $0.80 and $1.23, respectively.

15. Reduction in workforce

In September 2024, the Company's board of directors approved a restructuring action (the "Restructuring") following a comprehensive review of the Company's operations. The Restructuring includes a reduction of the Company's workforce by 94 employees, or approximately 25% of employees.

As a result of the Restructuring, the Company incurred aggregate charges of $2.8 million in restructuring costs, $2.5 million of which relates to cash expenditures for severance and employee termination-related costs to be paid out over multiple weeks through the first quarter of 2025, with the majority to be paid out by December 31, 2024, and $0.3 million in stock-based compensation expense associated with accelerated vesting of restricted stock units.

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the nine months ended September 30, 2024:

	For the nine months ended September 30,
	2024
Cash expenditure charges	$ 2,543
Amount paid through September 30, 2024	—
Amounts accrued at September 30, 2024	$ 2,543

16. Restatement of Previously Issued Financial Statements

As further described below, as well as in Note 2 - Basis of Presentation, the Company identified several prior period misstatements that impacted its unaudited quarterly condensed consolidated financial statements for the three and nine months ended September 30, 2023. Such restated and unaudited quarterly financial data and the related impacted amounts were presented in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

As part of the restatement, the Company recorded adjustments to correct the material misstatements related to accounting for embedded leases and other immaterial errors.

The following tables present the restated unaudited Condensed Consolidated Financial Information for the three and nine months ended September 30, 2023.

Consolidated Statements of Operations and Comprehensive Loss

	For the three months ended September 30, 2023			
	As Previously Reported	Adjustments to Embedded Leases	Other Adjustments	As Restated
Revenue:				
Product revenue, net	$ 12,281	$ —	$ —	$ 12,281
Other revenue	111	—	—	111
Total revenues	12,392	—	—	12,392
Cost of product revenue	10,955	(1,829)	—	9,126
Gross margin	1,437	1,829	—	3,266
Operating expenses:				
Selling, general and administrative	40,703	68	—	40,771
Research and development	45,463	14,757	(1,719)	58,501
Total operating expenses	86,166	14,825	(1,719)	99,272
Loss from operations	(84,729)	(12,996)	1,719	(96,006)
Interest income	2,454	—	—	2,454
Interest expense	—	(4,311)	—	(4,311)
Other income, net	10,544	168	(81)	10,631
Loss before income taxes	(71,731)	(17,139)	1,638	(87,232)
Income tax (expense) benefit	—	—	—	—
Net loss	(71,731)	(17,139)	1,638	(87,232)
Net loss per share - basic (1)	$ (0.66)	$ (0.16)	$ 0.02	$ (0.80)
Net loss per share - diluted (1)	$ (0.66)	$ (0.16)	$ 0.02	$ (0.80)
Weighted-average number of common shares used in computing net loss per share - basic:	109,098	—	—	109,098
Weighted-average number of common shares used in computing net loss per share - diluted:	109,098	—	—	109,098
Other comprehensive income (loss):				
Other comprehensive income (loss), net of tax (benefit) expense of $0.0 million for the three months ended September 30, 2023	137	—	—	137
Total other comprehensive income (loss)	137	—	—	137
Comprehensive loss	$ (71,594)	$ (17,139)	$ 1,638	$ (87,095)

(1) Due to differences in rounding to the nearest cent per basic or diluted share, totals may not equal the sum of the line items.

	For the nine months ended September 30, 2023			
	As Previously Reported	Adjustments to Embedded Leases	Other Adjustments	As Restated
Revenue:				
Product revenue, net	$ 21,414	$ —	$ —	$ 21,414
Other revenue	249	—	—	249
Total revenues	21,663	—	—	21,663
Cost of product revenue	23,895	(2,560)	—	21,335
Gross margin	(2,232)	2,560	—	328
Operating expenses:				
Selling, general and administrative	118,406	294	—	118,700
Research and development	133,881	52	(2,397)	131,536
Total operating expenses	252,287	346	(2,397)	250,236
Gain from sale of priority review voucher, net	92,930	—	—	92,930
Loss from operations	(161,589)	2,214	2,397	(156,978)
Interest income	7,961	—	—	7,961
Interest expense	(3)	(12,328)	—	(12,331)
Other income, net	30,152	106	(81)	30,177
Loss before income taxes	(123,479)	(10,008)	2,316	(131,171)
Income tax (expense) benefit	80	—	—	80
Net loss	(123,399)	(10,008)	2,316	(131,091)
Net loss per share - basic	$ (1.15)	$ (0.09)	$ 0.02	$ (1.23)
Net loss per share - diluted	$ (1.15)	$ (0.09)	$ 0.02	$ (1.23)
Weighted-average number of common shares used in computing net loss per share - basic:	106,924	—	—	106,924
Weighted-average number of common shares used in computing net loss per share - diluted:	106,924	—	—	106,924
Other comprehensive income (loss):				
Other comprehensive income (loss), net of tax (benefit) expense of $0.0 million for the nine months ended September 30, 2023	1,843	—	—	1,843
Total other comprehensive income (loss)	1,843	—	—	1,843
Comprehensive loss	$ (121,556)	$ (10,008)	$ 2,316	$ (129,248)

(1) Due to differences in rounding to the nearest cent per basic or diluted share, totals may not equal the sum of the line items.

Statements of Changes in Stockholders' Equity:

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
As Previously Reported						
Balances at December 31, 2022	82,923	$ 830	$ 4,186,086	$ (4,070)	$ (3,986,503)	$ 196,343
Vesting of restricted stock	382	3	(198)	—	—	(195)
Exercise of stock options	3	—	7	—	—	7
Purchase of shares under ESPP	62	1	226	—	—	227
Issuance of common stock for private equity placement	23,000	230	130,061	—	—	130,291
Stock-based compensation	—	—	5,843	—	—	5,843
Other comprehensive income (loss)	—	—	—	984	—	984
Net income (loss)	—	—	—	—	21,240	21,240
Balances at March 31, 2023	106,370	$ 1,064	$ 4,322,025	$ (3,086)	$ (3,965,263)	$ 354,740
Adjustments to Embedded Leases						
Balances at December 31, 2022	$ —	$ —	$ —	$ —	$ (59,700)	$ (59,700)
Vesting of restricted stock	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—
Purchase of shares under ESPP	—	—	—	—	—	—
Issuance of common stock for private equity placement	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—
Net income (loss)	—	—	—	—	(2,351)	(2,351)
Balances at March 31, 2023	—	$ —	$ —	$ —	$ (62,051)	$ (62,051)
Other Adjustments						
Balances at December 31, 2022	—	—	(98)	—	(2,212)	(2,310)
Vesting of restricted stock	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—
Purchase of shares under ESPP	—	—	—	—	—	—
Issuance of common stock for private equity placement	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—
Net income (loss)	—	—	—	—	41	41
Balances at March 31, 2023	—	$ —	$ (98)	$ —	$ (2,171)	$ (2,269)
As Restated						
Balances at December 31, 2022	82,923	830	4,185,988	(4,070)	(4,048,415)	134,333
Vesting of restricted stock	382	3	(198)	—	—	(195)
Exercise of stock options	3	—	7	—	—	7
Purchase of shares under ESPP	62	1	226	—	—	227
Issuance of common stock for private equity placement	23,000	230	130,061	—	—	130,291
Stock-based compensation	—	—	5,843	—	—	5,843
Other comprehensive income (loss)	—	—	—	984	—	984
Net income (loss)	—	—	—	—	18,930	18,930
Balances at March 31, 2023	106,370	$ 1,064	$ 4,321,927	$ (3,086)	$ (4,029,485)	$ 290,420

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
As Previously Reported						
Balances at March 31, 2023	106,370	$ 1,064	$ 4,322,025	$ (3,086)	$ (3,965,263)	$ 354,740
Vesting of restricted stock	65	1	(1)	—	—	—
Exercise of stock options	19	—	77	—	—	77
Purchase of shares under ESPP	—	—	—	—	—	—
Issuance of common stock for private equity placement	—	—	—	—	—	—
Stock-based compensation	—	—	6,388	—	—	6,388
Other comprehensive income (loss)	—	—	—	722	—	722
Net income (loss)	—	—	—	—	(72,908)	(72,908)
Balances at June 30, 2023	106,454	$ 1,065	$ 4,328,489	$ (2,364)	$ (4,038,171)	$ 289,019
Adjustments to Embedded Leases						
Balances at March 31, 2023	$ —	$ —	$ —	$ —	$ (62,051)	$ (62,051)
Vesting of restricted stock	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—
Purchase of shares under ESPP	—	—	—	—	—	—
Issuance of common stock for private equity placement	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—
Net income (loss)	—	—	—	—	9,482	9,482
Balances at June 30, 2023	—	$ —	$ —	$ —	$ (52,569)	$ (52,569)
Other Adjustments						
Balances at March 31, 2023	—	—	(98)	—	(2,171)	(2,269)
Vesting of restricted stock	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—
Purchase of shares under ESPP	—	—	—	—	—	—
Issuance of common stock for private equity placement	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—
Other comprehensive income (loss)	—	—	—	—	—	—
Net income (loss)	—	—	—	—	637	637
Balances at June 30, 2023	—	$ —	$ (98)	$ —	$ (1,534)	$ (1,632)
As Restated						
Balances at March 31, 2023	106,370	1,064	4,321,927	(3,086)	(4,029,485)	290,420
Vesting of restricted stock	65	1	(1)	—	—	—
Exercise of stock options	19	—	77	—	—	77
Purchase of shares under ESPP	—	—	—	—	—	—
Issuance of common stock for private equity placement	—	—	—	—	—	—
Stock-based compensation	—	—	6,388	—	—	6,388
Other comprehensive income (loss)	—	—	—	722	—	722
Net income (loss)	—	—	—	—	(62,789)	(62,789)
Balances at June 30, 2023	106,454	$ 1,065	$ 4,328,391	$ (2,364)	$ (4,092,274)	$ 234,818

	Common stock			Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares		Amount				
As previously reported							
Balances at June 30, 2023	106,454		$ 1,065	$ 4,328,489	$ (2,364)	$ (4,038,171)	$ 289,019
Vesting of restricted stock	566		6	(6)	—	—	—
Exercise of stock options	2		—	8	—	—	8
Issuance of common stock	—		—	(50)	—	—	(50)
Stock-based compensation expense	—		—	5,153	—	—	5,153
Other comprehensive income (loss)	—		—	—	137	—	137
Net income (loss)	—		—	—	—	(71,731)	(71,731)
Balances at September 30, 2023	107,022	107,022	$ 1,071	$ 4,333,594	$ (2,227)	$ (4,109,902)	$ 222,536
Balances at							
Adjustments to Leases							
Balances at June 30, 2023	—		—	—	—	(52,569)	(52,569)
Vesting of restricted stock	—		—	—	—	—	—
Exercise of stock options	—		—	—	—	—	—
Issuance of common stock	—		—	—	—	—	—
Stock-based compensation expense	—		—	—	—	—	—
Other comprehensive income (loss)	—		—	—	—	—	—
Net income (loss)	—		—	—	—	(17,139)	(17,139)
Balances at September 30, 2023	—		$ —	$ —	$ —	$ (69,708)	$ (69,708)
Balances at							
Other Adjustments							
Balances at June 30, 2023	—		—	(98)	—	(1,534)	(1,632)
Vesting of restricted stock	—		—	—	—	—	—
Exercise of stock options	—		—	—	—	—	—
Issuance of common stock	—		—	—	—	—	—
Stock-based compensation expense	—		—	—	—	—	—
Other comprehensive income (loss)	—		—	—	—	—	—
Net income (loss)	—		—	—	—	1,638	1,638
Balances at September 30, 2023	—		$ —	$ (98)	$ —	$ 104	$ 6
Balances at							
As Restated							
Balances at June 30, 2023	106,454		1,065	4,328,391	(2,364)	(4,092,274)	234,818
Vesting of restricted stock	566		6	(6)	—	—	—
Exercise of stock options	2		—	8	—	—	8
Issuance of common stock	—		—	(50)	—	—	(50)
Stock-based compensation expense	—		—	5,153	—	—	5,153
Other comprehensive income (loss)	—		—	—	137	—	137
Net income (loss)	—		—	—	—	(87,232)	(87,232)
Balances at September 30, 2023	107,022		$ 1,071	$ 4,333,496	$ (2,227)	$ (4,179,506)	$ 152,834

Consolidated Statement of Cash Flows

	For the nine months ended September 30, 2023			
	As Previously Reported	Adjustments to Leases	Other Adjustments	As Restated
Cash flows from operating activities:				
Net loss	$ (123,399)	$ (10,008)	$ 2,316	$ (131,091)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	3,124	16,648	(112)	19,660
Stock-based compensation expense	16,013	—	—	16,013
Noncash research and development expense (finance lease)	—	22,223	—	22,223
Noncash operating lease expense	—	23,965	—	23,965
Gain from sale of priority review voucher	(92,930)	—	—	(92,930)
Excess inventory reserve	5,333	1,554	2,315	9,202
Other non-cash items	19	—	81	100
(Gain) loss on foreign currency exchange rates	—	(1,062)	—	(1,062)
Changes in operating assets and liabilities:				
Accounts receivable	(23,000)	—	8,400	(14,600)
Prepaid expenses and other assets	(523)	2,640	—	2,117
Inventory	(24,931)	1,651	(2,917)	(26,197)
Operating right of use assets	40,101	(40,101)	—	—
Accounts payable	(5,787)	7,183	316	1,712
Accrued expenses and other liabilities	7,125	583	(1,999)	5,709
Accrued interest payable under finance lease	—	3,203	—	3,203
Operating lease liabilities	(30,506)	11,820	—	(18,686)
Deferred revenue	8,152	—	(8,400)	(248)
Net cash (used in) provided by operating activities	(221,209)	40,299	—	(180,910)
Cash flows from investing activities:				
Purchase of property, plant and equipment	(2,975)	—	—	(2,975)
Purchases of marketable securities	(43,297)	—	—	(43,297)
Proceeds from maturities of marketable securities	99,521	—	—	99,521
Proceeds from sales of marketable securities	5,853	—	—	5,853
Purchase of intangible assets	(868)	—	—	(868)
Proceeds from sale of priority review voucher	92,930	—	—	92,930
Net cash provided by investing activities	151,164	—	—	151,164
Cash flows from financing activities:				
Proceeds from exercise of stock options and ESPP contributions	93	—	—	93
Proceeds from vesting of restricted stock	(196)	—	—	(196)
Principal payments on finance lease	—	(40,299)	—	(40,299)
Proceeds from the secondary public offering, net of issuance costs	130,072	—	—	130,072
Net cash (used in) provided by financing activities	129,969	(40,299)	—	89,670
Increase in cash, cash equivalents and restricted cash	59,924	—	—	59,924
Cash, cash equivalents and restricted cash at beginning of year	158,445	—	—	158,445
Cash, cash equivalents and restricted cash at end of year	$ 218,369	$ —	$ —	$ 218,369
Reconciliation of cash, cash equivalents and restricted cash:				
Cash and cash equivalents	$ 165,347	$ —	$ —	$ 165,347
Restricted cash included in receivables and other current assets	8,885	—	—	8,885
Restricted cash included in restricted cash and other non-current assets	44,137	—	—	44,137
Total cash, cash equivalents and restricted cash	$ 218,369	$ —	$ —	$ 218,369
Supplemental cash flow disclosures:				
Right-of-use assets obtained in exchange for operating lease liabilities	44,819	(45,527)	—	(708)
Purchases of property, plant and equipment included in accounts payable and accrued expenses	941	—	—	941
Offering expenses included in accounts payable and accrued expenses	248	—	—	248
Right-of-use assets obtained in exchange for finance lease liabilities	—	21,508	—	21,508
Increase (reduction) of right of use asset and associated operating lease liability due to lease reassessment	8,003	(8,003)	—	—

Cash paid during the period for income taxes	5	—	—	5

17. Subsequent events

On November 6, 2024, the Company's stockholders approved a proposal to amend and restate the Company's 2023 Plan to (i) increase the aggregate number of shares authorized for issuance under the 2023 Plan by 15,000,000 shares to 20,200,000 shares, (ii) include minimum vesting requirements for certain awards granted thereunder, (iii) clarify the treatment of performance-based awards in the event of a change in control and (iv) extend the date following which incentive stock options can no longer be granted to September 12, 2034, the tenth anniversary of the date the Company's board of directors approved the amended and restated plan (such amended and restated plan, the "Amended 2023 Plan").

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission, or the SEC, on September 13, 2024 (the "2023 Annual Report on Form 10-K").

The Company restated the consolidated financial statements for the year ended December 31, 2022 presented in its 2023 Annual Report on Form 10-K. In addition, the Company restated its unaudited quarterly financial data for the period ended March 31, 2023. Such restated unaudited quarterly financial data and related impacted amounts were presented in the Company's 2023 Annual Report on Form 10-K. The following discussion gives effect to the restatement of our unaudited interim consolidated financial statements for the three and nine months ended September 30, 2023. See the related discussion in Note 2, "Basis of presentation, principles of consolidation and significant accounting policies" of the Notes to Unaudited Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "may," "expect," "anticipate," "estimate," "intend," "plan," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biotechnology company committed to researching, developing, and commercializing potentially curative gene therapies for severe genetic diseases based on our proprietary lentiviral vector ("LVV") gene addition platform. We currently market three gene therapies in the U.S.: ZYNTEGLO™ (betibeglogene autotemcel, also known as beti-cel), SKYSONA™ (elivaldogene autotemcel, also known as eli-cel), which were approved by the U.S. Food and Drug Administration (the "FDA") in 2022, and LYFGENIA™ (lovotibeglogene autotemcel, also known as lovo-cel), which received approval from the FDA in December 2023.

The FDA approved ZYNTEGLO for the treatment of adult and pediatric patients with ß-thalassemia who require regular red blood cell transfusions on August 17, 2022. The FDA granted accelerated approval of SKYSONA to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy ("CALD") on September 16, 2022. On December 8, 2023, LYFGENIA, was approved by the FDA for the treatment of patients 12 years of age or older with sickle cell disease ("SCD") and a history of vaso-occlusive-events.

We are focusing our development and commercialization efforts in the U.S. market. We have obtained the withdrawal of the marketing authorization for beti-cel and eli-cel in the European Union, which became effective in 2022 and 2021, respectively. We are continuing the long-term follow-up of patients previously enrolled within the clinical trial programs in Europe as planned but do not intend to initiate any new clinical trials in Europe for β-thalassemia, CALD or SCD.

Since our inception in 1992, we have devoted substantially all of our resources to our development and commercialization efforts relating to our products and product candidates, including activities to manufacture products and product candidates in compliance with good manufacturing practices (“GMP”) to conduct clinical studies of our product candidates, to provide selling, general and administrative support for these operations, to market, commercially manufacture and distribute our approved products and to protect our intellectual property. We have funded our operations primarily through the sale of common stock in our public offerings, issuance of warrants, the sale of two Rare Pediatric Disease Priority Review Vouchers ("PRVs"), debt financing agreements and through collaborations.

In August 2022 and September 2022 we received the two PRVs under an FDA program intended to encourage the development of treatments for rare pediatric diseases. In the fourth quarter of 2022, we sold our first PRV for aggregate net proceeds of $102.0 million. In the first quarter of 2023, we sold our second PRV for aggregate net proceeds of $92.9 million, inclusive of additional legal costs incurred.

In the first quarter of 2023, we sold 23.0 million shares of common stock (inclusive of shares sold pursuant to an option to the underwriters in connection with the offering) through an underwritten public offering at a price of $6.00 per share for aggregate net proceeds of $130.5 million, inclusive of additional offering costs incurred. In the fourth quarter of 2023, we sold 83.3 million shares of common stock through an underwritten public offering at a price of $1.50 per share for aggregate net proceeds of $118.1 million, after deducting for offering costs.

In March 2024, we entered into a five-year term loan facility agreement with Hercules Capital, Inc. to secure debt financing for up to $175.0 million, available in four tranches, based on amendments executed through August 2024.

As of September 30, 2024, we had cash and cash equivalents of approximately $70.7 million. Absent the sale of our PRVs, we have never been profitable and have incurred net losses in each year since inception. Our net loss was $60.8 million and $212.0 million for the three and nine months ended September 30, 2024, respectively, and our accumulated deficit was $4.5 billion as of September 30, 2024. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, and cost of product revenue. We expect to continue to incur significant expenses and operating losses for the foreseeable future, if and as we:

- fund activities related to the commercialization of ZYNTEGLO, SKYSONA, and LYFGENIA in the United States;
- scale our manufacturing capabilities in support of the commercialization of ZYNTEGLO, SKYSONA, and LYFGENIA;
- conduct clinical studies; and
- continue research and development-related activities for severe genetic diseases.

Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. We may not be able to generate substantial revenue from the sale of our products, and we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Until we reach profitability, if ever, we expect to continue to seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our business.

Business update

In September 2024, we announced that we were initiating a restructuring action (the "Restructuring") following a comprehensive review of our operations. The Restructuring is anticipated to reduce our cash operating expenses by approximately 20% when fully realized in the third quarter of 2025, compared to the prior reporting period. The Restructuring includes a reduction of our workforce by approximately 25% of employees during the fourth quarter of 2024. Refer to Note 15, *Reduction in workforce* to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information on the Restructuring.

We had cash and cash equivalents of approximately $70.7 million as of September 30, 2024. We will continue to generate operating losses and negative operating cash flows for the foreseeable future as we continue to commercialize ZYNTEGLO,

SKYSONA and LYFGENIA and we will require the need for additional funding to support our planned operations before becoming profitable.

We are engaging collaboratively with Hercules as we work to secure adequate cash runway to obtain additional financing and reach cash flow break-even. Based on current forecasts, which assume continued cost-saving initiatives, successfully renegotiating key contracts, and continued collaborative engagement from Hercules, we expect our existing cash and cash equivalents will enable us to fund our operations into the first quarter of 2025.

We have based this estimate on assumptions of revenues and operating costs that may prove to be wrong. Our cash runway estimate does not include use of our restricted cash, which as of September 30, 2024 was $48.0 million. The restricted cash was unavailable for use as of September 30, 2024, and we believe at least $43.6 million of this restricted cash is unlikely to be released in the near term. In addition, our future net product revenues will depend upon the demand for our products, the size of the markets, our ability to timely scale our manufacturing capabilities to meet market demand, our ability to achieve sufficient market acceptance, reimbursement from third-party payers, adequate market share in those markets and the performance of drug product subject to outcome-based programs. As a result, we could deplete our capital resources sooner than we currently expect. If, for any reason, our revenues or our expenses differ materially from our assumptions or we utilize our cash more quickly than anticipated, or if we are unable to obtain funding on a timely basis, we may be required to revise our business plan and strategy, which may result in bluebird failing to achieve profitability, significantly curtailing, delaying or discontinuing the commercialization of any products or may result in bluebird being unable to continue or expand our operations or otherwise capitalize on our business opportunities. As a result, our business, financial condition, and results of operations could be materially affected.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Financial operations overview

Product revenue

Our revenues were derived from product revenues associated with the sale of SKYSONA, ZYNTEGLO, and LYFGENIA in the United States.

Other revenue

We have recognized an immaterial amount of revenue associated with grants.

Cost of product revenue

Cost of product revenue includes costs associated with the sale of SKYSONA, ZYNTEGLO, and LYFGENIA in the United States.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, legal, business development, commercial, information technology, and human resource functions. Other selling, general and administrative expenses include facility-related costs, professional fees for accounting, tax, legal and consulting services, directors' fees and expenses associated with obtaining and maintaining patents. These expenses include lease expense related to 50 Binney Street and 100 Binney Street; however, sublease income is presented in other income, net.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations ("CROs") and clinical sites that conduct our clinical studies;

- expenses, including amortization of right-of-use assets when used in research and development, incurred under agreements with contract manufacturing organizations ("CMOs") related to pre-commercial manufacturing activities;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, information technology, insurance, and other supplies in support of research and development activities;
- costs associated with our research platform and preclinical activities;
- milestones and upfront license payments; and
- costs associated with our regulatory, quality assurance and quality control operations.

Research and development costs including those under executory contracts and variable costs related to arrangements that contain a lease are expensed as incurred. Right-of-use assets related to arrangements with CMOs and contract testing organizations ("CTOs") that contain a lease under ASC 842 but have no alternative future use under ASC 730 are immediately expensed to research and development expense at commencement or upon a modification until commercialization is achieved. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. We cannot determine with certainty the duration and completion costs of the current or future clinical studies of our products or to what extent we will generate revenues from the commercialization and sale of our approved products. The duration, costs, and timing of clinical studies and development of our products will depend on a variety of factors, any of which could affect our research and development expenses, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake;
- future clinical study results;
- uncertainties in clinical study enrollment rates;
- new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our LVV or drug product;
- regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and
- the timing and receipt of any regulatory approvals.

We plan to continue to incur research and development expenses for the foreseeable future as we continue to conduct research activities for our platform technology. We expect our research and development expenses to decrease in conjunction with an increase in commercial activities and selling, general and administrative expense due to the approvals of ZYNTEGLO, SKYSONA, and LYFGENIA. Our research and development expenses include expenses associated with the following activities:

- the long-term follow-up protocol associated with the clinical studies of ZYNTEGLO, and a postmarketing study for the same;
- the long-term follow-up protocol associated with the clinical studies of SKYSONA, and a postmarketing study for the same;
- HGB-210, the long-term follow-up protocol associated with the clinical studies of LYFGENIA, and a postmarketing study for the same;
- research and development activities for our platform technology; and
- the manufacture of clinical study materials in support of our clinical studies.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate salary and benefit costs that are directly related to specific programs. We do not allocate personnel-related discretionary bonus or stock-based compensation costs, laboratory and related expenses, certain license and other collaboration costs, depreciation or other indirect costs that are deployed across multiple projects under development and, as such, the costs are separately classified as other research and development expenses in the table below:

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
		(As Restated)		(As Restated)
LYFGENIA (lovo-cel)	$ 5,839	$ 32,856	$ 18,258	$ 59,108
SKYSONA (eli-cel)	1,119	1,164	4,572	4,951
ZYNTEGLO (beti-cel)	1,422	4,158	4,188	12,152
Preclinical programs	131	424	369	939
Total direct research and development expense	8,511	38,602	27,387	77,150
Employee-and contractor-related expenses	6,522	8,152	21,979	22,421
Stock-based compensation expense	681	2,065	2,736	8,075
License and other related expenses	1	1,877	1	1,988
Laboratory and other expenses	1,515	1,147	4,531	2,159
Facility expenses	5,944	6,658	16,774	19,743
Total other research and development expenses	14,663	19,899	46,021	54,386
Total research and development expense	$ 23,174	$ 58,501	$ 73,408	$ 131,536

Gain from sale of priority review voucher, net

Gain from sale of priority review voucher, net consists of gain from the sale of our priority review vouchers. In the first quarter of 2023, we sold our PRV for aggregate net proceeds of $92.9 million. We received the PRV in September 2022 under an FDA program intended to encourage the development of treatments for rare pediatric diseases.

Interest income

Interest income consists primarily of interest income earned on investments.

Interest expense

Interest expense consists primarily of interest expense associated with finance lease arrangements, factoring agreement, and term loan debt.

Other income, net

Other income, net consists primarily of sublease income, gains and losses on disposal of fixed assets, and gains and losses on foreign currency transactions.

Critical accounting policies and significant judgements and estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies. During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies as reported in our 2023 Annual Report on Form 10-K, except as otherwise described in Note 2, *Basis of presentation, principles of consolidation and significant accounting policies,* in the Notes to Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the three months ended September 30, 2024 and 2023:

	For the three months ended September 30,		
	2024	2023	Change
	(in thousands)		
		(As Restated)	
Revenue:			
Product revenue, net	$ 10,612	$ 12,281	$ (1,669)
Other revenue	—	111	(111)
Total revenues	10,612	12,392	(1,780)
Cost of product revenue	11,781	9,126	2,655
Gross margin	(1,169)	3,266	(4,435)
Operating expenses:			
Selling, general and administrative	39,765	40,771	(1,006)
Research and development	23,174	58,501	(35,327)
Restructuring expenses	2,811	—	2,811
Total operating expenses	65,750	99,272	(33,522)
Loss from operations	(66,919)	(96,006)	29,087
Interest income	1,640	2,454	(814)
Interest expense	(5,778)	(4,311)	(1,467)
Other income, net	10,191	10,631	(440)
Loss before income taxes	(60,866)	(87,232)	26,366
Income tax (expense) benefit	58	—	58
Net loss	$ (60,808)	$ (87,232)	$ 26,424

Revenues. Total revenue was $10.6 million for the three months ended September 30, 2024, compared to $12.4 million for the three months ended September 30, 2023. The decrease of $1.8 million is primarily attributable to one fewer infusion occurring in the third quarter of 2024 compared to the third quarter of 2023.

Cost of product revenue. Cost of product revenue was $11.8 million for the three months ended September 30, 2024, compared to $9.1 million for the three months ended September 30, 2023. The increase is primarily attributable to increased inventoriable expenses in the third quarter of 2024 compared to the third quarter of 2023.

Selling, general and administrative expenses. Selling, general and administrative expenses were $39.8 million for the three months ended September 30, 2024, compared to $40.8 million for the three months ended September 30, 2023. The net decrease of $1.0 million was primarily attributable to the following:

- $5.4 million of decreased net employee compensation, benefit, and other headcount-related expenses, driven by an overall decrease in headcount and related bonus expense, which includes a reversal of bonus accrual for employees included in the reduction in workforce and $0.8 million decrease in stock-based compensation expense;
- $2.7 million of decreased commercial readiness expense primarily driven by an overall decrease in marketing and advertising expense; and
- $1.1 million of decreased information technology and facility-related costs.

These decreased costs were partially offset by the following:

- $7.8 million of increased professional fees driven by increased accounting advisory costs.

Research and development expenses. Research and development expenses were $23.2 million for the three months ended September 30, 2024, compared to $58.5 million for the three months ended September 30, 2023. The net decrease of $35.3 million was primarily attributable to the following:

- $23.6 million of decreased manufacturing expenses primarily driven by material production for all commercial products now being included in inventory and cost of product revenue;
- $6.8 million of decreased net employee compensation, benefit, and other headcount related expenses, driven by related expenses being included in inventory and cost of product revenue for our commercial products, an overall decrease in headcount and related bonus expense, which includes a reversal of bonus accrual for employees included in the reduction in workforce, and a decrease of $1.4 million in stock-based compensation expense;
- $2.9 million of decreased consulting fees; and
- $2.3 million of decreased information technology and facility-related costs.

Restructuring expenses. The increase in restructuring expenses is related to costs associated with the reduction in workforce that was approved in the third quarter of 2024.

Interest income. The decrease in interest income is primarily related to overall decrease in total cash balances in 2024 compared to 2023.

Interest expense. The increase in interest expense is primarily due to interest expense associated with our term loan debt with Hercules that we entered into in March 2024 and our factoring agreement, partially offset by a decrease in the interest expense associated with finance lease arrangements.

Other income, net. The decrease in other income, net is primarily related to gains and losses on foreign currency transactions.

Comparison of the nine months ended September 30, 2024 and 2023:

	For the nine months ended September 30,		
	2024	2023	Change
	(in thousands)		
		(As Restated)	
Revenue:			
Product revenue, net	$ 45,274	$ 21,414	$ 23,860
Other revenue	12	249	(237)
Total revenues	45,286	21,663	23,623
Cost of product revenue	66,591	21,335	45,256
Gross margin	(21,305)	328	(21,633)
Operating expenses:			
Selling, general and administrative	136,479	118,700	17,779
Research and development	73,408	131,536	(58,128)
Restructuring expenses	2,811	—	2,811
Total operating expenses	212,698	250,236	(37,538)
Gain from sale of priority review voucher, net	—	92,930	(92,930)
Income (loss) from operations	(234,003)	(156,978)	(77,025)
Interest income	7,056	7,961	(905)
Interest expense	(16,875)	(12,331)	(4,544)
Other income, net	31,782	30,177	1,605
Income (loss) before income taxes	(212,040)	(131,171)	(80,869)
Income tax (expense) benefit	37	80	(43)
Net income (loss)	$ (212,003)	$ (131,091)	$ (80,912)

Revenues. Total revenue was $45.3 million for the nine months ended September 30, 2024, compared to $21.7 million for the nine months ended September 30, 2023. The increase of $23.6 million is primarily attributable to increased product sales during 2024.

Cost of product revenue. Cost of product revenue was $66.6 million for the nine months ended September 30, 2024, compared to $21.3 million for the nine months ended September 30, 2023. The increase is primarily attributable to increased product sales during 2024 and increased inventoriable expenses associated with contract manufacturing costs.

Selling, general and administrative expenses. Selling, general and administrative expenses were $136.5 million for the nine months ended September 30, 2024, compared to $118.7 million for the nine months ended September 30, 2023. The net increase of $17.8 million was primarily attributable to the following:

- $19.8 million of increased professional fees driven by increased accounting advisory costs; and
- $1.2 million of increased expenses relating to contractors primarily driven by an increased need for contractors and consultants, primarily related to the Company's 2023 restatement and turnover, across the selling, general and administration functions in 2024 compared to 2023.

These increased costs were partially offset by the following:

- $2.4 million of decreased commercial readiness expense primarily driven by an overall decrease in marketing and advertising expense; and
- $2.2 million of decreased information technology and facility-related costs.

Research and development expenses. Research and development expenses were $73.4 million for the nine months ended September 30, 2024, compared to $131.5 million for the nine months ended September 30, 2023. The net decrease of $58.1 million was primarily attributable to the following:

- $28.0 million of decreased manufacturing costs primarily driven by material production for all commercial products now being included in inventory and cost of product revenue;

- $14.4 million of decreased net employee compensation, benefit, and other headcount related expenses, driven by related expenses being included in inventory and cost of product revenue for our commercial products, an overall decrease in headcount and related bonus expense, which includes a reversal of bonus accrual for employees included in the reduction in workforce, and a decrease of $5.3 million in stock-based compensation expense;
- $7.4 million of decreased consulting fees;
- $5.2 million of decreased information technology and facility-related costs;
- $3.0 million of decreased clinical subject treatment costs; and
- $1.1 million of non-clinical services.

These decreased costs were partially offset by the following:

- $1.6 million of increased costs related to lab expenses driven by an increase in lab consumables.

Restructuring expenses. The increase in restructuring expenses is related to costs associated with the reduction in workforce that was approved in the third quarter of 2024.

Gain from sale of priority review voucher, net. The decrease in gain from sale of priority review voucher, net was related to the sale of a priority review voucher in the first quarter of 2023.

Interest income. The decrease in interest income was primarily related to an overall decrease in total cash balances in the first three quarters of 2024 compared to the first three quarters of 2023.

Interest expense. The increase in interest expense is primarily due to interest expense associated with our term loan debt with Hercules that we entered into in March 2024 and our factoring agreement, partially offset by a decrease in the interest expense associated with finance lease arrangements.

Other income, net. The increase in other income, net is primarily related to gains and losses on foreign currency transactions.

Liquidity and Capital Resources

As of September 30, 2024, we had cash and cash equivalents of approximately $70.7 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, when applicable, primarily with a view to liquidity and capital preservation. As of September 30, 2024, our funds are primarily held in U.S. government agency securities and treasuries, and money market accounts with maturities at date of purchase of 90 days or less.

We have incurred losses and cumulative negative cash flows from operations since our inception in April 1992, and as of September 30, 2024, we had an accumulated deficit of $4.5 billion. We expect our research and development expenses to decrease in conjunction with an increase in commercial activities and selling, general and administrative expense due to the commercialization of ZYNTEGLO, SKYSONA, and LYFGENIA.

In September 2024, we implemented the Restructuring designed to support our commercial focus and reduce our cash operating expenses. See also "Management's Discussion and Analysis - Overview".

We are engaging collaboratively with Hercules as we work to secure adequate cash runway to obtain additional financing and reach cash flow break-even. Based on current forecasts, which assume continued cost-saving initiatives, successfully renegotiating key contracts, and continued collaborative engagement from Hercules, we expect our existing cash and cash equivalents will enable us to fund our operations into the first quarter of 2025.

We have based this estimate on assumptions of revenues and operating costs that may prove to be wrong. Our cash runway estimate does not include use of our restricted cash of $48.0 million, which was unavailable for use as of September 30, 2024, and we believe at least $43.6 million of this restricted cash is unlikely to be released in the near term. In addition, our future net product revenues will depend upon the demand for our products, the size of the markets, our ability to timely scale our manufacturing capabilities to meet market demand, our ability to achieve sufficient market acceptance, reimbursement from third-party payers, adequate market share in those markets and the performance of drug product subject to outcome-based programs. As a result, we could deplete our capital resources sooner than we currently expect. If, for any reason, our revenues or our expenses differ materially from our assumptions or we utilize our cash more quickly than anticipated, or if we are unable

to obtain funding on a timely basis we may be required to revise our business plan and strategy, which may result in bluebird failing to achieve profitability, significantly curtailing, delaying or discontinuing one or more of our research or development programs or the commercialization of any products or may result in bluebird being unable to continue or expand our operations or otherwise capitalize on our business opportunities. As a result, our business, financial condition, and results of operations could be materially affected.

We have funded our operations principally from the sale of common stock in public offerings, the Loan Agreement, and the sale of the two PRVs. The following is a summary of recent financing transactions:

- In the first quarter of 2023, we sold our second PRV for aggregate net proceeds of $92.9 million.
- In the first quarter of 2023, we sold 23.0 million shares of common stock (inclusive of shares sold pursuant to an option to the underwriters in connection with the offering) in an underwritten public offering at a price of $6.00 per share for aggregate net proceeds of $130.5 million.
- In August 2023, we entered into an Open Market Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") to sell shares of our common stock up to $125.0 million, from time to time, through an “at the market” equity offering program under which Jefferies will act as sales agent. As of September 30, 2024, we have made no sales pursuant to the Sales Agreement.
- In December 2023, we sold 83.3 million shares of common stock in an underwritten public offering at a price of $1.50 per share for aggregate net proceeds of $118.1 million.
- In March 2024, we entered into the LSA for up to $175.0 million in debt financing.

Sources of Liquidity

Cash Flows

The following table summarizes our cash flow activity:

	For the nine months ended September 30,	
	2024	2023
	(in thousands)	
		(As Restated)
Net cash (used in) operating activities	$ (209,856)	$ (180,910)
Net cash provided by investing activities	1,432	151,164
Net cash provided by financing activities	52,479	89,670
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (155,945)	$ 59,924

Operating Activities. The $28.9 million increase in cash used in operating activities for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 was primarily due to the increase in net loss of $80.9 million, the increase in net working capital of $35.7 million, net changes of other non-cash items of $32.9 million, which is primarily driven by $22.2 million of non-cash research and development expense related to finance leases in 2023 only, offset by no adjustments in 2024 relating to the gain from the sale of priority review voucher of $92.9 million, which was sold in 2023, and by an increase in depreciation and amortization expense of $27.7 million.

Investing Activities. The $149.7 million decrease in cash provided by investing activities for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 was primarily due to no proceeds from sale of priority review voucher, compared to $92.9 million in proceeds from sale of priority review voucher during the nine months ended September 30, 2023. Additionally, the decrease was driven by having no activity in marketable securities for the nine months ended September 30, 2024 compared to $56.2 million net proceeds for the nine months ended September 30, 2023.

Financing Activities. The $37.2 million decrease in cash provided by financing activities for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 was primarily due to no proceeds from a public offering, compared to $130.1 million in proceeds from the secondary public offering, net of paid offering costs, issued during the nine months ended September 30, 2023, the increase in principal payments on finance lease of $29.3 million, offset by the proceeds from the issuance of debt and warrants of $74.0 million and the proceeds from factoring arrangement of $50.6 million during the nine months ended September 30, 2024.

Contractual Obligations and Commitments

Except as discussed in Note 9, *Leases*, and Note 10, *Commitments and contingencies*, in the Notes to Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q, there have been no material changes to our contractual obligations and commitments as included in our 2023 Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

We are exposed to market risk related to changes in interest rates. As of September 30, 2024 and December 31, 2023, we had cash and cash equivalents of $70.7 million and $221.8 million, respectively, primarily invested in U.S. government agency securities and treasuries, corporate bonds, commercial paper, equity securities, and money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities.

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13(a)- 15(e) and 15(d)- 15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), as of June 30, 2024, the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weakness in our internal control over financial reporting described below.

In connection with the Company’s preparation of its financial statements and the restatement (as further described within Note 2, Restatement of Previously Issued Financial Statements to the consolidated financial statements appearing in the Annual Report on Form 10-K filed September 13, 2024), the Company identified a material weakness in its internal controls over financial reporting, which failed to prevent or detect the identified misstatements requiring restatement.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis.

Our management concluded that a material weakness existed as of December 31, 2023, and in prior periods, with respect to the design and operating effectiveness of the Company’s controls over the accounting for arrangements that contain a lease. Specifically, the Company did not: (i) design controls to properly apply the Company's accounting policy to combine lease and non-lease components in lease arrangements, including embedded leases, (ii) operate controls to review the identification of leases and lease elements and accounting for lease arrangements, including embedded leases and lease modifications, by individuals with appropriate knowledge and competency, and (iii) operate controls to review the accounting for embedded leases with contract manufacturing organizations and contract testing organizations by individuals with appropriate knowledge and competency to determine the appropriate lease classification, presentation and commencement date.

This material weakness resulted in the restatement of the Company’s consolidated financial statements as of and for the year ended December 31, 2022, and the unaudited condensed consolidated financial information for each of the first three quarters of 2023 and 2022. Additionally, the material weakness could result in misstatements to the Company’s accounts and disclosures that would result in a material misstatement of the annual or interim consolidated financial statements that would not be prevented or detected.

Remediation Plan

Our management is committed to maintaining a strong internal control environment. In response to the identified material weakness above, management intends to take comprehensive actions to remediate the material weakness in internal control over financial reporting, including:

- reassess and enhance the design of existing internal controls over lease accounting and design and implement new or modified internal controls to ensure that financial statement assertion level risks (e.g. valuation, completeness, accuracy, presentation and disclosure) related to leases are addressed;

- strengthen the lease accounting technical knowledge and experience within the Company's accounting function to enhance the oversight of the processes related to accounting for leases and arrangements that could contain embedded leases or lease modifications;

- conduct training for individuals responsible for performing and reviewing the accounting and presentation for leases and arrangements with contract manufacturing and contract testing organizations which could contain embedded leases or modifications.

The remediation plan, when finalized, is expected to include a number of enhanced activities that reflect a continuation of activities the Company has started to undertake during the 2023 financial close process. We believe that the actions outlined above, when fully implemented, will remediate the material weakness. The material weakness will not be considered remediated, however, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We may also conclude that additional measures may be required to remediate the material weakness in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the material weakness expeditiously.

Changes in Internal Control over Financial Reporting

Other than the changes associated with the material weakness and corresponding remediation procedures described above, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13(a)-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, during the third quarter of 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment and other matters. The outcome of these proceedings and claims cannot be predicted with certainty. We believe no governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

On October 21, 2021, San Rocco Therapeutics, LLC, formerly known as Errant Gene Therapeutics, LLC, filed a complaint against us in the United States District Court for the District of Delaware for alleged infringement of U.S. Patent Nos. 7,541,179 and 8,058,061. The term of U.S. Patent No. 8,058,061 already expired on November 25, 2022, and U.S. Patent No. 7,541,179 expired on May 13, 2024. The allegations relate to our use of the BB305 lentiviral vector, including in connection with the beti-cel program and seeks injunctive relief and money damages. On February 21, 2022, the parties stipulated to amend the case caption, in light of the plaintiff's name change, from Errant Gene Therapeutics, LLC to San Rocco Therapeutics, LLC ("SRT"). The Court granted this stipulation and, accordingly, the case is now captioned, San Rocco Therapeutics, LLC v. bluebird bio, Inc. and Third Rock Ventures, LLC, C.A. No. 21-1478-RGA. On April 6, 2022, we—along with Third Rock Ventures, LLC—filed a motion seeking various relief including to stay the proceedings and compel arbitration on two threshold issues, which we argued warranted complete dismissal of the action as a matter of law, regardless of the merits of SRT's underlying infringement claims. On July 26, 2022, the Court granted our request to stay the proceedings and issued an Order compelling the parties to arbitrate the threshold issues we raised. On February 7, 2023, the Arbitrator issued a final award finding in favor of SRT on both threshold issues, thereby enabling SRT to pursue its claims for alleged infringement. On March 1, 2023, the parties jointly stipulated, subject to the approval of the United States District Court for the District of Delaware, to lift the stay. The Court lifted the stay on March 2, 2023, and on March 31, 2023, we filed our answer to SRT's complaint with counterclaims asserting that we do not infringe the patents-in-suit and that the patents-in-suit are invalid. Also, on April 22, 2024, the Patent Trial & Appeal Board of the U.S. PTO found that our two petitions for inter partes review did not show by a preponderance of the evidence that the challenged claims of the patents-in-suit are unpatentable, and we filed notices of appeal with the U.S. Court of Appeals for the Federal Circuit on June 21, 2024. Our opening brief is currently due on December 6, 2024, SRT's responsive brief is due January 15, 2025, and our reply brief is due February 5, 2025. On June 17, 2024, the Court entered a claim construction order in bluebird's favor. On July 17, 2024, the Court granted our request for leave to file a case-dispositive motion for summary judgment of noninfringement, and on July 25, 2024, the Court ordered a stay of discovery pending a decision on the summary judgment motion. On August 1, 2024, we filed our motion for summary judgment of noninfringement, SRT filed an opposition on September 3, 2024 and we filed our reply on September 17, 2024. Briefing is now complete, and we have requested oral argument. We plan to vigorously defend against SRT's claims in this action.

On April 27, 2023, SRT filed another complaint against us (as well as against Mr. Nick Leschly, Mr. Mitchell Finer, Mr. Philip Reilly, Third Rock Ventures LLC, and 2Seventy Bio, Inc.) in the United States District Court for the District of Massachusetts. This complaint alleges civil violations of the Federal Racketeer Influenced and Corrupt Organizations Act, violations of Mass. Gen. Laws ch. 93A, § 11, and fraudulent inducement of SRT into a release provision in a November 2020 confidential settlement agreement we executed with, inter alia, SRT. The allegations relate to our use of the BB305 lentiviral vector, including in connection with the beti-cel program, and SRT seeks declaratory relief and money damages. On July 3, 2023, we (in conjunction with the other defendants) moved to dismiss all claims with prejudice brought by SRT in its Complaint for failure to state a claim upon which relief may be granted. On August 7, 2023, SRT filed an amended complaint, adding Craig Thompson as a defendant, and adding additional claims of alleged antitrust violations under federal and state law. The case is now captioned San Rocco Therapeutics, LLC v. Nick Leschly, Mitchell Finer, Philip Reilly, Craig Thompson, Third Rock Ventures LLC, bluebird bio, Inc. and 2Seventy Bio, Inc., C.A. No. 1:23-cv-10919-ADB. On September 18, 2023, we (in conjunction with the non-Thompson defendants), moved to dismiss with prejudice once again. SRT filed an opposition to that motion on October 12, 2023. On October 24, 2023, we filed a motion for leave to file a reply brief, which was granted on October 30, 2023. SRT filed a sur-reply brief on November 2, 2023. On September 30, 2024, the court issued a Memorandum and Opinion granting the motion to dismiss filed by the non-Thompson defendants as well as a motion to dismiss filed by Mr. Thompson. On October 2, 2024, the court issued an Order dismissing SRT's amended complaint, and closing the case. SRT's time to file any notice of appeal has expired, rendering the court's ruling a final non-appealable decision.

On April 15, 2024, SRT filed a Demand for Arbitration with the American Arbitration Association, accusing us of breaching a November 2020 confidential settlement agreement by initiating a proceeding before the Patent Trial & Appeal Board (PTAB) of the United States Patent & Trademark Office in October 2022, asserting invalidity of two patents licensed to

SRT. SRT seeks reimbursement of its costs and fees, including attorney's fees, incurred in the PTAB proceeding, totaling approximately $1.5 million. On August 26, 2024, the parties submitted their respective opening dispositive briefs. We filed our response on September 24, 2024, when SRT also filed its opposition to our dispositive motion. The parties' respective replies were due on October 8, 2024. On October 29, 2024, the arbitrator granted our early dispositive motion and dismissed SRT's claim in its entirety.

On March 28, 2024, a class action lawsuit captioned Garry Gill v. bluebird bio, Inc. et al., Case No. 1:24-cv-10803-PBS (the "*Gill* Action"), was filed against us in the United States District Court for the District of Massachusetts. An amended complaint was filed on August 15, 2024. The amended complaint purports to assert claims against us and certain of our current and former officers pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, on behalf of a putative class of investors who purchased or otherwise acquired the Company's shares between April 24, 2023 and December 8, 2023 (the "class period"). Plaintiff seeks to recover damages allegedly caused by purported misstatements and omissions regarding (i) whether the Company could obtain FDA approval for the lovo-cel BLA without a black box warning for hematologic malignancies; and (ii) whether the Company would be granted a priority review voucher by the FDA in connection with the BLA, which it could sell in order to strengthen its financial position. The amended complaint claims these alleged statements and omissions operated to artificially inflate the price paid for our common stock during the class period. On September 2, 2024, the Court entered the parties' stipulated schedule for briefing a motion to dismiss the amended complaint. Our opening brief in support of a motion to dismiss was filed on October 11, 2024; the opposition brief is due December 5, 2024; and a reply brief in further support of a motion to dismiss is due December 20, 2024. We intend to vigorously defend against the claims in this action.

On June 27, 2024, a shareholder derivative lawsuit captioned *Šimaitis v. Obenshain et al.*, Case No. 1:24-cv-11674-PBS, was filed nominally on our behalf against certain current and former members of Company management and the Board of Directors in the United States District Court for the District of Massachusetts. The complaint purports to assert derivative claims pursuant to Sections 10(b), 14(a), and 21D of the Securities Exchange Act of 1934, as well as for breach of fiduciary duties, unjust enrichment, waste of corporate assets, gross mismanagement, and abuse of control. Plaintiff seeks to recover damages on our behalf allegedly caused by purported materially false and misleading public statements and omissions, including in the April 28, 2023 proxy statement, regarding (i) whether the Company could obtain FDA approval for the lovo-cel BLA without a black box warning for hematologic malignancies; and (ii) whether the Company would be granted a priority review voucher by the FDA in connection with the BLA, which it could sell in order to strengthen its financial position. The complaint claims these allegedly misleading statements and omissions operated to artificially inflate the Company's common stock price during the relevant time period. To support its derivative claims, the complaint alleges that a legally required pre-suit demand on the Board would be futile and should be excused. On July 25, 2024, the case was consolidated with *Syracuse v. Obenshain et al.*, Case No. 1:24-cv-11752 (D. Mass. July 8, 2024). The consolidated actions were recaptioned *In re bluebird bio, Inc. Stockholder Derivative Litigation*, Case No. 1:24-cv-11674-PBS. On September 19, 2024, the consolidated case was stayed pending resolution of the motion to dismiss filed in the *Gill* Action.

On July 8, 2024, a shareholder derivative lawsuit captioned *Syracuse v. Obenshain et al.*, Case No. 1:24-cv-11752-PBS, was filed nominally on our behalf against certain current and former members of Company management and the Board of Directors in the United States District Court for the District of Massachusetts. The complaint purports to assert derivative claims against pursuant to Section 14(a) of the Securities Exchange Act of 1934, as well as for breach of fiduciary duties, gross mismanagement, waste of corporate assets, and unjust enrichment. Plaintiff seeks to recover damages on our behalf allegedly caused by purported materially false and misleading public statements and omissions, including in the April 28, 2023 proxy statement, regarding (i) whether the Company could obtain FDA approval for the lovo-cel BLA without a black box warning for hematologic malignancies; and (ii) whether the Company would be granted a priority review voucher by the FDA in connection with the BLA, which it could sell in order to strengthen its financial position. The complaint claims these allegedly misleading statements and omissions operated to artificially inflate the Company's common stock price during the relevant time period. To support its derivative claims, the complaint alleges that a legally required pre-suit demand on the Board would be futile and should be excused. On July 25, 2024, the case was consolidated with *Šimaitis v. Obenshain et al.*, Case No. 24-cv-11674 (D. Mass. July 27, 2024). The consolidated actions were recaptioned *In re bluebird bio, Inc. Stockholder Derivative Litigation*, Case No. 1:24-cv-11674-PBS. On September 19, 2024, the consolidated case was stayed pending resolution of the motion to dismiss filed in the *Gill* Action.

Item 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of

any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

We have incurred significant losses since our inception and we may not achieve our goal of becoming profitable in the timeframe we expect, or at all.

We have incurred significant net losses since our inception in 1992, including net losses from continuing operations of $211.9 million for the year ended December 31, 2023. As of September 30, 2024, we had an accumulated deficit of $4.5 billion. To date, we have devoted significant financial resources to building our commercial infrastructure and research and development, including our clinical and preclinical development activities. We will continue to incur net losses for the foreseeable future and we may not become profitable on the timeline we anticipate, or at all. To date, we have financed our operations primarily through our loan agreement with Hercules Capital, Inc., the sale of equity securities and priority review vouchers, and, to a lesser extent, through collaboration agreements and grants from governmental agencies and charitable foundations. We did not generate material revenues from the sale of ZYNTEGLO in the European Union and are just beginning to recognize revenue from our approved products in the U.S. given the treatment cycle time, in which revenue is recognized upon infusion. Our future revenues will depend upon the size of any markets in which our products have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payers and adequate market share for our products in those markets.

We anticipate that our expenses may increase substantially, we may continue to incur operating losses, and we may not generate profit if and as we:

- grow our capabilities to support our commercialization efforts for ZYNTEGLO, SKYSONA and LYFGENIA, including continuing to establish a sales, marketing and distribution infrastructure in the United States;
- obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;
- attract and retain skilled personnel;
- initiate additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- continue our ongoing and planned clinical development of ZYNTEGLO, SKYSONA and LYFGENIA, including completion of the HGB-210 clinical trial and long-term follow-up studies;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- incur expenses for legal, accounting, and other professional services in connection with the restatement of our consolidated financial statements;
- defend against lawsuits, including patent or stockholder litigation; and
- experience any delays or encounter issues with any of the above.

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. Further, there is no assurance that we will ever achieve profitability. In addition, in any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our commercial programs, product development efforts or other operations.

Based on our current business plan as of the date hereof, management has concluded that there is substantial doubt regarding our ability to continue as a going concern. See Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" of this Quarterly Report on Form 10-Q for a discussion of our expected cash runway. Accordingly, we will need to raise additional funding in order to execute on our current business plans and strategy, including prior to becoming profitable or generating free cash flow.

We cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity, traditional debt or other debt-like arrangements, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. Further, our ability to sell such additional securities is limited due to our existing shares outstanding. We are seeking stockholder approval to effect a reverse stock split which, if approved, would effectively increase our authorized shares of common stock. However, there is no guarantee stockholders will approve this proposal. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. See also "Risk Factors – *"Our existing and any future indebtedness could adversely affect our ability to operate our business"*. We could also be required to seek funds through arrangements with collaborative partners or otherwise, which may require us to relinquish rights to some of our technologies or products or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, our efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our products.

Furthermore, as a result of the restatement of our consolidated financial statements for the year ended December 31, 2022 and the quarterly periods in the years ended December 31, 2022 and 2023, we were delayed in filing our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2024 and June 30, 2024. As a result, we will not be eligible to sell securities under our existing shelf registration statement on Form S-3 or file a new Form S-3 until we have regained compliance with the requirements of Form S-3. See "Risk Factor — *The restatement of our consolidated financial statements for the year ended December 31, 2022 and the quarterly periods in the years ended December 31, 2022 and 2023 has subjected us to a number of additional risks and uncertainties, including increased possibility of legal proceedings*". Our inability to use Form S-3 could make it more difficult and costly for us to obtain funding through a sale of securities.

Moreover, as a result of recent volatile market conditions, the cost and availability of capital has been and may continue to be adversely affected. Lenders and institutional investors may reduce, and in some cases, cease to provide credit to businesses and consumers. Continued turbulence in the U.S. market and economy may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet liquidity needs. In addition, we maintain the majority of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we have projected, we may be required to further revise our business plan and strategy, which may result in us significantly curtailing, delaying or discontinuing the commercialization of any current or future products or may result in our being unable to continue or expand our operations or otherwise capitalize on our business opportunities. As a result, our business, financial condition and results of operations could be materially affected.

Among other potential adverse events, insertional oncogenesis is a significant risk of gene therapies using viral vectors that can integrate into the genome. Any such adverse events may require us to halt or delay further clinical development of our products or any future product candidates or to suspend or cease commercialization, and the commercial potential of our products and any such future product candidates may be materially and negatively impacted.

Adverse events or other undesirable side effects caused by our products or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval by the FDA or other comparable foreign regulatory authorities. A potentially significant risk

in any gene therapy product using viral vectors that can integrate into the genome is that the vector will insert in or near cancer-causing genes, leading to the proliferation of certain cellular clones that could cause cancer in the patient, known as insertional oncogenesis. For instance, multiple patients with CALD treated with eli-cel (now SKYSONA) in our clinical studies have been diagnosed with myelodysplastic syndrome (“MDS”) or acute myeloid leukemia ("AML"), likely mediated by Lenti-D LVV insertion. SKYSONA’s label includes a boxed warning for the known risk of hematologic malignancy and, accordingly, we expect additional cases to arise over time. In April 2024, the boxed warning was revised to include updated information on hematologic malignancies diagnosed in our clinical study patients, as well as other updates to monitoring procedures and alternative treatment options. We continue to closely monitor potential cases of hematologic malignancy in patients treated with SKYSONA and we are communicating regularly with treating physicians and regulatory authorities. We cannot make assurances that additional patients treated with SKYSONA, ZYNTEGLO or LYFGENIA in the clinical or commercial setting will not be diagnosed with hematologic malignancy.

Moreover, in December 2021, the FDA placed the lovo-cel clinical development program under a partial clinical hold for patients under the age of 18. The hold related to a case of persistent anemia in an adolescent patient with two α-globin gene deletions (−α3.7/−α3.7), also known as alpha-thalassemia trait, who was treated with lovo-cel. In December 2022, the FDA lifted its partial clinical hold for patients under the age of 18 in studies evaluating lovo-cel for SCD. Notwithstanding the lifting of this partial clinical hold, additional adverse events or new data or analyses regarding previously reported events may indicate significant safety issues, and the FDA could potentially impose or reimpose a clinical hold in the future on studies evaluating lovo-cel. Moreover, laboratory results following gene therapy can be difficult to interpret, resulting in different or changing diagnoses by treating physicians. For instance, on January 31, 2023, we received a physician diagnosis of MDS in a patient treated with lovo-cel, in response to lab results obtained through routine monitoring of the same adolescent patient with two α-globin gene deletions subject to the partial clinical hold noted above. Consistent with established safety protocols, the information was reviewed by an independent Data Monitoring Committee which concluded that available evidence did not support a diagnosis of MDS and additional data would be needed to confirm such diagnosis, and that lovo-cel clinical studies should continue. Test results received since the investigator’s initial report (including integration site analysis) demonstrated no evidence of insertional oncogenesis and as of August 27, 2024, the patient remained clinically stable with stable laboratory results and was not undergoing treatment for an MDS diagnosis. Study investigators and the FDA were informed and we will continue to monitor additional analyses as further test results are received.

Furthermore, treatment with our products and any future product candidates involves or may involve chemotherapy or myeloablative treatments, which can cause side effects or adverse events that may impact the perception of the potential benefits of our products and any future product candidates. For instance, MDS leading to AML is a known risk of certain myeloablative regimens. Accordingly, it is possible that the events of MDS and AML previously reported in our HGB-206 clinical study of lovo-cel in SCD were caused by underlying SCD, transplant procedure, and stress on the bone marrow following drug product infusion in connection with the lovo-cel treatment. The product label for LYFGENIA includes a boxed warning for the known risk of hematologic malignancy. Additionally, the procedures associated with the administration or collection of cells for ZYNTEGLO, SKYSONA, or LYFGENIA, could potentially cause other adverse events that have not yet been predicted. The inclusion of patients with significant underlying medical problems in our clinical studies may result in deaths, or other adverse medical events, due to other therapies or medications that such patients may be using, or the progression of their disease.

Moreover, patients treated with our therapies, including lovo-cel, have exhibited persistent oligoclonality, which we define as two consecutive instances of (i) any LVV insertion site observed at >=10% relative frequency, or (ii) two or more insertion sites observed at >= to 5% relative frequency, as measured by integration site analysis. Based on our clinical protocols, we increase monitoring of patients who exhibit persistent oligoclonality. It is not clear at this time whether persistent oligoclonality represents an increased risk of developing hematologic malignancy in the future, but it is a criterion used by the FDA to evaluate the safety of gene therapies over time.

Additionally, there is the potential risk of other delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. The FDA has stated that LVVs possess characteristics that may pose high risks of delayed adverse events.

If any such adverse events occur, including insertional oncogenesis, further advancement of our ongoing and future clinical studies and other development efforts could be halted or delayed, and we may be unable to commercialize our approved products in the manner we expect, or at all. It is possible that upon occurrence or recurrence of any of these events, the FDA may place one or more of our programs on hold, impose requirements that result in delays for regulatory approvals for our products or any future product candidates, require the implementation of risk evaluation or mitigation strategies, or may cause

us to cease commercialization of our approved products. If any of these were to occur, the commercial potential of our programs may be materially and negatively impacted.

Although ZYNTEGLO, SKYSONA and LYFGENIA have been approved by the FDA, serious safety events may result in an approved product being removed from the market or its market opportunity being significantly reduced. For instance, it is possible that as we commercialize our products, conduct long-term follow-up, or test any future product candidates in larger, longer and more extensive clinical trials, or as use of these products or any future products becomes more widespread, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects (that may or may not be related to our products or any future product candidate) are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. Other patients receiving our products may develop hematologic malignancies in the future, which may negatively impact the commercial prospects of our products and any future product candidates. We or others may later identify undesirable side effects or adverse events caused by such products, or side effects or adverse events could accumulate over time, and a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, "Dear Healthcare Provider" or "Dear Doctor" letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-marketing studies;
- we may be required to create a risk evaluation and mitigation strategy, or REMS which could include elements to assure safe use, or a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- patients and/or treating physicians could perceive the risk of undesirable side effects or adverse events caused by the product to exceed its potential benefit and choose not to use the product;
- we could choose to remove such product from the market;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could impair our ability to develop or commercialize our products or any future product candidates, and their commercial potential may be materially and negatively impacted.

We rely on complex, single-source supply chains for SKYSONA, ZYNTEGLO, and LYFGENIA, respectively. The manufacture, testing and delivery of LVV and drug products present significant challenges for us, and we may not be able to produce our vector and drug products at the quality, quantities, or timing needed to support our clinical programs and commercialization.

We rely on third parties to manufacture the LVV and the drug product for ZYNTEGLO, SKYSONA and LYFGENIA. The manufacture of LVV and drug products is complex and requires significant expertise. Even with the relevant experience and expertise, manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production, managing the transition from clinical manufacturing to manufacturing in the commercial setting, and ensuring that the product meets required specifications. These problems include difficulties with production costs and yields, quality control, quality assurance testing, operator error, scarcity of qualified manufacturing and quality control testing personnel, shortages of any production raw materials as well as compliance with strictly enforced federal, state and foreign regulations. Further, the transition from clinical to commercial manufacturing is complex and has resulted in, and may continue

to result in, lower operational success rates due to, among other things, tighter specifications and higher regulatory standards associated with commercial products. We cannot make any assurances that these problems will not occur in the future, or that we will be able to resolve or address in a timely manner or with available funds problems that occur. Because of this complexity, transitioning production of either LVV or drug products to backup or second source manufacturing requires a lengthy technology transfer process and regulatory review and approval, which often takes significant time and may require additional significant financial expenditures.

We currently have only one manufacturer of final drug product and one manufacturer of LVV for both ZYNTEGLO and SKYSONA and, separately, one manufacturer of final drug product and one manufacturer of LVV for LYFGENIA; accordingly, any significant disruption or change in our supplier relationships could harm our business. For instance, we have recently provided notice to our manufacturer of LVV for ZYNTEGLO and SKYSONA that we intend to wind down production as we explore alternative manufacturing methods and plans for LVV used in these products. Since any change to manufacturing methods requires FDA approval, we may be delayed in transitioning to such alternatives. Additionally, we have experienced challenges in manufacturing adherent LVV, which is currently used in ZYNTEGLO and SKYSONA. As a result of these events or delays, or other difficulties related to our manufacturing relationships and processes, we may be unable to meet our manufacturing forecasts. Any inability to meet our manufacturing forecasts could impact the ongoing commercialization of these drug products, and hinder our ability to meet our financial goals. Further, we source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain key materials that are used to manufacture SKYSONA, ZYNTEGLO, and LYFGENIA. Such suppliers may not sell these key materials to us or to our manufacturers at the times we need them or on commercially reasonable terms. We do not control the process for acquisition of all key materials and shortages may occur for reasons beyond our control.

We continue to advance plans to make additional investment in manufacturing to expand capacity and, to date, we have secured adequate commercial-scale drug product manufacturing capacity in order to meet our near-term sales forecasts for ZYNTEGLO, SKYSONA and LYFGENIA, including recent approval to double our manufacturing capacity for ZYNTEGLO and SKYSONA; however, any plans to further expand our manufacturing capacity are subject to FDA approval, which we may not receive in connection with any planned expansions. If we fail to secure adequate capacity to manufacture our drug products or LVV used in the manufacture of our drug products in accordance with our forecasts we may be unable to execute on our commercialization plans on the timing that we expect, or at all.

The actual cost to manufacture our LVV and drug products could be greater than we expect and could materially and adversely affect the commercial viability of SKYSONA, ZYNTEGLO, or LYFGENIA. If we or our third-party manufacturers are unable to produce the necessary quantities of LVV and drug product, or in compliance with GMP or other pertinent regulatory requirements, and within our planned time frame and cost parameters, including due to reduced operational success rates as a result of the transition to commercial manufacturing, the development and commercialization of our products and future product candidates may be materially harmed, result in delays in our plans or increased capital expenditures.

Additionally, since the hematopoietic stem cells ("HSCs") used as starting material for our products have a limited window of stability following procurement from a patient, we have initially established transduction facilities in areas that we believe can adequately service patients from regions where we are commercializing SKYSONA, ZYNTEGLO, and LYFGENIA. However, we cannot ensure that such facilities will enable us to produce and deliver drug product in a timely manner; any issues with production and delivery of drug product could have a material adverse effect on our successful commercialization or further development of our products or any future product candidates. Moreover, establishing additional facilities in appropriate regions may be financially impractical or impeded by technical, quality, or regulatory issues related to these new sites and we may also run into technical or scientific issues related to transfer of our transduction process or other developmental issues that we may be unable to resolve in a timely manner or with available funds.

Changes in our manufacturing processes may cause delays in our clinical development and commercialization plans.

The manufacturing processes for our LVV and our drug products are complex. We explore improvements to our manufacturing processes on a continual basis, as we evaluate clinical and manufacturing data and based on discussions with regulatory authorities. In some circumstances, changes in the manufacturing process may require us to perform additional comparability studies, collect additional data from patients, submit additional regulatory filings, or comply with additional requirements, which may lead to delays in our clinical development and commercialization plans. Such changes may require regulatory review and approval including reaching agreement with the FDA on an acceptable comparability data package. The FDA may require us to conduct additional clinical studies, collect additional data, develop additional assays, or modify product specifications relating to such comparability analysis and, therefore, the proposed change may not be approved in a timely

manner, if at all. Any such requests or delays may impact our commercialization plans and may require substantial additional funds.

Risks related to commercialization

We have limited experience as a commercial company and the marketing and sale of ZYNTEGLO, SKYSONA and LYFGENIA may be unsuccessful or less successful than anticipated.

We have limited experience as a commercial company as we recently launched our three FDA-approved products, ZYNTEGLO, SKYSONA and LYFGENIA. Consequently, there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry in the U.S. To execute our business plan, we will need to successfully:

- sustain adequate pricing and reimbursement for ZYNTEGLO, SKYSONA and LYFGENIA across all U.S. payer segments;
- establish and maintain, in the regions where we hope to treat patients, relationships with qualified treatment centers who will be treating the patients who receive ZYNTEGLO, SKYSONA, and LYFGENIA;
- manage our manufacturing capabilities and supply chain operations in the coordination and delivery of drug product to patients at qualified treatment centers;
- manage our spending as we engage in commercialization efforts;
- manage the patient uptake process for each of our products, including with respect to overall timing and potential barriers such as clinical assessment periods and payer approval processes; and
- initiate, develop and maintain successful strategic alliances.

If we are not successful in accomplishing these objectives, we may not be able to effectively commercialize ZYNTEGLO, SKYSONA or LYFGENIA, raise capital, expand our business, or continue our operations. For instance, the phasing of LYFGENIA patient starts has affected the timing of our revenue expectations. If we are unable to meet our forecasts, our business may suffer.

The commercial success of ZYNTEGLO, SKYSONA and LYFGENIA will depend upon the degree of market acceptance by physicians, patients, payers and other stakeholders.

The commercial success of ZYNTEGLO, SKYSONA, and LYFGENIA will depend in part on the medical community, patients, and third-party or governmental payers accepting gene therapy products in general, and ZYNTEGLO, SKYSONA, and LYFGENIA, in particular, as medically useful, cost effective, and safe. ZYNTEGLO, SKYSONA, and LYFGENIA may not gain market acceptance by physicians, patients, payers and other stakeholders. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable and our future business prospects will be adversely impacted. The degree of market acceptance of ZYNTEGLO, SKYSONA, and LYFGENIA will depend on a number of factors, including:

- our ability to compete with alternative treatments, including other approved gene therapies for similar indications, including with respect to potential and perceived efficacy and other potential advantages;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling; for instance, each of the LYFGENIA and SKYSONA product labels includes a boxed warning for the risk of hematologic malignancy;
- the prevalence and severity of any side effects resulting from the chemotherapy and myeloablative treatments associated with the procedure by which our products are administered, including the possible prejudicial effects that chemotherapy can have on fertility;

- relative convenience and ease of administration, including patients' willingness and ability to travel to qualified treatment centers within our network;
- given the complexity of manufacturing product and the reduced operational success rates in connection with the transition to commercial manufacturing, the perception or possibility that issues may continue to arise in the supply of product which could delay treatment;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the pricing of our products, including in comparison to competitors;
- publicity concerning our products, or competing products and treatments;
- sufficient insurance coverage or reimbursement;
- the possible occurrence of adverse clinical findings or decreased effectiveness of a product or product candidate over time identified during continued monitoring and evaluation of patients; and
- the mix of private and governmental payer coverage, which can impact both the total reimbursement for the drug and the time-to-reimbursement, and the conditions to coverage imposed by the various payers, including non-preferred or exclusion decisions in favor of our competitor.

Even if a product displays a favorable efficacy and safety profile in clinical studies, market acceptance of the product will not be known until some period after it is launched. Our efforts to educate the medical community and payers on the benefits of our products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors. Any of these factors may cause ZYNTEGLO, SKYSONA, or LYFGENIA to be unsuccessful or less successful than anticipated.

If the market opportunities for our commercial products or any future product candidates are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

Our platform focuses on treatments for severe genetic diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products or any future product candidates we may develop, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower or more difficult to identify than expected. Additionally, the potentially addressable patient populations for our products or any future product candidates may be limited or may not be amenable to treatment with such products or product candidates. For instance, each of the SKYSONA and LYFGENIA product labels includes a boxed warning for the risk of hematologic malignancy, which may impact market opportunity.

Any of these factors may negatively affect our ability to generate revenues from sales of our products as forecasted and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

We have limited sales and distribution experience and limited capabilities for marketing and market access. Although we have invested and expect to continue to invest significant financial and management resources, if we are unable to establish and maintain these commercial capabilities and infrastructure, or to enter into agreements with third parties to market and sell our products, we may be unable to generate sufficient revenue to sustain our business.

We have limited prior sales or distribution experience and limited capabilities for marketing and market access, and we did not generate meaningful product sales following the commercial launch of ZYNTEGLO following marketing approval in Europe. To successfully commercialize ZYNTEGLO, SKYSONA, and LYFGENIA, we will need to further develop these capabilities. We may need to expand our infrastructure to further support commercial operations in the United States, either on

our own or with others. Commercializing an autologous gene therapy is resource-intensive and has required, and will continue to require, substantial investment in commercial capabilities. We are competing with companies that currently have extensive and well-funded marketing and sales operations. Without significant commercial experience as a company or the support of a third party to perform these functions, including marketing and sales functions, we may be unable to compete successfully against these more established companies.

Furthermore, a significant proportion of the patient populations for ZYNTEGLO, SKYSONA, and LYFGENIA lies outside of the United States. We currently expect to focus our operations and efforts on markets in the United States and will need to rely heavily on third parties for commercializing any products in geographies outside of the United States, if at all. We may enter into collaborations with third parties to utilize their mature marketing and distribution capabilities, but we may be unable to enter into agreements on favorable terms, if at all. If we do not enter into collaboration arrangements with third parties to pursue regulatory authorization or commercialization of our programs for markets outside of the United States, or if our future collaborative partners do not commit sufficient resources to such efforts, we may be unable to generate sufficient revenue to sustain our business.

We may encounter challenges with engaging or coordinating with qualified treatment centers needed for the ongoing commercialization of ZYNTEGLO, SKYSONA and LYFGENIA.

Our commercial strategy is to engage apheresis and transplant centers as qualified treatment centers for the collection of patient HSCs and infusion of the drug product once manufactured. To ensure that the qualified treatment centers are prepared to collect patient HSCs and to ship them to our transduction facilities in accordance with our specifications and regulatory requirements, we train and conduct quality assessments of each center as part of engagement. These qualified treatment centers are the first and last points on our complex supply chain to reach patients in the commercial setting. We may encounter challenges or delays in engaging and interacting with our qualified treatment centers, and such challenges could impact a qualified treatment center's willingness and ability to administer our products.

Furthermore, we may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the drug product back to the patient. Logistical and shipment delays and problems caused by us, our third-party vendors, and other factors not in our control, such as weather, could prevent or delay the manufacture of or delivery of drug product to patients. If our qualified treatment centers fail to perform satisfactorily, we may suffer reputational, operational, and business harm. Additionally, delays with infusion at the qualified treatment centers, due to, for instance, the patient's schedule or health condition or such center's capacity or the availability of manufacturing slots at our CMOs, or due to the need for multiple cell collections, could result in a patient becoming medically ineligible for our treatment or selecting an alternative treatment, the drug product becoming unusable and loss of medical coverage, which would have a material adverse effect on commercial sales. These delays may also impact our relationship with our qualified treatment center network. Any failure in our engagement or interaction with our qualified treatment centers due to delays in treatment or complications related to manufacturing, among other things, may limit patient access to our therapies and, accordingly, have a material adverse effect on our commercial forecasts and business.

We are required to maintain a complex chain of identity and chain of custody with respect to patient material as it moves through the manufacturing process, from the qualified treatment center to the transduction facility, and back to the patient. Failure to maintain chain of identity and chain of custody could result in adverse patient outcomes, loss of product or regulatory action.

The insurance coverage and reimbursement status of newly-approved products in the United States is uncertain. Due to the novel nature of our technology and the potential for our products to offer lifetime therapeutic benefit in a single administration, we face unique and additional challenges in obtaining adequate coverage and reimbursement for our products. Failure to obtain or maintain adequate coverage and reimbursement for any new or current product, including to the extent that payers 'non-prefer' any or all of our therapies to our competitors, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford healthcare, and especially expensive medicines, such as gene therapy products. Sales of our products depend substantially on the extent to which our products are covered by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or are reimbursed by government health administration authorities, private health coverage insurers and other payers. There is no assurance that payers will be willing to, or continue to, reimburse providers at the company-established list price or that reimbursement levels that payers will be willing to pay will be sufficient. Moreover, given that our therapies are generally administered in the inpatient care setting, it is important that our products are either

reimbursed as a separate item from the underlying services incurred during the patient's hospitalization or that, if reimbursement for our therapies is "bundled" with reimbursement for the hospital stay, the bundled payment rate adequately reflects the price of our therapy. We cannot assure you that payers will agree to either "separate reimbursement" or an appropriate bundled payment rate. Accordingly, the estimation of potential revenues is complex and it is difficult to predict what payers will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

In the U.S., regional Medicare Administrative Contractors ("MACs") are responsible for making a determination with regard to whether a new therapy meets the federal standard of "reasonable and necessary" such that it is covered and reimbursed by Medicare. For the Medicaid program, each State Medicaid Agency is responsible for establishing coverage criteria, billing policies, and reimbursement rates for FDA-approved drugs. Reimbursement methodologies in Medicare and Medicaid can vary based on the type of therapeutic agent and setting of care, and for Medicaid, the reimbursement methodologies also vary by state. There is uncertainty with this process both in terms of the timing of the decision-making process and the coverage decision itself. We anticipate that Medicaid coverage will be significant for the potential patient population for our products. On the other hand, we anticipate that Medicare coverage will be less significant, given that only a small percentage of our patient population may be Medicare eligible. We expect these patients may be dually eligible for Medicare and Medicaid based on meeting federally-established disability standards, in which case Medicare serves as the primary payer and Medicaid as the secondary payer for any service not otherwise covered by Medicare that is covered under a State's Medicaid program.

Moreover, increasing efforts by governmental and third-party payers to cap or reduce healthcare costs may cause such payers to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for ZYNTEGLO, SKYSONA, or LYFGENIA. The reimbursement policies of reinsurers, stop-loss carriers, and self-insured employers, including those that exclude coverage for gene therapies, could negatively impact our ability to market our therapies. We expect to experience pricing pressures in connection with the sale of our products due to greater scrutiny on list prices and total prescription drug spending across all payer channels as well as additional legislative changes at the state and federal level; moreover, public pressure from payers or negative public opinion regarding our list prices could affect the perception of our company and the value or cost-effectiveness of our therapies, which could impact our ability to successfully market our products. Further, net prices for drugs may be reduced by mandatory discounts or rebates required by government or private payers. As a result, increasingly high barriers are being erected to the entry of new products, often in the form of limiting the patient population for whom a new therapy is deemed "medically necessary." Even if coverage is provided, the amount payers are willing to reimburse may not be sufficient.

Furthermore, because a provider is responsible for costs associated not just with obtaining our medicines but also with the underlying hospital stay in which the administration of our therapies occurs, the pricing and reimbursement dynamics that impact patient access are not entirely within our control as providers and payers negotiate separately for the cost of the associated items and services, decisions in which we cannot and do not play a role. These services include the collection of HSCs from the patient, followed by chemotherapy and myeloablative treatments, and inpatient hospital stay following drug product infusion. If our customers are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our products will be adversely affected.

We have entered into and continue to engage with payers across all channels around outcomes-based contracts for ZYNTEGLO and LYFGENIA. In the event that a payer opts for the outcomes-based contract, we will need to reserve a certain portion of revenue from each sale to account for the potential that a rebate will be owed if the pre-established outcome metric is not achieved over a designated period of time, which differs depending on the product and the agreement, following drug product administration. The amount of revenue reserved for a potential rebate depends on the product and payer type; for instance, our outcomes-based contract for ZYNTEGLO could require us to remit up to 80% of the cost of the therapy to a payer based on patient outcomes achieved. In the event that rebates are due under these contracts, we may be required to adjust revenue previously recognized. Despite our efforts to engage with CMS and work with experts to ensure all of our payer contracting efforts comply with relevant federal and state regulations, including government price reporting obligations, given the complexity of these arrangements, it is not possible to completely mitigate the risk that our interpretation differs from that of the regulatory authorities such that we may not be able to satisfy the compliance requirements, which may result in significant fines and liability.

Collectively, these factors could affect our ability to successfully commercialize our products and generate or recognize revenues, which would adversely impact our business, financial condition, results of operations and prospects.

Risks related to the research and development of our products and any future product candidates

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced, safer or more effective than ours, which may adversely affect our financial condition and our ability to successfully develop and commercialize ZYNTEGLO, SKYSONA and LYFGENIA.

We are engaged in the development and commercialization of gene therapies for severe genetic diseases, which is a competitive and rapidly changing field. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, more experienced manufacturing capabilities, or more established commercial infrastructure. For instance, the FDA has approved a gene therapy for the treatment of sickle cell disease and beta thalassemia from Vertex Pharmaceuticals, Inc., which does not have a boxed warning and has a lower wholesale acquisition cost in the United States than that of LYFGENIA and ZYNTEGLO. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, safer, or less costly than any products that we may develop, or achieve patent protection, marketing approval, product commercialization and market penetration earlier than us. Additionally, technologies developed by our competitors may render our products or any future product candidates uneconomical or obsolete. As a result of any of these factors, we may not be successful in marketing our products against competitors.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our products and any future product candidates.

In order to obtain and maintain marketing approval from regulatory authorities for the commercialization of our products and future product candidates, we must conduct extensive clinical studies to demonstrate the safety, purity and potency, and/or efficacy, of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. There is a high failure rate for therapies proceeding through clinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical studies even after achieving promising results in earlier stage clinical studies. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development of our products and product candidates 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 or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, and QTCs participating in post-approval registry studies, 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 or ethics committee approvals at each clinical trial and/or QTC registry site;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our future product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of drug product or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;

- imposition of a clinical hold by regulatory agencies, including after review of an IND or amendment or equivalent foreign application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants or after an inspection of our clinical study operations or study sites or due to unforeseen safety issues;

- failure by our CROs, other third parties or us to adhere to clinical trial protocols or 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;

- occurrence of adverse events associated with the product or product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies, particularly due to the fact that we are required to follow patients in our clinical and registry studies for an extended period of time (up to 15 years);

- changes to the clinical trial protocols;

- clinical sites deviating from trial protocol or dropping out of a trial;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;

- the cost of clinical trials of our products or future product candidates being greater than we anticipate;

- clinical trials of our products or future product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;

- transfer of manufacturing processes to larger-scale facilities operated by a CMO and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; or

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted.

Further, conducting clinical trials in foreign countries, as we may do for our products or any future product candidates, presents additional risks that may delay completion of 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, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our products or product candidates.

Delays in the completion of any clinical trial of our products or product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence or continue product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We depend on enrollment of patients in our registry studies to complete required post marketing studies for our products, and on enrollment of patients in any future clinical trials we may conduct. If we experience delays or difficulties enrolling in our registry studies or any future clinical trials, our research and development efforts, business, financial condition, and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials, including additional trials that the FDA may require we complete prior to or as part of approval of our products or future product candidates, will require that we enroll a sufficient number of patient candidates. For instance, we are required to conduct long-term observational registry studies evaluating the safety of ZYNTEGLO, SKYSONA and LYFGENIA. These registry studies and other trials we may decide to conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the study or halt further development. If we are unable to complete required registry studies or any other post-marketing requirements under the terms specified by the FDA, we could be subject to FDA enforcement action, including restrictions on our ability to sell our products, misbranding charges and civil monetary penalties.

Additionally, any future clinical trials we may conduct could compete with other clinical trials that are in the same therapeutic areas as any future product candidates, and this competition could reduce the number and types of patients available to us, as some patients who might have opted to enroll in our trials or to receive our commercial therapies may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites for the patient populations we pursue may be limited, we may conduct one or more future clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of future clinical studies may further limit the pool of available study participants as we may require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;

- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our registry studies or any future clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial may increase our costs, slow down our development process and could delay, or potentially jeopardize, our ability to obtain and maintain required regulatory approvals, commercialize our products or any future product candidates and generate revenue.

Data from our clinical trials that we announce or publish from time to time may change as more patient data become available either through long-term patient follow-up and/or as such data are audited and verified, which could result in material changes to clinical and safety profiles for our products.

From time to time, we may disclose top-line, interim or preliminary data from our clinical trials. Such data from clinical trials that we may complete 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 for their disease. In addition, the clinical trials evaluating our products, and likely those evaluating any future product candidates, generally require that we continue to monitor and evaluate safety and efficacy in patients over an extended period of time following treatment, including for up to fifteen years for some studies, which may result in changes to the safety or efficacy profile over time. Changes in the efficacy and safety profile of our products or any future product candidates over time could significantly harm our business prospects including resulting in volatility in the price of our common stock.

Additionally, preliminary or top-line data 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 related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Interim data from clinical trials that we may conduct are further 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. As a result, the top-line, interim or preliminary 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. Further, disclosure of such data by us or by our competitors could also result in volatility in the price of our common stock. 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 product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular 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 others, including regulatory authorities, disagree with the conclusions reached with respect to such information and assessments, our ability to obtain approval for, and commercialize, our products and any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Although we have received accelerated approval from the FDA for SKYSONA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

In September 2022, SKYSONA received accelerated approval from the FDA and we may in the future seek accelerated approval for one or more future product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, one or more additional confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. For example, we agreed to provide confirmatory long-term clinical data to the FDA as a condition of the SKYSONA accelerated approval, and continued approval for the approved indication will be contingent upon verification of clinical benefit with confirmatory clinical data. Moreover, certain payers, including state Medicaid agencies, may scrutinize therapies that reach the market through accelerated approval, which can lead to delays in broader access after approval and require additional company resources to address any concerns.

In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, provided FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

We did not receive a priority review voucher in connection with the FDA approval of LYFGENIA and the FDA denied our request for an appeal through its Formal Dispute Resolution process.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

We obtained a rare pediatric disease designation for lovo-cel for the treatment of SCD and in October 2023, we entered into an agreement to sell a priority review voucher, if received by March 31, 2024, for $103.0 million. However, upon FDA approval of LYFGENIA in December 2023, we did not receive a priority review voucher. In October 2024, the FDA denied our request for an appeal of this decision through its Formal Dispute Resolution process. Although we are continuing to pursue this matter, there is no guarantee that we will receive the voucher. Moreover, the dispute process is time consuming and may result in substantial costs and distraction to our management. Because we did not receive a priority review voucher by March 31, 2024, the outside date under our previously announced sale agreement has passed and the buyer has the right to terminate the agreement at any time.

Our biological products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first 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. The 12-year exclusivity blocks the submission and approval of biosimilars under the abbreviated pathway only. 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. This exclusivity is only available to the "first licensure" of the reference biological product. If a biological product has a related structure to a previously licensed product from the same sponsor, it may not qualify as a first licensure. If LYFGENIA and ZYNTEGLO are considered to have a related structure, it is possible that LYFGENIA will not be granted its own 12-year exclusivity period and accordingly would be protected under ZYNTEGLO's 12-year exclusivity period.

Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our 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 factors that are still developing. This may further incentivize the development of competing versions or our products under the full BLA pathway rather than the biosimilars pathway.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our products and any future product candidates or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for our products and any future product candidates.

Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our products or any future product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in our clinical studies, potential regulatory delays in the testing or approval of our products or any future product candidates, stricter labeling requirements for our approved products, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our products or any future product candidates or reduce demand for any approved products.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA may also slow the time necessary for new drugs, medical devices and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

A Regenerative Medicine Advanced Therapy designation by the FDA, even if granted for any future product candidate, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that such future product candidate will receive marketing approval.

We have obtained Regenerative Medicine Advanced Therapy ("RMAT") designation for LYFGENIA for the treatment of SCD, and we may seek additional RMAT designations for our future product candidates. A biological product candidate is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, which the FDA defines as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) the candidate is intended to treat, modify, reverse, or cure a serious disease or condition; and (3) preliminary clinical evidence indicates that the candidate has the potential to address unmet medical needs for such disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review of BLAs. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or through reliance upon data obtained from a meaningful number of sites, including through expansion to a sufficient number of sites, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as appropriate, be able to fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

RMAT designation is within the sole discretion of the FDA. Accordingly, even if we believe one of our future product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to make such designation. RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the product candidate fails to meet the qualifications as clinical data continue to emerge.

We have obtained orphan drug designation for our products, but we may be unable to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our product revenue, if any, to be reduced.

We have obtained orphan drug exclusivity for certain diseases or conditions for LYFGENIA, ZYNTEGLO and SKYSONA. Under the Orphan Drug Act, the FDA may designate a biological product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, waivers from certain pediatric clinical trial requirements, and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product candidate receives the first FDA approval for the disease or condition for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for a disease or condition broader than the orphan designated disease or condition and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation for a future product candidate, we may not be the first to obtain marketing approval for any particular orphan disease or condition due to the uncertainties associated with developing pharmaceutical products. Further, we have received orphan drug exclusivity from the FDA for ZYNTEGLO for the treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell (RBC) transfusions; for SKYSONA for the slowing of progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy; and for LYFGENIA for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events. These orphan drug exclusivities, and any exclusivities we may obtain in the future may not effectively protect the product from competition because different drugs can be approved for the same disease or condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Risks related to our reliance on third parties

We rely on third parties to conduct some or all aspects of our LVV production, drug product manufacturing, and testing, and these third parties may not perform satisfactorily.

We do not independently conduct all aspects of our LVV production, drug product manufacturing, and testing. We currently rely, and expect to continue to rely, on third parties with respect to these items, including manufacturing and testing in the commercial context.

Our reliance on these third parties for manufacturing, testing, research and development activities reduces our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for products that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical studies are conducted in accordance with the study plan and protocols, and that our LVV and drug products are manufactured in accordance with GMP as applied in the relevant jurisdictions.

If these third parties do not successfully carry out their contractual duties, including as a result of insolvency, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or

manufacture our LVV and drug products in accordance with GMP, we will not be able to support commercialization of SKYSONA, ZYNTEGLO and LYFGENIA. Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us at any time. If we need to enter into alternative arrangements, our product development and commercialization activities could be delayed.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the products ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, including the inability to negotiate favorable terms to increase capacity to meet future forecasted demand;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- the risk that these activities are not conducted in accordance with our study plans and protocols, including the potential for failed product batches that have resulted, and may in the future result, in delays in treatment of patients;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including, for example, the bankruptcy or financial condition of the manufacturer or supplier.

We may be forced to manufacture LVV and drug product ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills required to manufacture our LVV or future product candidates may be unique or proprietary to the original manufacturer, and we may have difficulty or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Any of these events could lead to clinical study delays or impact our ability to obtain required regulatory approvals or successfully commercialize our products or any future product candidates. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our products, or those we may use for any future product candidates, are subject to extensive regulation. Some components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products or any future product candidates that may not be detectable in final product testing. We or our contract manufacturers must adhere to the FDA's or other regulator's good laboratory practices ("GLP"), and GMP regulations enforced by the FDA or other regulator through facilities inspection programs. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors may be required to successfully complete a pre-approval inspection for compliance with GMPs and other applicable regulations as a condition of certain regulatory approvals. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not successfully complete any required inspections, it is possible FDA or other marketing approvals may be delayed, prevented or otherwise adversely affected.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the

temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Further, any plans to expand our manufacturing capacity are subject to the review and approval of regulatory authorities and there is no guarantee that we will receive such approval on the timelines we anticipate. Delays in our expansion of manufacturing capacity could affect our ability to meet demand and could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulators can impose regulatory sanctions including, among other things, refusal to approve a pending application for a biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. The number of manufacturers with the necessary manufacturing capabilities is limited. In addition, an alternative manufacturer would need to be qualified through a BLA supplement or similar regulatory submission which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our products or any future product candidates, cause us to incur higher costs and prevent us from successfully commercializing our products or any future product candidates. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies or commercial production may be delayed and we could lose potential revenues.

We rely on third parties to conduct, supervise and monitor our clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical study sites to ensure our clinical studies are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol and in accordance with applicable GCPs, GLPs and other legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's and other regulatory authorities' GCPs for conducting, recording and reporting the results of clinical studies to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical studies may be deemed unreliable and the FDA and other regulatory authorities may require us to perform additional clinical studies before approving any marketing applications.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to successfully commercialize our products or any future product candidates. As a result, our financial results and the commercial prospects for our products or any future product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our vectors and our drug products, and because we collaborate with various organizations and academic institutions on the advancement of our gene therapy platform, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information.

These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks related to our financial condition and capital requirements

We have not generated material revenue from product sales and may never be profitable.

Our ability to generate revenues and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully commercialize ZYNTEGLO, SKYSONA and LYFGENIA and other potential future product candidates (if and when approved). Our ability to generate revenues from product sales depends heavily on our success in:

- developing a sustainable, commercial-scale, reproducible, and transferable manufacturing process for our vectors and drug products;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development for our product candidates and commercial demand for our approved products;
- launching and commercializing our approved products with a sustainable field-based team and marketing and distribution infrastructure;
- obtaining sufficient pricing and reimbursement for our approved products from private and governmental payers;
- obtaining market acceptance and adoption of our approved products and gene therapy as a viable treatment option;
- addressing any competing technological and market developments;
- completing research and preclinical and clinical development of future product candidates;
- seeking and obtaining regulatory and marketing approvals for future product candidates for which we complete clinical studies;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how.

We expect to continue to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase, which costs may increase further as competitors enter the market. Even if we are able to generate material product revenues, we may not become profitable and may need to obtain additional funding to continue operations.

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements are incorrect, our actual results may vary from those reflected in our projections and accruals.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct. We may be incorrect in our assumptions regarding the applicability of drug pricing programs and rebates that may be applicable to our products and future product candidates, which may result in our under- or over-estimating our anticipated product revenues especially as applicable laws and regulations governing pricing evolve over time. In addition, to the extent payment for our products and future product candidates is subject to outcomes-based arrangements over time, as it is for ZYNTEGLO and LYFGENIA, the total payments received from product sales may vary, our cash collection of future payments and revenue assumptions from product sales will be at risk, and the timing of revenue recognition will not correspond to the timing of cash collection.

Further, from time to time we issue financial guidance relating to our expectations for our cash, cash equivalents, and marketable securities available for operations, which guidance is based on estimates and the judgment of management. Moreover, our future net product revenues will depend upon the size of the markets in which the products have received approval, the ability to manufacture and deliver drug product to patients, the ability of such products to achieve sufficient market acceptance, reimbursement from third-party payers, adequate market share in those markets and performance of the drug product subject to outcome-based programs. If, for any reason, our expenses differ materially from our guidance or we utilize our cash more quickly than anticipated, we may have to adjust our publicly announced financial guidance. If we fail to meet, or if we are required to change or update any element of, our publicly disclosed financial guidance or other expectations about our business, including with respect to revenue generation, our stock price could decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We expect that revenues from product sales will be difficult to predict from period to period, given the absence of significant historical sales data for ZYNTEGLO, SKYSONA, and LYFGENIA.

Further, changes in our operations, such as undertaking of additional programs, or business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses.

The cumulative effects of these factors, further exacerbated by the impact of the ongoing volatility in macro-economic conditions, will likely result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

On March 15, 2024, we entered into a Loan and Security Agreement, by and among the Company, the several banks and other financial institutions or entities party thereto, as lenders (the "Lender"), and Hercules Capital, Inc., as administrative agent and collateral agent, which we amended on April 30, 2024, July 9, 2024, August 13, 2024 and August 29, 2024 (as amended, the "LSA"). The LSA provides a secured term loan facility of up to $175.0 million (collectively, the "Term Loans"), consisting of: (a) an initial tranche of term loans in an aggregate amount of $75.0 million, which was funded at closing (the "Initial Loan"); (b) an additional tranche of term loans in an aggregate amount of $25.0 million, which will be available, subject to customary terms and conditions, during the period commencing on the date the Company has (x) received at least $75.0 million in gross cash proceeds from qualified financing transactions by December 20, 2024 and (y) completed patient starts (cell collections) for at least 50 LYFGENIA patients by March 31, 2025 or 70 LYFGENIA patients by June 30, 2025 (the "Tranche 2 Milestone") and ending on the earlier of (i) the date that is 30 days immediately following achievement of the Tranche 2

Milestone and (ii) July 31, 2025; (c) an additional tranche of term loans in an aggregate amount of $25.0 million, which will be available, subject to customary terms and conditions, during the period commencing on the date the Company has (x) received at least $100.0 million in gross cash proceeds from qualified financing transactions by December 20, 2024 or at least $125.0 million by June 30, 2025 and (y) completed 70 drug product deliveries within a given six-month period ending no later than December 31, 2025, at least 40 of which are for LYFGENIA (the "Tranche 3 Milestone") and ending on the earlier of (i) the date that is 30 days immediately following the date the Company achieves the Tranche 3 Milestone and (ii) December 31, 2025; and (d) an additional tranche of term loans of $50.0 million, available in the sole discretion of the lenders, and subject to customary terms and conditions, until December 15, 2026. Although our entry into the LSA and receipt of funds thereunder extends our cash runway, our outstanding indebtedness, including any additional indebtedness beyond our borrowings under the LSA, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product candidate development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

The Term Loans are secured by a lien on substantially all of our assets. We intend to satisfy our current and future debt service obligations with our then-existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the LSA or any other debt instruments. Failure to make payments or comply with other covenants under the LSA or such other debt instruments could result in an event of default and acceleration of amounts due. Other events of default under the LSA include, among others: (i) the occurrence of any event that the Lender interprets as a material adverse effect (including potentially with respect to our declining cash position or negative data results), (ii) a change in control as delineated under the Loan Agreement, and (iii) breaches of covenants in the LSA, including, among others, a minimum cash coverage requirement and a covenant that requires us to meet certain revenue levels; if we do not meet our projections, we may be unable to satisfy these covenants. For example, the Company projects that it may not maintain its minimum cash coverage requirement within the next 12 months. Upon the occurrence and continuance of an event of default, the Lender has the right to require us to repay the Term Loans immediately, which we would be unable to do given our current cash position. Any declaration by the Lender of an event of default would significantly harm our business and prospects and could cause the price of our common stock to decline or force us to discontinue our operations immediately and seek bankruptcy protection. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Amounts under our factoring arrangement are subject to terms that may adversely affect our operations and financial condition.

We entered into an accounts receivable factoring agreement in December 2023. The factoring agreement provides for us to have access to up to $100.0 million on a revolving basis, measured by the outstanding balance of purchased accounts from time to time. Upon receipt of the upfront purchase price for any purchased accounts, we will have sold and assigned all of our rights in such purchased accounts and all proceeds thereof. The buyer has the right to require that we repurchase any purchased account that was ineligible as of the date of purchase or with respect to which any account debtor asserts a dispute that is not resolved by the related due date. The buyer does not have recourse to us for the insolvency or other credit risk of the account debtors. We have granted the buyer a security interest in the purchased accounts, and proceeds thereof, as more fully described in the agreement, in order to perfect the buyer's ownership interest in the purchased accounts and secure the payment and performance of all our obligations to the buyer under the agreement. If the buyer demands repurchase and we fail to do so, or if we cause or permit any other event of default as defined in the agreement, or fail to comply with covenants set forth in the

agreement, we would be subject to additional expenses and lose access to this agreement to fund further accounts receivable. Such results could have a material adverse effect on our operations and financial condition.

Risks related to our business operations

Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel.

We are highly dependent on our executive team and key employees, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success, and our financial condition has made it more challenging to recruit and retain qualified personnel. In addition, there is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and our turnover rate has been high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives.

Our restructuring and reduction in force undertaken to optimize our cost structure may not achieve our intended outcome.

In September 2024, we implemented a restructuring plan designed to support our commercial focus and reduce our cash operating expenses. This restructuring plan included a reduction of our workforce by approximately 25% of our headcount. These reductions in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the reductions in force, or if we experience significant adverse consequences from the reductions in force, our business, financial condition, and results of operations may be materially adversely affected. We may undertake further similar cost-saving initiatives, which may include additional restructuring or workforce reductions. These types of cost-reduction activities can be complex and result in unintended consequences and costs, including further attrition beyond the intended number of employees due to decreased employee morale, loss of institutional knowledge and expertise and adversely impact our business.

Our products remain subject to regulatory scrutiny.

For any regulatory approvals that we have or may receive, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products and/or any future product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we may conduct. 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 cGMP regulations and standards. Even though we have obtained regulatory approval in the U.S. for ZYNTEGLO, SKYSONA and LYFGENIA, any regulatory approvals we receive will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such product, and such approvals 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 typically advises that patients treated with integrating gene therapy undergo follow-up observations for potential adverse events for a 15-year period. Furthermore, we have agreed to provide confirmatory long-term clinical data to the FDA as a condition of the SKYSONA accelerated approval, and continued approval for the approved indication will be contingent upon verification and description of clinical benefit in a confirmatory trial. If our confirmatory trials fail to adequately verify or describe the anticipated clinical benefit of SKYSONA, or if we fail to conduct such trials in a timely manner, the FDA could withdraw its approval for SKYSONA on an expedited basis.

Additionally, the holder of an approved BLA is obligated to monitor and report adverse events. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject

to FDA review, in addition to other potentially applicable federal and state laws. We have experienced interruptions in clinical programs due to safety concerns arising from our SKYSONA and LYFGENIA programs, and we can make no assurance that we will not experience interruptions in any clinical studies, marketing or other commercialization activities in the future, whether due to safety concerns in any approved or investigational products, or due to events arising from programs that utilize technologies similar to or related to ours.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices ("GMP") and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following marketing approval for a product, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical studies;
- refuse to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved product and generate revenues.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any future product candidates we develop. We also 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 be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs and biologics. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe, pure and potent, or effective, by the FDA. For example, the current FDA-approved indication for ZYNTEGLO is limited to the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell transfusions; the FDA-approved indication for SKYSONA is limited to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active CALD, which is defined to include to asymptomatic or mildly symptomatic (neurologic function score, NFS $\leq$ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging and Loes scores of 0.5-9; and the FDA-approved indication for LYFGENIA is limited to the treatment of sickle cell disease in patients ages 12 and older who have a history of VOEs.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory

authorities, our ability to manufacture and promote any products will be narrowly limited to those indications that are specifically approved by the FDA. If we are found to have manufactured and promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any of our products, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and false claims laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, reputational harm, and diminished profits and future earnings.

In the United States, the research, manufacturing, distribution, sale, and promotion of drugs and biologic products are subject to regulation by various federal, state, and local authorities in addition to FDA, including CMS, other divisions of the HHS, (e.g., the Office of Inspector General), the United States Department of Justice offices of the United States Attorney, the Federal Trade Commission and state and local governments. Our operations are directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations.

These laws apply to, among other things, our sales, marketing, patient services and educational programs and include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the False Claims Act, or FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statutes or specific intent to violate them;

- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical

nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous or related foreign, state or local laws and regulations, including anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have recently increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co-pay support, funding of independent charitable foundations and other programs that offer benefits for patients. Several investigations into these programs have resulted in significant civil and criminal settlements. In addition, in July 2024, the Office of Inspector General (OIG) issued two negative opinions to pharmaceutical companies seeking to offer fertility support for gene therapy patients insured by Medicaid and other federal healthcare programs. OIG stated that it lacked data to conclude that the fertility support programs would pose a sufficiently low risk of fraud and abuse under the federal Anti-Kickback Statute to grant prospective immunity.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations (collectively, "HIPAA"), imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of

individually identifiable health information. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data), which are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA") requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission ("FTC") has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of the FTC Act. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. The FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive, including by. regulating the presentation of website content.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, the European Union General Data Protection Regulation ("GDPR") went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area ("EEA"). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses ("SCCs") - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, after the end of the transition period following the United Kingdom's departure from the European Union, we are also subject to the United Kingdom data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the United Kingdom Extension to the DPF came into effect (as approved by the United Kingdom Government), as a data transfer mechanism from the United Kingdom to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and

fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in governmental programs that impose extensive drug price reporting and payment obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program (the "MDRP"), as a condition of federal funds being made available for our covered outpatient drugs under Medicaid and certain drugs or biologicals under Medicare Part B, we pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the Average Manufacturer Price ("AMP") for each drug and, in the case of innovator products, best price. In connection with Medicare Part B, a pharmaceutical manufacturer must provide CMS with average sales price ("ASP") information for certain drugs or biologicals on a quarterly basis. ASP is calculated based on a statutorily defined formula, as well as regulations and interpretations of the statute by CMS. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information on a timely basis or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, in which case payment would not be available for our covered outpatient drugs under Medicaid or, if applicable, Medicare Part B.

Federal law requires that any company that participates in the MDRP also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program is administered by HRSA and requires us, as a participating manufacturer, to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs when used in an outpatient setting.. To date, bluebird's therapies have been administered in the inpatient setting exclusively and we anticipate that most patients will continue to receive bluebird's therapies in an inpatient setting. However, in the event that patients are treated in an outpatient setting, the 340B "ceiling price" requirement may apply to these transactions if otherwise eligible under 340B legal standards. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low income patients. A drug that is designated for a rare disease or condition by the Secretary of Health and Human Services is not subject to the 340B ceiling price requirement with regard to the following types of covered entities: rural referral centers, sole community hospitals, critical access hospitals, and free standing cancer hospitals. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized a revised administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. In addition, legislation may be introduced that, if enacted, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we must also participate in the VA/FSS pricing program. Under the VA/FSS program, we must report the Non-FAMP for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If we fail to provide timely information or are found to have knowingly submitted false information, we may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and states may impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with

drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase our costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or undercharge in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B, if applicable, for our covered outpatient drugs. Pursuant to the Inflation Reduction Act of 2022 (the "IRA"), the AMP figures we report will also be used to compute rebates under Medicare Part D triggered by price increases that outpace inflation. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our products or product candidates harm patients, or is perceived to harm patients even when such harm is unrelated to our products or product candidates, our marketing approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of products and product candidates in clinical studies and the sale of products for which we have obtained marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients participating in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products and any future product candidates. There is a risk that our products and any future product candidates may induce adverse events. For instance, each of the LYFGENIA and SKYSONA product labels includes a boxed warning for the risk of hematologic malignancy. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to develop our product candidates or commercialize any approved product; and
- decreased demand for any approved product.

We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs and approved products; however, we may not be able to maintain insurance coverage at commercially reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our products and product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our products and product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain marketing approval for any approved product, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an

adverse event is related to our products and product candidates the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our marketing approval process in other countries, or impact and limit the type of marketing approval our product candidates may receive or our approved products maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental and social matters has resulted in the adoption of new laws and regulations, including new reporting requirements, and may result in the adoption of additional laws and regulations in the future. New reporting requirements may be particularly difficult or expensive to comply with and, if we fail to comply, we may be required to issue financial restatements, suffer harm to our reputation or otherwise have our business be adversely impacted. Such ESG matters may also impact our suppliers or patients, which may adversely impact our business, financial condition and results of operations.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States has enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell products for which we have obtained marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; (iv) additional record-keeping requirements; or (v) directly or indirectly limit the net price of sales to federal healthcare programs that form a substantial portion of our business. If any such changes were to be imposed, they could adversely affect the operation of our business.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the level of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. For example, in March 2010, the Affordable Care Act ("ACA") was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care plans; established a Medicare Part D coverage gap discount program (to be replaced by a new program in 2025, as discussed below); subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, led to

reductions of Medicare payments to providers, which will remain in effect through 2032 unless additional Congressional action is taken. More recently, in March 2021, President Biden signed into law the American Rescue Plan Act of 2021, which eliminated the statutory cap on the Medicaid drug rebate beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

Most significantly, in August 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026); imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. HHS has issued and will continue to issue and update guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

In addition, the Center for Medicare and Medicaid Innovation initiated the Cell and Gene Therapy ("CGT") Access Model in 2023. This voluntary payment model is designed to test whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies would improve Medicaid beneficiaries' access to innovative treatment. If CMS proceeds with implementing the CGT model as currently anticipated, states may begin to participate in the model in 2025. The possible impact of the CGT model is uncertain.

At the U.S. state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or provider reimbursement constraints, patient out-of-pocket cost caps for certain classes of therapy, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payers.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products and any future product candidates. Such reforms could have an adverse effect on anticipated revenue from products and any future product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop such future product candidates.

Our information technology systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of any future product candidates' development programs and activities related to our approved products and have a material adverse effect on our reputation, business, financial condition or results of operations.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including our mobile and web-based applications, our e-commerce platform and our enterprise software. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data, and personal information (collectively, "Confidential Information") of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Our information technology systems and those of our current or future third-party collaborators, service providers, contractors and consultants may fail and are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), misconfigurations, "bugs" or other vulnerabilities, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-

state-supported actors or unauthorized access or use by persons inside our organizations, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. The prevalent use of mobile devices and unauthorized applications also increases the risk of data security incidents. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our current or future third-party collaborators', service providers', contractors' and consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if we were to experience a system failure, accident or security breach that causes interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in significant reputational, financial, legal, regulatory, business or operational harm. For example, the loss of clinical trial data for any future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or our products and any future product candidates, or inappropriate disclosure of Confidential Information, we could incur liabilities and the further development of any future product candidates could be delayed. In addition, we rely on third-party service providers for management of the manufacture and delivery of drug product to patients in the commercial context, including for chain of identity and chain of custody. We also rely on third-party service providers for aspects of our internal control over financial reporting and such service providers may experience a material system failure or fail to carry out their obligations in other respects, which may impact our ability to produce accurate and timely financial statements, thus harming our operating results, our ability to operate our business, and our investors' view of us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to material failures, security breaches, cyberattacks and other related breaches.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us. These events could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Risks related to the separation of our oncology programs and portfolio

We may incur operational difficulties or be exposed to claims and liabilities as a result of the separation of 2seventy bio.

On November 4, 2021, we distributed all of the outstanding shares of 2seventy bio, Inc. ("2seventy") common stock to our stockholders in connection with the separation of our oncology programs and portfolio. In connection with the distribution, we entered into a separation agreement and various other agreements (including a tax matters agreement, an employee matters agreement, transition services agreements and an intellectual property license agreement). These agreements govern the separation and distribution and the relationship between us and 2seventy going forward, including with respect to the assignment and assumption of assets and liabilities and potential tax-related losses associated with the separation and distribution. They also provide for the performance of services by each company for the benefit of the other for a period of time.

As a result of the separation, we remain contractually liable in connection with certain agreements transferred to 2seventy; for instance, we may be liable in the event of a breach by 2seventy of an assigned lease agreement, which could result in material expenses. Although the separation agreement provides for indemnification obligations designed to make 2seventy financially responsible for many liabilities that may exist relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation, we cannot guarantee that 2seventy will be able to satisfy its indemnification obligations, including as related to the lease agreement. It is also possible that a court would disregard the allocation agreed to between us and 2seventy and require us to assume responsibility for obligations allocated to 2seventy. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to 2seventy, including those related to assets or liabilities allocated to us, may be significant. These risks could negatively affect our business, financial condition or results of operations.

If the distribution of shares of 2seventy, together with certain related transactions, does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

The completion of the distribution of shares of 2seventy was conditioned upon, among other things, our receipt of a private letter ruling from the U.S. Internal Revenue Service (the "IRS"), and an opinion from Goodwin Procter LLP, both satisfactory to our board of directors and both continuing to be valid, together confirming that the distribution, together with certain related transactions, generally is tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). We have received a favorable private letter ruling from the IRS addressing one significant issue of the qualification of the distribution under Section 355 of the Code. However, the private letter ruling does not address the remaining issues that are relevant to determining whether the distribution, together with certain related transactions, qualifies as a transaction that is generally tax-free for U.S. federal income tax purposes. This can include events that occur following the distribution such as subsequent public offerings by us or 2seventy or share sales to persons that engaged in negotiations over share purchases prior to the distribution. Subsequent tax opinions have been obtained by us and 2seventy in connection with certain post-distribution sales of 2seventy's shares. The IRS private letter ruling, the opinion of Goodwin Procter LLP and tax opinions related to certain subsequent post-distribution sales of 2seventy shares were based, among other things, on various facts and assumptions, as well as certain representations, statements and undertakings from us and 2seventy (including those relating to the past and future conduct of us and 2seventy) and were subject to certain caveats. If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or 2seventy breach any of our respective covenants relating to the separation, the IRS private letter ruling and tax opinion may be invalid. Moreover, the opinion is not binding on the IRS or any courts. Accordingly, notwithstanding receipt of the IRS private letter ruling and an opinion of Goodwin Procter LLP at the time of the distribution, the IRS could determine that the distribution and certain related transactions should be treated as taxable transactions for U.S. federal income tax purposes.

If the distribution, together with certain related transactions, were to fail to qualify as a transaction that is generally tax-free under Sections 355 and 368(a)(1)(D) of the Code, in general, for U.S. federal income tax purposes, we would recognize taxable gain as if we have sold 2seventy’s distributed common stock in a taxable sale for its fair market value and our stockholders who receive shares of 2seventy common stock in the distribution would be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares.

In connection with the distribution, we and 2seventy entered into a tax matters agreement pursuant to which each party is responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, if the distribution, together with certain related transactions, were to fail to qualify as a transaction that is generally tax-free for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Code, and if and to the extent that such failure results from a prohibited change of control in us under Section 355(e) of the Code, or an acquisition of our stock or assets or certain actions, omissions or failures to act, by us, then we will bear any resulting taxes, interest, penalties and other costs. If and to the extent that such failure results from a prohibited change of control in 2seventy under Section 355(e) of the Code or an acquisition of 2seventy stock or assets or certain actions by 2seventy, then 2seventy will be obligated to indemnify us for any resulting taxes, interest, penalties and other costs, including any reductions in our net operating loss carryforwards or other tax assets. If such failure does not result from a prohibited change of control in us or 2seventy under Section 355(e) of the Code and both we and 2seventy are responsible for such failure, liability will be shared according to relative fault. If neither we nor 2seventy is responsible for such failure, we will bear any resulting taxes, interest, penalties and other costs.

Risks related to our intellectual property

If we are unable to obtain or protect intellectual property rights related to our products, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our products, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold or have in-licensed with respect to our programs or our products fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our products, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our current and future products. Several patent applications covering our products have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any future product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available however the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, and information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the U.S. Patent and Trademark Office ("U.S. PTO") and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products may be subject to claims of infringement of the patent rights of third parties.

Third parties have asserted and in the future may assert that we are employing their proprietary technology without authorization. For example, as discussed in Part II, Item 1, "Legal Proceedings", San Rocco Therapeutics, LLC, formerly known as Errant Gene Therapeutics, LLC has alleged that our use of the BB305 lentiviral vector, including in connection with the beti-cel program infringes U.S. Patent Nos. 7,541,179 and 8,058,061, and seeks equitable, injunctive and monetary relief, including royalties, treble damages, attorney fees and costs. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further commercialize one or more of our products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorney's fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to gene therapy product components and processes for our programs through acquisitions and in-licenses.

Presently we have rights to the intellectual property, through licenses from third parties and under patents that we own, to manufacture and commercialize our products. Because our programs may involve additional technologies that may 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 proprietary rights. For instance, we may elect to leverage advancements in complementary technologies such as in reduced toxicity conditioning or in stem cell mobilization. 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. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or clinical development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

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. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. Pursuant to an intellectual property license agreement with 2seventy, we granted sublicenses to 2seventy to certain existing license agreements. If we fail to comply with our obligations under these agreements, we or 2seventy materially breach these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance the development of future product candidates or allow commercialization of our products, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products or product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our approved products, or future products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected approved products or product candidates.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products and product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact 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.

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

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We have had in the past, and we may also have in the future, ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our products and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or

ownership. 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our potential products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

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

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

Risks related to ownership of our common stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the price at which you purchase them.

Companies trading in the stock market in general, and The Nasdaq Global Select Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and biotechnology and pharmaceutical industry factors, such as the recent volatility and disruption experienced in the global economy and rising interest and inflation rates, may negatively affect the market price of our common stock, regardless of our actual operating performance.

The market price of our common stock has been volatile in the past, and may continue to be volatile for the foreseeable future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in preclinical or clinical studies;
- reports of adverse events, either from patients participating in our clinical trials or in connection with sales of our commercial products or other gene therapy products in the market;
- inability to obtain additional funding;
- failure to successfully manage and sustain the commercial launch of ZYNTEGLO, SKYSONA or LYFGENIA, including failure to manage our supply chain operations in the coordination and delivery of drug product to patients at qualified treatment centers;
- failure to obtain sufficient pricing and reimbursement for ZYNTEGLO, SKYSONA or LYFGENIA from private and governmental payers;
- failure to obtain market acceptance and adoption of ZYNTEGLO, SKYSONA or LYFGENIA;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;
- inability to obtain adequate product supply for ZYNTEGLO, SKYSONA or LYFGENIA, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- announcements of clinical trial results or progress in the development of programs by our competitors, and the introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partner 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 scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- global macroeconomic conditions, including as impacted by geopolitical conflicts and war;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

The restatement of our consolidated financial statements for the year ended December 31, 2022 and the quarterly periods in the years ended December 31, 2022 and 2023 has subjected us to a number of additional risks and uncertainties, including increased possibility of legal proceedings.

As discussed elsewhere in this Quarterly Report, our management determined that our consolidated financial statements for the year ended December 31, 2022 and the quarterly periods in the years ended December 31, 2022 and 2023 should be restated due to errors relating to our accounting for lease arrangements, including embedded leases, and the application of our accounting policy for the treatment of non-lease components in lease arrangements, including embedded leases. The restatement of our consolidated financial statements has caused us to incur substantial expenses for legal, accounting, and other professional services and has diverted our management's attention from our business and could continue to do so. As a result of the restatement, we were delayed in filing our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for each of the three-month periods ended March 31, 2024 and June 30, 2024. There can be no assurance that we will be able to timely file our required reports for future periods. In addition, as a result of the restatement, investors may lose confidence in our financial reporting, the price of our common stock could decline and we may be subject to litigation or regulatory enforcement actions.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. We identified a material weakness in our internal controls related to our accounting for lease arrangements, including embedded leases, and the application of our accounting policy for the treatment of non-lease components in lease agreements, including embedded leases. The material weakness resulted in the restatement of the Company's previously issued consolidated financial statements for the year ended December 31, 2022 and the quarterly periods in the years ended December 31, 2022 and 2023. As a result of the material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2023. Additionally, the material weakness in our internal control over financial reporting has resulted in our management concluding that our disclosure controls and procedures were not effective as of December 31, 2023.

Our management, under the oversight of the Audit Committee of our Board of Directors and in consultation with outside advisors, has begun evaluating and implementing measures designed to remediate the material weakness. Management intends to implement enhancements to its internal control over financial reporting, which are expected to include refinements and enhancements to the complement of personnel, design and operation of its controls related to the accounting for, and identification of, leases. The Company intends to begin to implement these enhancements to the design of its controls during 2024. However, this material weakness will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The Company will monitor the effectiveness of the remediation plan and will refine the remediation plan, as needed. Until remediated, the material weakness could result in future errors to the Company's financial statements.

In addition, we cannot assure you that the measures we are taking will be sufficient to remediate the material weakness or avoid the identification of additional material weaknesses in the future. Our failure to implement and maintain effective internal

control over financial reporting could result in the identification of additional errors in our consolidated financial statements that could result in a further restatement of our financial statements and could cause us to fail to meet our periodic reporting obligations, any of which could diminish investor confidence in us, cause a decline in the price of our common stock and subject us to litigation or regulatory enforcement actions.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

On April 24, 2024, we received a notification from the listing qualifications department of Nasdaq indicating that as a result of the untimely filing of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, we were not in compliance with the requirements for continued listing under Listing Rule 5250(c)(1) (the "Filing Listing Rule"), which requires listed companies to timely file all required periodic financial reports with the SEC. On July 15, 2024, Nasdaq granted us a grace period of 180 calendar days from the due date of the Form 10-K, or until October 14, 2024, in which to regain compliance with the Filing Listing Rule. On August 20, 2024, we received additional notifications from Nasdaq with respect to the untimely filing of our Quarterly Reports on Form 10-Q for each of the three-month periods ended March 31, 2024 and June 30, 2024.

Although we have completed our delayed filings and regained compliance with the Filing Listing Rule, there can be no assurance that we will regain compliance with the bid price requirement, as described below, or that we will not receive future notifications regarding noncompliance with any of the requirements for continued listing on Nasdaq.

On September 30, 2024, we received written notice from the listing qualifications department of Nasdaq notifying us that, for the last 32 consecutive business days, the bid price for our common stock had closed below the $1.00 minimum bid price requirement for continued inclusion on the Nasdaq Global Select Market. The notice had no immediate effect on the listing of our common stock, which continues to trade on the Nasdaq Global Select Market under the symbol "BLUE". Pursuant to the Nasdaq listing rules, we were provided a period of 180 calendar days, or until March 31, 2025, to regain compliance with the minimum closing bid price requirement of at least $1.00 per share for a minimum of 10 consecutive business days. If we do not regain compliance with this requirement by March 31, 2025, we may be eligible for an additional 180-calendar day compliance period by transferring the listing of our common stock to the Nasdaq Capital Market and satisfying certain requirements. To qualify for the additional grace period, we would be required to submit a transfer application for transfer between Nasdaq market tiers and pay an application fee. In addition, we would be required to meet the continued listing requirement for the market value of our publicly held shares and all other applicable initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second grace period. If we fail to regain compliance during the compliance period (including a second compliance period provided by a transfer to the Nasdaq Capital Market, if applicable), then Nasdaq will notify us of its determination to delist our common stock, at which point we may appeal Nasdaq's delisting determination to a Nasdaq hearing panel or pursue other available options to regain compliance.

We intend to actively monitor the closing bid price of our common stock and we are considering all available options to regain compliance with the minimum bid price requirement. We are seeking stockholder approval to effect a reverse stock split and have adjourned our 2024 Annual Meeting of Stockholders to December 4, 2024, for the purpose of soliciting additional votes in support of this proposal. However, there can be no assurance that any such reverse stock split, if approved by the stockholders and implemented, would increase the market price of our common stock in proportion to the reverse split ratio or result in a sustained increase in the market price of our common stock. In addition, it is possible that the reduced number of issued shares of common stock resulting from such a reverse stock split could adversely affect the liquidity of our common stock. There can also be no assurance that we will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, maintain compliance with the other Nasdaq listing requirements, or be successful in appealing any delisting determination.

If we fail to comply with Nasdaq's continued listing requirements, our common stock could be delisted from Nasdaq. The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely lead to a limited amount of analyst coverage, have a negative effect on the price of our common stock and impair our stockholders' ability to sell or purchase our common stock. In addition, a delisting could cause our stock to be deemed a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities.

Actual or potential sales of our common stock by our employees, including our executive officers, pursuant to pre-arranged stock trading plans could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, and our policies regarding stock transactions, a number of our employees, including executive officers and members of our board of directors, have adopted and may continue to adopt stock trading plans pursuant to which they have arranged to sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors require public filings. Actual or potential sales of our common stock by such persons could cause the price of our common stock to fall or prevent it from increasing for numerous reasons.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. 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. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2023 Incentive Award Plan (as amended and restated, the "2023 Plan") we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The 2023 Plan authorizes the issuance of up to 20.2 million shares. We also make equity grants to certain new employees joining the Company pursuant to an inducement plan, and our compensation committee may elect to increase the number of shares available for future grant under the inducement plan without stockholder approval. We also have an Employee Stock Purchase Plan and any shares of common stock purchased pursuant to that plan will also cause dilution.

We may be subject to litigation, which may result in substantial costs and a diversion of management's attention and resources, which could harm our business.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and we have in the past litigated class action complaints in the United States District Court for the District of Massachusetts and for the District of Delaware, filed by purported stockholders against us and certain of our directors and officers. For instance, on March 28, 2024, a class action lawsuit captioned Garry Gill v. bluebird bio, Inc. et al., Case No. 1:24-cv-10803-PBS, was filed against us in the United States District Court for the District of Massachusetts and we may face additional securities class action litigation in the future. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years, and we expect to experience continued stock price volatility. Separately, two purported bluebird shareholders, derivatively and purportedly on behalf of bluebird, have each filed a shareholder derivative action in the United States District Court for the District of Massachusetts against our directors and certain members of management alleging, among other things, breaches of their fiduciary duties. Defending against our current and any future litigation could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

We are also a party to litigation and subject to claims incident to the ordinary course of business. The outcome of litigation is inherently unpredictable and an adverse result in any litigation could materially harm our financial condition, reputation and business. Regardless of the outcome, litigation can have an adverse impact on us because of defense costs, diversion of management resources and other factors.

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

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change,” generally defined as a cumulative change of greater than 50% (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards ("NOLs") and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited. We have completed several financings since our inception, which we believe have resulted in shifts in our equity ownership. We completed a study through December 2023 confirming no ownership changes have occurred since our initial public offering in 2013. We may have experienced ownership changes since December 2023, and we may also experience ownership changes in the future as a result of

subsequent shifts in our equity ownership, some of which are outside our control. There is a significant likelihood that we will experience an ownership change as a result of future equity offerings, although whether we experience an ownership change will depend on the specific facts that apply at the time of any offering. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or other pre-change tax attributes if we undergo a future ownership change. Accordingly, 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 may be subject to limitations, which could potentially result in significant increased future tax liability to us, which could materially adversely affect our profitability and cash position. In addition, at the state level, there may be periods during which the use of NOLs and other pre-change tax attributes is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We do not intend to pay cash dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and by-laws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation, amended and restated by-laws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and by-laws, include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation and amended and restated by-laws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated certificate of incorporation and amended and restated by-laws specify that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders, other than suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the "Exchange Act") or any other claim for which the federal courts have exclusive jurisdiction and any action that the Court of Chancery of the State of Delaware has dismissed for lack of subject matter jurisdiction, which may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated by-laws also specify that, unless we consent in writing to the selection of an alternate forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"). Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated by-laws described above.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes or federal judges experienced in resolving Securities Act disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees, and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees, or agents and result in increased costs for stockholders to bring a claim. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and by-laws has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation and amended and restated by-laws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation or amended and restated by-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

Changes in tax law and regulations could adversely affect our business, financial condition and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future earnings. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, potentially with retroactive effect, could have an adverse effect on our business, financial conditions and results of operations. We are unable to predict whether such changes will occur and, if so, the ultimate impact on our business. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, fluctuating interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates, geopolitical conflicts and war, and uncertainty about economic stability. If the equity and credit markets continue to deteriorate or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers or other third-party providers may not survive an economic downturn or recession. As a result, our business, results of operations and price of our common stock may be adversely affected.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

(a) None.

(b) None.

(c) During the quarter ended September 30, 2024, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth in the Exhibit Index below, which is incorporated herein by reference.

Exhibit Index

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File no.	Exhibit	Filing Date
2.1*	Separation Agreement, dated as of November 3, 2021, by and between the Registrant and 2seventy bio, Inc.	8-K	001-35966	2.1	November 4, 2021
2.2*	Asset Purchase Agreement, dated as of November 29, 2022, by and between bluebird bio, Inc. and argenx BV	8-K	001-35966	2.1	November 30, 2022
2.3*	Asset Purchase Agreement, dated as of January 5, 2023, by and between bluebird bio, Inc. and Bristol-Myers Squibb Company	8-K	001-35966	2.1	January 6, 2023
2.4*	Asset Purchase Agreement, dated as of October 26, 2023, by and between bluebird bio, Inc. and Novartis Pharma AG	8-K	001-35966	2.1	October 30, 2023
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-35966	3.1	June 24, 2013
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-35966	3.1	June 20, 2023
3.3	Amended and Restated By-laws of the Registrant	8-K	001-35966	3.1	December 18, 2023
4.1	Specimen Common Stock Certificate	S-1/A	333-188605	4.1	June 4, 2013
4.2**	Form of Warrant Agreement	8-K	001-35966	4.1	August 14, 2024
4.3	Form of Warrant Agreement Amendment	8-K	001-35966	4.2	August 14, 2024
10.1	Second Amendment to Loan and Security Agreement, dated as of July 9, 2024, between the Registrant, as Borrower, and Hercules Capital, Inc., as Lender	8-K	001-35966	10.1	July 11, 2024
10.2	Third Amendment to Loan and Security Agreement, dated as of August 13, 2024, between the Registrant, as Borrower, and Hercules Capital, Inc., as Lender	8-K	001-35966	10.1	August 14, 2024
10.3	Fourth Amendment to Loan and Security Agreement, dated as of August 29, 2024, between the Registrant, as Borrower, and Hercules Capital, Inc., as Lender	8-K	001-35966	10.1	August 30, 2024
10.4**†	Master Services Agreement for Viral Vector Services, dated as of September 15, 2024, between the Registrant and Henogen SRL, as part of Thermo Fisher Scientific	—	—	—	Filed herewith
10.5#	bluebird bio, Inc. 2023 Incentive Award Plan, as amended and restated, and forms of award agreements thereunder	—	—	—	Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
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.	—	—	—	Furnished herewith
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)				Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)	—	—	—	Filed herewith

* Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant will furnish copies of any such schedules and exhibits to the SEC upon request.

** Exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant will furnish copies of any such exhibits to the SEC upon request.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

bluebird bio, Inc.

Date: November 14, 2024

By: /s/ Andrew Obenshain

Andrew Obenshain
President, Chief Executive Officer and Director
(Principal Executive Officer and Duly Authorized Officer)

Date: November 14, 2024

By: /s/ O. James Sterling

O. James Sterling
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.4

MASTER SERVICES AGREEMENT for VIRAL VECTOR SERVICES

THIS MASTER SERVICES AGREEMENT (this "**MSA**") is effective as of September 15, 2024 ("**Effective Date**") between Henogen SRL, part of Thermo Fisher Scientific with offices located at 16 rue Clement Ader 6041 Gosselies Belgium ("**Patheon**") and bluebird bio, Inc., a Delaware corporation, with offices located at 455 Grand Union Boulevard, Somerville, MA 02145 ("**Client**"). Patheon and Client may be referred to in this MSA separately as a "**Party**" or together as the "**Parties**".

Background

Client is engaged in the development, manufacture, distribution, or sale of developmental or commercial pharmaceutical products. Patheon is engaged in the business of providing development and commercial services within the pharmaceutical, biotech, life sciences and research industries.

Client may wish to retain Patheon to perform services in connection with certain projects Client is conducting, in which case the terms and conditions for each project will be set forth in a Project Agreement to be issued under this MSA. Project Agreements will incorporate and be governed by this MSA.

Patheon is willing to provide these services to Client in accordance with the terms and conditions of this MSA and any associated Project Agreement(s).

Client and Patheon are parties to that certain Commercial Manufacturing Services Agreement, effective as of November 3, 2017, as amended on November 3, 2022, and June 5, 2023 (the **"Prior Agreement"**). The Parties desire to replace the Prior Agreement with this MSA.

NOW, THEREFORE, for good and valuable consideration contained in this MSA, the exchange, receipt and sufficiency of which are acknowledged, the Parties agree as follows:

1. DEFINITIONS:

The defined terms used throughout this MSA will have the meanings as set forth in the DEFINITIONS APPENDIX. Any terms defined elsewhere in this MSA or associated Project Agreement will be given equal weight and importance as though they were set forth in the DEFINITIONS APPENDIX.

2. SCOPE:

2.1 Patheon hereby agrees to provide to, or procure for, Client, the Services identified in each Project Agreement.

2.2 The terms and conditions contained in the body of this MSA will apply to each Project Agreement and to Work Orders No. 33 and 36 under the Prior Agreement. For purposes of this MSA, as of the Effective Date, Work Orders No. 33 and 36 under the Prior Agreement shall each be considered a Project Agreement hereunder.

2.3 The supplement terms and condition contained in the Development Schedule to this MSA will apply to Services, if any, for investigation products up to and including completion of process validation ("**Development Services**").

2.4 The supplemental terms and conditions contained in the Commercial Schedule to this MSA will apply to the Services approved by a regulatory agency for commercial sale or distribution ("**Commercial Services**").

2.5 The Parties may enter into a Quality Agreement. The terms of this MSA will control if any conflict occurs between the terms and provisions of this MSA and the Quality Agreement, except with respect to quality related matters.

3. SERVICES:

3.1 Patheon will perform the Services as set out in the applicable Project Agreement in compliance with the applicable Performance Standards. Client acknowledges that the Services may include non-cGMP activities as specified in further detail in the Project Agreement.

3.2 The Parties agree that any Affiliate of Patheon in the business of performing the applicable Services may perform the Services under this MSA through the execution of a Project Agreement and a Quality Agreement, to which the Patheon Affiliate will be a party. In this case: (i) all references to Patheon in this MSA shall be deemed to be to such Patheon Affiliate; (ii) such Patheon Affiliate will be solely responsible for its own obligations, and (iii) each Project Agreement, together with this MSA, shall constitute a distinct contract enforceable according to its terms between Client and the Patheon Affiliate that executed the Project Agreement.

3.3 **Price Assumptions**. Client agrees that the Price set out in the Project Agreement are estimates and based upon the assumptions contained therein and may require adjustment by Patheon if those assumptions are incorrect or changed. Changes to the Project Agreement must be agreed in writing and must include any changes to the Price, scope and estimated timing of the performance of the Services.

3.4 Commencement of Services and all estimated timelines are dependent on Patheon having timely received the appropriate payments in accordance with the Project Agreement and the necessary Client approvals, consents, information and Client-Supplied Materials. Client will be solely responsible for any delays due to Client's failure to provide necessary approvals, consents, information or Client-Supplied Materials within the specified time frame.

3.5 Patheon shall ensure that the Facility will meet all statutory and regulatory requirements applicable to the manufacture of Product. Patheon shall be responsible for ensuring that all validated processes are carried out in accordance with the terms of such processes, all in accordance with Applicable Laws. Patheon shall obtain and maintain during the Term, at its own expense, any Facility-related Regulatory Approvals and any other permits necessary for the manufacture of Product under this Agreement, excluding, if applicable, the marketing authorization for the Product or Bluebird Drug Product and any other Product or Bluebird Drug Product-specific approvals. Upon Client's request and at its expense, Patheon will assist Client with all regulatory matters relating to the Services, including by providing any documentation reasonably requested by Client as agreed upon in a Project Agreement.

3.6 Nothing contained in this MSA shall be deemed to limit Client's right at any time to qualify additional suppliers for the Product at Client's sole cost.

4. COMPENSATION:

4.1 Payment Terms.

(a) Patheon will invoice, and Client will pay Patheon for, the Services as set out in the Project Agreement, including any applicable advance payments, non-refundable fees to reserve slots or capacity, and Costs including the Handling Fee, each as specified therein.

(b) Each Patheon invoice will be due and payable on or before [***] days following the date of Client's receipt of the electronic invoice. If any portion of an invoice is disputed in good faith, Client will pay Patheon the undisputed amount and the Parties will use good faith efforts to resolve the disputed amount as soon as practicable. If the disputed amount of an invoice is not resolved on or before [***] days of the invoice date, the

Parties will escalate to senior management. Interest on undisputed, past due amounts will accrue at a rate of [***] per month.

(c) Upon [***] days' written notice to Client, Patheon may suspend all Services until all undisputed outstanding amounts have been paid in full, and Patheon will have no liability to Client if this suspension results in delayed performance of any Services, cancellation or rescheduling of any manufacturing slots, or obsolescence of any Materials.

4.2 **Currency.** All monetary amounts will be invoiced and paid in US Dollars ($), or the currency as set forth in the Project Agreement.

4.3 **Price Adjustments.** The Price set out in the Project Agreement is based on the then-current costs for labor, materials, commodities, energy, foreign exchange rates, and complying with Applicable Laws. Patheon may adjust the Price as follows:

(a) **Annual Adjustments:** [***]

(b) **Extraordinary Adjustments:** [***]

(c) **Currency Fluctuations**. [***]

4.4 **Taxes.**

(a) ***VAT*.**

(i) Fees for Services and any other payments due to Patheon under a Project Agreement are exclusive of value added taxes ("**VAT**"), turnover taxes, sales taxes or similar taxes, including any related interest and penalties (together, "**Transaction Tax**"), which will be added to the invoice amount and reimbursed to Patheon by Client.

(ii) Patheon will use commercially reasonable efforts to ensure that its invoices to Client are issued in a way to meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so.

(iii) If Patheon is acting as Client's buying agent, Patheon will always charge to Client the Transaction Tax in the relevant territory in addition to the amount paid by Patheon to the applicable supplier.

(b) Reference to the Services in this Section 4.4 also includes any element (or the entirety) of the Services characterized as a supply of goods by Patheon, its Third-Party Subcontractors or any tax authority for Transaction Tax purposes.

(c) ***Duties*.** Client will bear the cost of all duties, levies, tariffs and similar charges (and any related interest and penalties) (together, "**Duties**") however designated, arising from the performance of the Services, including those imposed as a result of shipments to, from or between Patheon Facilities. If these Duties are incurred by Patheon, then Patheon will be entitled to invoice Client for these Duties at the time that they are incurred.

(d) **Withholding Tax.**

(i) Where any sum due to be paid to Patheon hereunder is subject to any withholding or similar tax, Client will pay the withholding or similar tax to the appropriate government authority and deduct the amount then due to Patheon, in a timely manner and promptly transmit to Patheon an official certificate or other evidence of the withholding sufficient to enable Patheon to claim payment of these taxes. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate or enable the recovery of any tax withholding or similar obligations for royalties, milestone payments, and other payments made by Client to Patheon under a Project Agreement.

(ii) Patheon will provide Client with any tax forms that may be reasonably necessary for Client not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.

(iii) Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, or similar obligations resulting from payments made under a Project Agreement, any recovery to be for the benefit of the Party bearing the withholding tax.

5. SUPPLY OF MATERIALS:

5.1 **Patheon-Supplied Materials.** Patheon will source the Patheon-Supplied Materials as set forth under the terms of the applicable Project Agreement.

5.2 **Client-Supplied Materials.** Client will, at its expense, supply Patheon with enough Client-Supplied Materials for Patheon to perform the Services. All shipments of Client-Supplied Materials from Client or Client's supplier to Patheon will be [***]. All shipments of Client-Supplied Materials will be accompanied by the required documentation (including, certificates of analysis from the manufacturer and safety data sheet).

5.3 Client is responsible for vendor qualification of Client-Supplied Materials to be used for cGMP purposes and for providing upon request a certificate of compliance consistent with the requirements of cGMP, Applicable Laws and any applicable Quality Agreement between the Parties. If Client wishes Patheon to use a specific vendor for Materials, testing, or other services and this vendor is not an approved vendor currently used by Patheon, it will be Client's responsibility to audit and approve the vendor. At Client's request and for an additional fee, Patheon will audit the vendor on Client's behalf and provide an audit report to Client. If Client requires Patheon to incorporate any of the results of release testing performed by Client or a third party into a certificate of analysis issued by Patheon in connection with the Services, Patheon will have the right upon reasonable notice and at reasonable times to audit the sites or laboratories conducting the testing as set forth in the Quality Agreement or as required by Applicable Laws. If Patheon chooses to source Patheon-Supplied Materials from a new vendor solely on its own accord in order to have multiple vendors and not related to specific items for Client or requested by Client, and this vendor is not an approved vendor currently used by Patheon, it will be Patheon's responsibility to audit and approve vendor.

5.4 Client will pay the full Price for any failed or non-conforming Services that are the result of defects or other non-conformities in Client-Supplied Materials that could not have been discovered by Patheon by reasonable inspection or by using the agreed-upon testing methods (if any).

5.5 If applicable, Patheon and Client will reasonably cooperate to permit the import of Client-Supplied Materials into the country where the Services will be performed. Client or Client's broker will be the "**Importer of Record**" (or equivalent under Applicable Law) for Client-Supplied Materials unless agreed otherwise, and Client is responsible for compliance with Applicable Laws, and the cost of compliance, relating to that role. Client's obligation will include obtaining the proper release of Client-Supplied Materials from the applicable customs agency and Regulatory Authority.

5.6 **Inspection by Regulatory Authorities**.

(a) Patheon will notify Client, in accordance with the Quality Agreement, of any inspection of the Facility scheduled with any Regulatory Authority that directly relates to the Product. As may be agreed upon in a Quality Agreement, Patheon will provide Client with a copy of any report or other written communication (redacted as appropriate) received from such Regulatory Authority which is directly related to the Product as well as a copy of Patheon's final responses (redacted as appropriate) in accordance with the

terms of the Quality Agreement and Client must provide necessary information in a timely matter to enable Patheon to respond to such Regulatory Authority by the applicable deadline. Notwithstanding, Patheon reserves the right to respond to the Regulatory Authority without Client's prior approval, if, in the opinion of Patheon's legal counsel, it is required or reasonable to do so.

(b) If Client does not provide comments on a communication with a Regulatory Authority as described in the Quality Agreement or documents as requested under this Section or the Quality Agreement in a timely manner, and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized as a result of further delay, Patheon may, in its sole discretion, submit such communication without Client's Input or delay or postpone any inspection by the Regulatory Authority.

5.7 Client shall disclose to Patheon any specific safe handling instructions and other health related information applicable to the Client-Supplied Materials in advance of delivery to Patheon.

5.8 **Packaging and Artwork.** If applicable, Client will be responsible for all packaging, labels, inserts and artwork development for the Product (including obtaining all required approvals and translations) and all associated costs. Patheon's name will not appear on the label or anywhere else on the Product unless: (a) required by any Applicable Laws or (b) Patheon consents in writing. Within a reasonable time to be agreed between the Parties before the start of the Services for which new or modified artwork is required, Client will provide to Patheon and in accordance with the applicable specifications, final camera-ready artwork for all packaging components to be used in the Services.

5.9 **Storage of Client-Supplied Materials.**

(a) Patheon will store all Client-Supplied Materials, in quantities determined by Client, for the timeframe reasonably needed to provide the Services at the Facility [***]. Patheon reserves the right to refuse to store any quantity of Materials greater than the amount necessary for the performance of the Services under the applicable Project Agreement at its sole discretion at any time. If Patheon is unable to provide such storage at the Facility, a Patheon Affiliate or other qualified third party may be used for storage outside the Facility.

(b) Prior to the transfer of Materials to any such Patheon Affiliate or third, Client shall provide written approval of the transfer and related costs. At all times Client retains title to and will insure all Client-Supplied Materials while at the Facility or other storage site. Patheon may request in writing Client's Instructions to either dispose of or transfer any Remaining Materials, and Section 7.6(c) will apply if Instructions are not received from Client on or before [***] days after the request.

(c) On a quarterly basis, Patheon shall provide a report on the inventory of Client-Supplied Materials in Patheon's possession.

5.10 **Storage of Patheon-Supplied Materials.**

(a) Patheon will store all Patheon-Supplied Materials [***].

(b) As specified in the Commercial Schedule, Patheon shall provide a report on the inventory of all Patheon-Supplied Materials in Patheon's possession and/or purchased on Client's behalf.

6. DELIVERY:

6.1 **Outbound Delivery/Shipment**. Subject to Section 6.5, the Parties will coordinate delivery upon Patheon Release, as defined below. Any outbound delivery by or on behalf of Patheon for Client will be [***] unless otherwise agreed. Each shipment will be packaged for transport in accordance with the Quality Agreement and any applicable Instructions and Project Agreement. Client is responsible for obtaining transportation insurance covering the shipment after Patheon

delivers the shipment to the carrier. Client will be Exporter of Record and will obtain any required licenses and authorizations necessary for export or import (unless otherwise agreed in writing) and will otherwise comply with all Applicable Laws and pay any applicable export or import fees, duties and taxes.

6.2 **Carrier Management through TTM**. If it is agreed that Patheon will coordinate collection of Product or Material using Patheon's carriers, as set out in the Project Agreement, including through Patheon's Total Transportation Management service ("TTM"), the following terms will apply: Client agrees that Patheon is to coordinate the transport of Product or Materials, and Patheon will do so as an agent of Client and at Client's sole risk and expense. In addition to the terms and conditions outlined in this MSA and the Project Agreement, Client agrees to the following:

(a) Client will pay, to Patheon, all freight charges as referenced in the Project Agreement and Client will be responsible for all final freight charges based on actual shipping characteristics and all charges for services that were not contemplated in the Project Agreement including charges for accessorial services such as detention and demurrage;

(b) Client approves and accepts Patheon's selection of transportation mode and carrier;

(c) Client agrees to grant Patheon the ability to coordinate customs clearance up to, and including, paying duties and taxes on Client's behalf, and Client agrees that the shipment will be subject to the terms and conditions of the selected carrier's waybill and that Client's sole recovery for loss, damage, destruction, or delay will be directly against the underlying carrier, which carrier may limit its liability. Patheon will not be considered a freight forwarder or carrier in the provision of Services.

6.3 **Client Managed Shipping (Client Carrier)**. If Client elects to provide its own transportation, Client will coordinate collection of Product or Material using its own carrier and (a) Patheon will tender the shipment to Client's carrier as instructed at the Facility, (b) the shipment will be at Client's sole risk and expense, and (c) Client will ensure that all costs of shipment are billed directly to Client by Client's carrier.

6.4 **Title and Risk**. For Manufacturing Services, Patheon will deliver the release Batch Documents to Client ("**Patheon Release**"), immediately after which, any title to Product that Patheon has will transfer to Client. Client will bear the risk of loss in the Product, and will be obliged to insure Product, at all times.

6.5 **Storage of Product**. Subject to capacity, Patheon will store Product at no charge for up to [***] days after Patheon Release. If Patheon is unable to provide Product storage, with Client prior notification and approval, a Patheon's Affiliate or qualified third party may be used for storage outside the Facility. Client retains title to and will insure all Product while at the Facility or other storage site.

7. <u>TERM AND TERMINATION</u>:

7.1 **Term.** This MSA will remain in effect until [***] years following the Effective Date ("**Initial Term**") and will automatically renew for additional [***] periods ("**Renewal Terms**", collectively with the Initial Term, the "**Term**"), unless either Party gives the other Party notice of non-renewal more than [***] months before the end of the Initial Term and any Renewal Term, but the Term will automatically be extended (even if notice of non-renewal has been given) to allow for completion of Services under any active Project Agreement.

7.2 **Termination by Either Party.** Either Party may terminate this MSA or a Project Agreement:

(a) on written notice, if the other Party files a petition in bankruptcy, applies for or consents to the appointment of a receiver or trustee, makes an assignment for the benefit of its creditors or becomes subject to involuntary proceedings under any bankruptcy or insolvency law (which proceedings remain undismissed for [***] days);

(b) if the other Party is in material breach of any part of this MSA or the applicable Project Agreement and fails to remedy the breach on or before [***] days after receiving notice of the breach from the aggrieved Party; provided, however, that if such breach is not capable of being cured within [***] days and the breaching Party has commenced and diligently continued actions to cure such breach within [***] days, the cure period shall be extended to [***] days, so long as the breaching Party continues to make diligent efforts to cure during such period; or

(c) in the event of a Force Majeure event, in accordance with Section 13.5.

7.3 **Effect of Termination.** If a Project Agreement is completed, expires, or is terminated by either Party for any reason:

(a) both Parties will dispose of Confidential Information as required by Section 8.5.

(b) Patheon will:

(i) Promptly cease performance of the applicable Services and take all commercially reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith, including by canceling any third-party obligations (if cancellable);

(ii) credit any outstanding balances owed to Client; and

(iii) provide Client with a written notice of the amount and location of any Remaining Materials except where any outstanding amounts are payable by Client under the Project Agreement and Patheon has terminated the Project Agreement under Section 7.2.

(c) Client will:

(i) pay the Price due to Patheon for the Services performed or for Patheon-Supplied Materials procured or committed by non-cancellable order including any handling fees up to the date of completion, expiry or termination;

(ii) pay all actual costs and expenses including any applicable handling fee incurred by Patheon to complete wind-down activities as agreed by the Parties; and

(iii) [***]

(iv) [***]

(v) on or before [***] days from the date of the Remaining Materials notice described in Section 7.6(b): (A) remove all the Remaining Materials from each Facility identified in the notice; or (B) provide Instructions detailing and directing how and where Patheon should either ship, return or dispose, at a location neither owned nor operated by Patheon, of all the Remaining Materials (together "**Disposition**").

(vi) If Client provides Patheon with Instructions regarding shipment or disposal of Remaining Materials, the shipment or disposal will be provided under a Project Agreement. If this MSA has been terminated or is expired, this MSA will survive and will govern any applicable Project Agreement, including a new Project Agreement, if required, until shipment or destruction is completed; and

(vii) If Client fails to Disposition Remaining Materials on or before [***] days from the date of the Remaining Materials notice, Patheon will provide a second notice ("Second Notice") and if Client fails to disposition Remaining Materials on or before [***] days from the Second Notice, Patheon may, in its sole discretion, dispose of Remaining Materials. If this occurs, Patheon is hereby authorized to

name Client as the generator of any waste generated for and upon the disposal. Patheon will retain all statutory and common law rights regarding the disposal, and Client hereby waives its right to assert and agrees to defend and indemnify Patheon from, any cause of action or claim arising from any removal by Client or Disposition by Patheon of any Remaining Material. Patheon will invoice Client and Client agrees to pay all fees and expenses associated with Patheon's disposal of the Remaining Materials.

8. CONFIDENTIALITY:

8.1 The Receiving Party shall keep strictly confidential all Confidential Information and shall not disclose the same to a third party without prior written consent of the Disclosing Party. The foregoing obligations of confidentiality shall not apply to any portion of the Confidential Information that the Receiving Party can demonstrate by documentary evidence:

(a) Was fully in its possession prior to receipt from the Disclosing Party;

(b) Was in the public domain at the time of receipt from the Disclosing Party;

(c) Became part of the public domain through no fault of the Receiving Party;

(d) Was lawfully received by the Receiving Party from a third party having a right of further disclosure and who did not, directly or indirectly, receive such Confidential Information from the Disclosing Party; or

(e) Is independently developed by the Receiving Party without reference to or reliance upon Disclosing Party's Confidential Information.

8.2 Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because such information is embraced by general disclosures in the public domain or in the possession of the Receiving Party. In addition, any combination of Confidential Information shall not be considered to be in the public domain or in the possession of the Receiving Party merely because individual elements thereof are in the public domain or in the possession of the Receiving Party.

8.3 If the Receiving Party is required by law, regulation, rule, act or order of any governmental authority or agency, or stock exchange, to disclose any Confidential Information, the Receiving Party will give the Disclosing Party prompt written notice of such requirement, and the Receiving Party will take commercially reasonable and lawful actions to minimize the degree of such disclosure to only the portion which is responsible to such requirement or request. The Receiving Party will cooperate reasonably with the Disclosing Party in any efforts to seek a protective order or other similar order with respect to such Confidential Information, at Disclosing Party's cost.

8.4 Confidential Information shall not be used by the Receiving Party other than for the purpose of the Agreement. The Parties shall only disclose Confidential Information to Affiliates, directors, employees, consultants, and independent contractors who have a genuine need to access such information in order to fulfil the Parties' obligations under this Agreement (and, in the case of Client, for the exploitation of Product); provided that: (a) such recipients are bound by obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information that are at least as restrictive as those set forth in this Agreement and (b) the Receiving Party remains liable for the compliance of such recipients with such obligations.

8.5 The Receiving Party agrees that, at the Disclosing Party's request, or upon expiration or termination of this MSA (whatever the reason), the Receiving Party shall forthwith return to the Disclosing Party any and all parts of the Confidential Information provided in documentary form and will return or destroy any copies or other tangible embodiments thereof made by the Receiving Party; except for one copy that may retained in a secure file (segregated from the Receiving Party's other files) for compliance purposes only.

8.6 Neither Party shall, without the prior written consent of the other Party, disclose to any third party the terms of this MSA, which shall be treated as the Confidential Information of both Parties provided, however, that Client may disclose the terms of this MSA to bona fide prospective or current investors, lenders, collaborators or acquirers in connection with licensing, financing and acquisition activities, and due diligence processes related to such activities provided who are bound prior to such disclosure by commercially reasonable written obligations of confidentiality and non-use and that Client will remain responsible for failure by any of the foregoing third parties to whom Confidential Information is provided.

8.7 These obligations of confidentiality and non-use are valid during the Term and for a period of [***] years thereafter, except in the case of trade secrets, for which the obligations of confidentiality and non-use are valid for the Term and for as long as Disclosing Party continues to treat such Confidential Information as a trade secret or until such time as the information becomes subject to one of the exceptions under Section 8.1(a) - (e).

9. <u>INTELLECTUAL PROPERTY</u>:

9.1 Defined terms:

(a) "**Arising Client Intellectual Property**" means all Intellectual Property generated by Patheon or its Third-Party Subcontractors as a consequence of performing the Services that is specific to, (i) Product; or (ii) any other deliverable set out in the Project Agreement that is the subject of the Services (together, the "**Deliverables**").

(b) "**Client Background IP"** means Intellectual Property in possession of Client prior to the date of this MSA or that is developed by Client independently of this MSA without using any Patheon Confidential Information.

(c) "**Intellectual Property**" includes [***].

(d) "**Patheon Background IP**" means Intellectual Property developed, owned, or licensed by Patheon which is outside the scope of this MSA or a Project Agreement or the Services and which is developed without using any Client Confidential Information.

(e) "**Patheon Intellectual Property**" means, (i) Patheon Background IP; and (ii) all Intellectual Property generated by or licensed to Patheon as a consequence of performing the Services which is not Arising Client Intellectual Property.

9.2 For the term of the applicable Project Agreement, Client hereby grants to Patheon, a non-exclusive, fully paid-up, royalty-free, non-transferable license to Client's Background IP and Arising Client Intellectual Property that is reasonably necessary for Patheon or its Third-Party Subcontractors to perform the Services. Any license granted by Client to Patheon will be terminated upon the earlier of expiration, completion or termination of the applicable Project Agreement.

9.3 All Arising Client Intellectual Property and Client Background IP will be the exclusive property of Client.

9.4 All Patheon Intellectual Property will be the exclusive property of Patheon.

9.5 Unless otherwise agreed in a separate license agreement or Project Agreement, Patheon hereby grants to Client [***] license to the Patheon Intellectual Property if Patheon Intellectual Property is incorporated into a Deliverable under a Project Agreement so that Client can use, sell, offer for sale, import, export or otherwise exploit or dispose of the Deliverable (the "**License**"). The License does not apply to Patheon Intellectual Property generally employed in the operation of any Facility or equipment, including [***].

9.6 Subject to the terms and conditions of this MSA, Client may sublicense its rights to the License, but Client must enter into a written agreement with the sublicensee requiring that the sublicense (a) include confidentiality and non-use terms and conditions at least as restrictive as those set forth in the Confidentiality Agreement, (b) prohibit the assignment, transfer or further

sublicensing by the sublicensee, and (c) prohibit the use of the License for any purpose other than performing services for Client in connection with Product ("**Manufacturing Sublicense**"). Client must give Patheon written notice of the sublicense Manufacturing Sublicense agreement on or before [***] days after entering into such Manufacturing Sublicense agreement. This notice must name the applicable sublicensee, set forth the scope of the sublicense granted by Client under the License, the expected duration of the Manufacturing Sublicense and certify that the sublicense agreement complies with Sections 9.5 and 9.7 On or before [***] days following termination of the sublicense, Client will inform Patheon in writing that the sublicense has been terminated and confirm that Client requested the return or destruction of all Patheon Confidential Information. Client will be liable for any breach of the Manufacturing Sublicense by the sublicensee as if the breach were a breach of the License. The Manufacturing Sublicense granted hereunder will terminate upon the termination of the License. The Manufacturing Sublicense does not include the right for Client to provide manufacturing or development services to a third party or to use Patheon Intellectual Property in connection with products that are not identical to Product. Any breach of this MSA by Client, including the confidentiality obligations will be cause for immediate termination of the License and Manufacturing Sublicense. Client acknowledges that nothing in this MSA or a Project Agreement will restrict Patheon from using any Patheon Intellectual Property, in performing Services for other clients or on its own behalf.

9.7 **Technology Transfer.** Upon Client's written notice to Patheon requesting technology transfer from Patheon to Client, and subject to Section 9.6 and entering into a mutually agreed upon Project Agrement, Patheon may provide technology transfer support reasonably necessary for properly skilled personnel of Client or its designee to manufacture the Product ("Technology Transfer"). Patheon makes no representations or warranties as to a successful Technology Transfer. Patheon shall provide commercially reasonable support through the Technology Transfer to enable Client or its designee to replicate the manufacturing process developed by Patheon as part of the Services. [***]

10. AUDIT AND CONSULTATION RIGHTS:

10.1 Client will have a right of access to the Facility solely for the purpose of conducting a quality audit in accordance with the applicable Quality Agreement. All visits will be during Patheon's normal business hours on weekdays and conducted consistent with Patheon's policies and procedures, and in a manner that does not unreasonably interfere with Services or normal business activities. [***] Patheon will permit Client or its agents to consult with Patheon during the performance of the Services.

10.2 **Client Access**. Patheon also agrees that Client, upon reasonable request and with Patheon's permission, shall be permitted reasonable access during Patheon's normal business hours in order to observe performance of Services. Any such visit, the scope, conditions and limitations shall be conducted consistent with Patheon's policies and procedures or the Quality Agreement and in a manner that does not unreasonably interfere with Services or normal business activities subject to reasonable restrictions to preserve the confidentiality of Patheon and its clients, and safety.

11. COVENANTS AND WARRANTIES:

11.1 **Authority.** Each Party covenants, represents, and warrants that it has the full right and authority to enter into this MSA and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this MSA.

11.2 **Client Warranties.** Client covenants, represents, and warrants that:

(a) on receipt by Patheon, the Client-Supplied Materials will conform to the specifications (as applicable) and will be adequately contained, packaged, and labelled in accordance with Applicable Laws and will conform to the affirmations of fact on the container; and

(b) Client-Supplied Materials will be suitable for the intended use, not adulterated and free of Contaminants.

11.3 **Patheon Warranties.** Patheon covenants, represents, and warrants that:

(a) it will perform the Services in accordance with the Performance Standards, using individuals who are appropriately trained and qualified;

(b) the Facility and all equipment utilized in the performance of the Services by Patheon shall be maintained and operated in accordance with all Applicable Laws, including cGMPs;

(c) for Batches that are designated and manufactured under cGMP at the time of release by Patheon, Product will conform with Batch Documentation and be transferred free of any liens or encumbrances;

(d) it will not in the performance of its obligations under this MSA use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b); and

(e) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act.

11.4 **Emergency Management and Recovery Planning.** Patheon will comply with its Emergency Management and Recovery Planning Corporate Standard ("EMRPCS"). The EMRPCS shall be considered Patheon's Confidential Information and may be shared with Client upon reasonable request, subject to the confidentiality and non-use provisions of Section 8.

11.5 **No Warranty.** NEITHER PARTY makes ANY warranty or condition of any kind, either expressed or implied, by fact or law, other than those expressly set out in this MSA OR A PROJECT AGREEMENT. [***]

12. INDEMNIFICATION, REMEDIES AND LIABILITY:

12.1 **Indemnification by Client.** Subject to Sections 12.2 and 12.3, Client will defend and indemnify the Patheon Indemnitees from all third-party (other than Affiliates) actions, causes of action, subpoenas, costs (including reasonable legal fees), claims, damages, liabilities, and expenses ("**Losses**") relating to or arising from: [***]

This indemnity will not apply to the extent that these Losses are those for which Patheon is obliged to indemnify Client Indemnitees under Section 12.2.

12.2 **Indemnification by Patheon.** Subject to Sections 12.1 and 12.3, Patheon will defend and indemnify Client Indemnitees from all Losses relating to or arising from: [***]

This indemnity will not apply to the extent that these Losses are those for which Client is obliged to indemnify the Patheon Indemnitees under Section 12.1.

12.3 **Indemnification Procedure.** If a claim occurs under Section 12.1 or 12.2, the indemnified Party will: (a) promptly notify the indemnifying Party of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with the indemnifying Party in the defense of the claim; and (d) permit the indemnifying Party to control the defense and settlement of the claim, all at the indemnifying Party's cost and expense.

12.4 **Deficient Services**. Services will be considered "**Deficient Services**" if Patheon fails to comply with the applicable Performance Standards. Any disagreement between the Parties as to whether Deficient Services exists will be treated as a Technical Dispute and handled in accordance with Section 13.4.

12.5 **Remedies**. If Patheon performs Deficient Services, then Client's sole remedy whether in contract, tort, equity or otherwise will be: [***]

12.6 **Indirect/Consequential Loss**. [***]

12.7 **Limitation of Liability**. Subject to any limitations set out in the Development Schedule or Commercial Schedule, Patheon's total liability under any Project Agreement in contract, tort, equity, negligence, breach of statutory duty or otherwise will not exceed [***].

12.8 [***]

13. MISCELLANEOUS:

13.1 **Assignment and Subcontracting.**

(a) Neither this MSA nor a Project Agreement, nor any of either Party's rights or obligations hereunder, may be assigned, novated or otherwise transferred by either Party without the prior written consent of the other Party, this consent not to be unreasonably withheld or delayed. But either Party may, upon written notification to the other Party, assign, in whole or part, its rights and obligations under this MSA or a Project Agreement to an Affiliate or, in connection with a merger, consolidation or sale of substantially all of the business to which this MSA or a Project Agreement relates, to an unrelated third party.

(b) With Client's advance, written consent, Patheon may subcontract the Services hereunder to an Affiliate as specified in the Project Agreement or arrange for any of its Affiliates to perform specific Services under a Project Agreement. Client agrees that Patheon will remain exclusively liable to Client for any breach of this MSA or a Project Agreement or negligence by its Affiliates in the course of performing Services. Patheon may also arrange for Third-Party Subcontractors to perform specific Services under a Project Agreement with Client's advance, written consent or at Client's request. Subject to Section 13.1(c) below, Client agrees that Patheon will be responsible for such Third-Party Subcontractors' compliance in the course of performing Services with the terms of this Agreement subject to all limitations on Patheon's liablitlity as set out in this MSA.

(c) [***]

13.2 **Anti-Bribery**. The Parties agree:

(a) to comply with all Applicable Laws, statutes and regulations relating to anti-bribery and anti-corruption including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act;

(b) to have and maintain in place throughout the Term their own policies and procedures to ensure compliance with the U.S. Foreign Corrupt Practices Act and the UK Bribery Act (and to provide a copy to the other Party on request) and to appropriately enforce those policies and procedures, including providing training;

(c) that no employee, contractor, supplier, agent, broker, or representative of such Party will offer or pay anything of value to a public or private official intending to influence or induce an official act or decision or to obtain an improper advantage; and

(d) that a breach of this Section 13.2 will be considered a material breach of this MSA and the aggrieved Party will have the right to terminate this MSA and any Project Agreement pursuant to Section 7.2(b).

13.3 **Choice of Law.** This MSA and any Project Agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation is governed by the laws of the State of New York without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. The Parties hereby submit to the exclusive jurisdiction of the courts in the State of New York. The Parties further expressly

agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this MSA or any Project Agreement.

13.4 **Dispute Resolution**.

(a) If any dispute arises out of this MSA or any Project Agreement, the Parties will first try to resolve it amicably. Upon receipt of written notice of a dispute, the Parties agree to use commercially reasonable efforts, including engagement of senior management as necessary, to resolve the dispute on or before [***] days.

(b) If the Parties are unable to resolve the dispute, then after [***] days the Parties agree to enter into mediation in good faith to settle the dispute and will do so in accordance with the CEDR Model Mediation Procedure. Unless otherwise agreed between the Parties on or before [***] days after the initial written notice of the dispute, the mediator will be nominated by CEDR.

(c) Except where proceedings are required for the purpose of equitable relief or to preserve a Party's legal position pending the outcome of negotiation or mediation, neither Party may commence any court proceedings in relation to a dispute until the required mediation has ended without resolving that dispute or a Party fails to participate in that mediation. Where a Party decides not to take part in mediation in contravention of this Section 13.4, it will send written notice of that decision to the other Party.

(d) **Technical Disputes**. If a dispute arises between the Parties that is exclusively related to technical aspects of the Services (a "**Technical Dispute**"), the Parties will use all reasonable efforts to resolve the dispute by amicable negotiations as provided in Section 13.4(a) above, including by involving members of each Party's quality assurance department. If the Parties are unable to resolve a Technical Dispute by negotiation, the Technical Dispute will, at the written request of either Party, be referred to an expert for determination in the following manner: [***].

13.5 **Force Majeure**. If a Force Majeure event occurs that may affect a Party's ability to perform under this MSA or a Project Agreement, except for Client's payment obligations, neither Party will be responsible for delay of failure in performance and the affected Party shall promptly notify the other in writing and use commercially reasonable efforts to resume performance or otherwise mitigate the effects of the Force Majeure Event as quickly as practicable. If the performance by either Party of any of its obligations under this MSA or a Project Agreement is prevented or delayed by a Force Majeure Event for [***], then the other Party shall have the right to terminate this MSA or the applicable Project Agreement upon written notice. Patheon will not be responsible for any loss or damage caused to any Product caused by a Force Majeure event.

13.6 **Notices**. Any notice required or permitted to be given hereunder by either Party must be in writing and will be considered effectively given or delivered: (a) on the date delivered if delivered personally, (b) on the first business day after the date sent if sent by recognized overnight courier, or (c) on the second business day after the date deposited if mailed by certified mail, return receipt requested, postage prepaid. All notices to each Party will be sent to the address for that Party set forth in the applicable Project Agreement. If no address is provided in the Project Agreement, then notices will be sent as follows:

If to Client:
[***]

If to Patheon:
[***]

Legal Notices to Patheon shall be emailed to [***].

13.7 **Survival**. Any termination or expiration of this MSA or a Project Agreement will not affect any outstanding obligations or payments due hereunder before the termination or expiration, nor will it prejudice any other remedies that the Parties may have under this MSA or Project Agreement. The following will survive the expiration or termination of this MSA or a Project Agreement in accordance with their terms: Section 5 – Supply of Materials, Section 7 – Term and Termination, Section 8 – Confidentiality, Section 9 – Intellectual Property, Section 11 – Warranties and Section 12 – Indemnification, Remedies and Liability.

13.8 **Independent Contractors**. The Parties are independent contractors and this MSA, or a Project Agreement will not be construed to create between Patheon and Client any other relationship such as, for example only, that of employer-employee, principal, agent, joint-venturer, co-partners, or any similar relationship.

13.9 **Insurance**.

(a) Each Party will maintain during the term of the applicable Project Agreement general liability and product liability insurance which is sufficient to cover their respective liability and obligations under the applicable Project Agreement with insurers rated [***] through the term of this MSA and for [***]. Either Party will provide valid evidence of this insurance upon the request of the other Party.

[***]

13.10 **Capital Agreement**. If applicable, the Parties may enter into a separate agreement that addresses the rights and responsibilities of the Parties regarding equipment and Facility modifications necessary to provide Services.

13.11 **Data Privacy Agreement**. If applicable for the Services, the Parties will enter into a separate agreement that addresses obligations regarding personal data or health information.

13.12 **Entire Agreement**. This MSA together with any Project Agreements and Quality Agreements are the complete agreement between the Parties for this subject matter and supersedes all other prior agreements (including the Prior Agreement), representations and understandings, whether written or oral. Except as otherwise provided in this MSA, any modifications, amendment, or supplement to this MSA or any Project Agreement must be in writing and signed by authorized representatives of the Parties. The Parties are in agreement that Work Order 33 and Work Order 36 that were previously executed under the Prior Agreement will now be governed by this Agreement; provided however, if there is any conflict between the terms of this Agreement and the terms of Work Order 33 and/or Work Order 36 that the terms of Work Order 33 and 36 shall control.

13.13 **Severability**. If any provision of this MSA or any Project Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.14 **Counterparts & "pdf"**. This MSA or any Project Agreement may be executed in two or more counterparts, by original or electronic (including "pdf") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

13.15 **Construction**. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein will mean including, without limiting the generality of any description preceding that term.

13.16 **No Third-Party Benefit or Right.** Nothing in this MSA or any Project Agreement will confer or be construed as conferring on any third party, other than a Patheon's Affiliate performing Services hereunder in accordance with Section 3.2, any benefit or the right to enforce any express or

implied term of this MSA or Project Agreement. The rights of the Parties to terminate, rescind or agree on any variation, waiver or settlement under this MSA or any Project Agreement are not subject to the consent of any other person.

13.17 **Waiver**. Neither the waiver by any of the Parties of a breach of or a default under any of the provisions of this MSA, nor the failure of any of the Parties, on one or more occasions, to enforce any of the provisions of this MSA or to exercise any right or privilege hereunder will thereafter be construed as a waiver of any subsequent breach or default of a similar nature, or as a waiver of any of the provisions, rights, or privileges hereunder.

13.18 **Embargoed Countries**. Patheon will not support distribution, regulatory or quality services (including site inspections) with respect to Services to the government of embargoed countries, as defined in the Thermo Fisher Scientific GTC Controls Policy as may be updated from time to time.

13.19 **Binding Effect.** This MSA will apply to, inure to the benefit of and be binding upon the Parties and upon their respective successors and permitted assigns.

[Signature Page Follows]

IN WITNESS WHEREOF, this MSA has been executed and delivered by the Parties by their duly authorized representatives as of the Effective Date.

Henogen SRL
By: /s/ Bernard Jacques
Name: Bernard Jacques
Title: General Manager VVS EU Henogen

bluebird bio, Inc.
By: /s/ Anne Kantardjieff
Name: Anne Kantardjieff
Title: Vice President, Manufacturing

DEFINITIONS APPENDIX

"Affiliate" means, for (i) Client, any entity that controls, is controlled by or is under common control with Client, and (ii) Patheon, any entity that controls, is controlled by or is under common control with Patheon. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, more than 50% of the outstanding voting securities or other ownership interest of the entity.

"**Applicable Laws**" means: (i) for Patheon's obligations, the Laws applicable to the performance of the Services in the jurisdiction where the Facility is located; and (ii) for Client's obligations, the Laws applicable to the performance of Client's obligations hereunder and the Product.

"**Batch**" means [***].

"**Batch Documents**" means Batch documents released by Patheon that may include: [***].

"**Bluebird Drug Product**" means a product manufactured by Client which incorporates Product.

"**cGMP**" means current good manufacturing practices according to the United States Food and Drug Administration and European Medicines Agency together with applicable rules and guidance documents issued by the applicable Regulatory Authority pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time in each case as applicable in the country where the Facility is located.

"**Client Indemnitees**" means collectively Client or any of its Affiliates and their respective directors, officers, employees, and agents.

"**Client-Supplied Materials**" means any Materials as specified in the Project Agreement to be procured on behalf of or provided by Client to Patheon.

"Confidential Information" means, all know-how (and all tangible and intangible embodiments thereof), and all other secret, confidential or proprietary information, data or materials, whether provided in written, oral, graphic, video, computer or other form, or by observation at the Party's facilities, which is disclosed or made available by or on behalf of a Party (the "**Disclosing Party"**) to the other Party (the "**Receiving Party"**) pursuant to this MSA or which arises as a result of this MSA, and any copies thereof, and which: (i) if disclosed in written, graphic, electronic or other tangible form, is labeled as confidential or proprietary, (ii) if disclosed orally or visually, is identified as confidential or proprietary at the time of disclosure, or (iii) by its nature, should reasonably be considered to be confidential or proprietary. Confidential Information of Client includes, but is not limited to, business, technical and financial data concerning the Client-Supplied Materials, and/or the Product. Confidential Information of Patheon includes, but is not limited to, proprietary technical data, know-how, and trade secrets concerning Patheon's production and purification methods, Patheon's equipment parameters and techniques, Patheon's facilities and their design and operation, as well as business and financial data.

"**Contaminants**" means any adventitious agent including noxious or toxic agents, infectious agents, including any microbiological or viral agents of infection (e.g., bacteria, fungae, mycoplasmas, prions, and viruses) or corrosive agents.

"**Costs**" means the cost of all Patheon-Supplied Materials, capital expenditures and third-party services or expenses, including any applicable handling fee (which shall be [***] ("**Handling Fee**"), provided, procured, or incurred by Patheon on behalf of Client.

"**Excluded Materials**" means any Client-Supplied Materials, the raw materials (including [***]; and any other materials as may be further stated in the Project Agreement.

"**Facility**" means the facility where the Services are being performed.

"Fees" means the amounts to be charged by Patheon to Client as set forth in the applicable Project Agreement for performing the Services. Fees do not include Costs.

"**Force Majeure**" means the delay or failure in performance resulting from acts beyond the reasonable control and without the fault or negligence of the Party, including, strikes or other labor disturbances, lockouts, quarantines, communicable disease outbreaks, riots, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components or compliance with any order or regulation of any government entity.

"**Instructions**" means Client's written instructions agreed and accepted by Patheon.

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees, or orders of any Regulatory Authority.

"**Manufacturing Services**" means [***].

"**Materials**" means all supplies needed to complete the Services including [***]. Materials includes Patheon-Supplied Materials and Client-Supplied Materials.

"**Non-manufacturing Services**" means [***].

"Performance Standards" means the performance standards as defined in the Development Schedule or Commercial Schedule, as applicable.

"**Patheon Indemnitees**" means collectively, Patheon, its Affiliates and their respective directors, officers, employees, and agents.

"**Patheon-Supplied Materials**" means any Materials to be sourced by Patheon on behalf of Client to perform the Services.

"**Price**" means the Fees and the Costs to be charged by Patheon as set forth in each Project Agreement.

"**Product**" means the deliverable from Manufacturing Services, including Batch Documents.

"**Project Agreement**" means a separate signed document, entered into by Patheon or Patheon's Affiliate and Client or Client's Affiliate containing a description of the Services, the Price assumptions, and the specific technical, pricing, and supplementary legal terms (if any) for a particular project and may be variously referred to as a work order, scope of work (SOW), change of scope (COS), work statement, Project Agreement, product agreement, project proposal, proposal, product addendum, quotation, or a similar term. Upon the Effective Date, Work Orders No. 33 and 36 under the Prior Agreement are Project Agreements under this MSA.

"**Quality Agreement**" means a detailed document specifying the quality and regulatory procedures and responsibilities of the Parties with respect to the Services applicable to the Development Schedule or Commercial Schedule.

"**Regulatory Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission, or other similar body, whether federal, state, provincial, county, or municipal, with competent jurisdiction over a Party, the Services, or the relevant Product (or its use).

"**Remaining Materials**" means Materials or works in process at the Facility which have not been used or are otherwise not required to perform Services by Patheon under this MSA or any Project Agreement.

"**Services**" means [***].

"**Third-Party Subcontractors**" means any non-Affiliate third-party subcontractor used in the performance of the Services with the consent of Client.

DEVELOPMENT SCHEDULE
DEVELOPMENT SERVICES

In addition to the body of the MSA, the following supplemental terms and conditions apply to Development Services. Capitalized terms used and not defined herein have the meanings as provided in the DEFINITIONS APPENDIX.

1. **"Performance Standards"** means the terms of this MSA, the Project Agreement, the Quality Agreement, Applicable Laws, cGMP (where applicable), and Instructions.

2. **"Validation Batches"** means [***].

3. **Materials**.

3.1 Patheon will invoice Client for the Costs plus the Handling Fee as specified in the Project Agreement. The amounts for Costs set forth in the Project Agreement are estimates only, and Client will be responsible for the actual Costs. Specialized or high-cost items including [***] may be agreed and charged separately, including the applicable handling fee. The terms of this Section 3.1 of this Schedule do not apply to Materials procured for Clinical Trial Services.

4. **Reservation and Cancellation Fees.**

4.1 **Reservation Fees.** [***]

4.2 **Cancellation Fees.** [***]

4.3 **Termination by Client.** Client may terminate a Project Agreement by giving [***] days' written notice for any business reason. Unless terminated by Client for a material breach of this MSA by Patheon, Client will pay any non-refundable and non-cancellable fees and expenses in the Project Agreement including Reservation Fees, Cancellation Fees and Remaining Materials.

4.4 **Termination by Patheon.** Patheon may terminate a Project Agreement if Patheon reasonably determines that it is unable to perform the Services or manufacture Product in a safe and effective way in accordance with applicable regulatory requirements or applicable specifications.

5. **Miscellaneous**.

5.1 **No Warranty**. [***]

5.2 **No Consultancy**. Unless otherwise expressly agreed in a Project Agreement, if Patheon provides advice or guidance, this advice or guidance is made without any representation or warranty and Patheon will not be considered a consultant.

5.3 [***]

COMMERCIAL SCHEDULE
COMMERCIAL SERVICES

In addition to the terms set forth in the body of the MSA, the following supplemental terms and conditions apply to Commercial Services. Capitalized terms used and not defined herein have the meanings as provided in the DEFINITIONS APPENDIX.

1. DEFINED TERMS. Additional defined terms specific to Commercial Services:

"**Annual Volume**" means [***].

"**Calendar Year**" means, in the first year of this MSA or a Project Agreement, as applicable, the time from the Effective Date up to and including December 31 of the same calendar year, and after that, will mean January 1 through December 31.

"**Commercial Product**" means any Product generated as a result of Commercial Services.

"**Latent Defect**" means a defect that is not reasonably susceptible to discovery upon receipt.

"**Minimum Purchase Quantity**" means [***].

"**Minimum Order Quantity**" means [***].

"**Performance Standards**" for Commercial Services will mean Applicable Laws, cGMP (where applicable), the MSA, the Project Agreement, the Quality Agreement, and the Processing Instructions.

"**Processing Instructions**" means documents relating to each Commercial Product, as mutually agreed in writing, including: [***]

"**Recall**" means any action by Client or any Regulatory Authority or Patheon to (i) withdraw Commercial Product from the market (including involuntarily) or (ii) refrain from shipping Commercial Product.

"**Release Date**" means [***].

2. SERVICES.

2.1 **Commercial Services.** Patheon will perform the Commercial Services for the Price as set out in the Project Agreement, in accordance with the Performance Standards.

2.2 **Development Services**. Where Product is manufactured by Patheon under the Development Schedule or a separate pharmaceutical development or technology transfer agreement and is subsequently released by Patheon for commercial sale or distribution by Client, the performance of the Development Services or applicable services under the separate agreement, including the manufacture of the Commercial Product, will be governed by the terms of Development Schedule or the applicable separate agreement. The terms of this Commercial Schedule and the applicable Project Agreement will only apply to any Commercial Product after release for commercial distribution by Patheon.

3. **INVOICING.**

Patheon will issue invoices in accordance with the invoicing schedule set out in the Project Agreement.

4. **PROCESSING INSTRUCTIONS AND MATERIALS.**

4.1 **Processing Instructions.** Before the start of Commercial Services, Client and Patheon will agree on the Processing Instructions. Client is solely responsible for ensuring that the Processing Instructions comply and remain in compliance with the applicable, current regulatory approvals and Applicable Laws. All changes to Processing Instructions will be agreed in advance in writing

and will comply with the change control process in the Quality Agreement. The relevant Project Agreement will specify the financial responsibility for any one-time and ongoing costs of such change and will define any compliance obligations that must be completed before the change takes effect.

4.2 **Materials.**

[***]

4.3 **Other Materials.**

[***]

5. FORECASTS.

5.1 **Long Term Forecasts**. [***]

5.2 **Rolling Forecasts**. [***]

5.3 **Binding and Semi-Binding Forecasts.** [***]

6. ORDERS.

6.1 Purchase orders must be raised in accordance with the: (a) Client purchase order submission period [***]; b) Rolling Forecasts; and (c) the Minimum Order Quantity and must specify the purchase order number, quantities by Commercial Product type, and specific requested Release Date in the month for each order.

6.2 **Acceptance of purchase orders.** If Patheon fails to acknowledge receipt of a purchase order on or before [***] business days, the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the Parties (a "**Firm Order**"). Patheon shall not unreasonably reject a purchase order that is in alignment with Section 6.1. Once accepted, the Parties will negotiate and agree on any change to the Release Date. Neither Party may unreasonably reject an alternative Release Date requested under this Section but, if the Parties cannot agree, the original Release Date accepted by Patheon will apply.

6.3 **Cancellation or Postponement by Client.**

(a) Patheon will determine the manufacturing schedule of all Commercial Product covered by Rolling Forecasts and Firm Orders (the "**Manufacturing Plan**"). If Client causes (including as a result of its failure to supply Client-Supplied Materials, documents or approvals [***]) or requests a Cancellation, postponement or reduction of volume in the Manufacturing Plan, the Cancellation or postponement provisions [***] apply.

(b) Notwithstanding Section 6.3(a), both Parties shall agree to any reasonable request to reschedule Services covered by the Manufacturing Plan, so long as such rescheduling is within the Binding Forecast period.

6.4 [***]

7. CLAIMS AND RECALL.

7.1 **Deficient Services and Claims**.

(a) Subject to Section 12.5 of the body of this MSA, the following shall further apply:

(i) regardless of Client's election pursuant to paragraph 12.5(a) or (c) of the body of the MSA, Patheon shall also pay or credit to Client of [***] for each Batch affected by Deficient Services, capped annually at [***].

(ii) for the avoidance of doubt, any repeat Services or reprocessing of Commercial Product under Section 12.5 of the body of the MSA shall not negatively impact Client's Binding Forecast or otherwise impact Patheon's commercially reasonably available capacity for performance of the Services.

(b) Client will inspect (both visually and via its own release testing process) applicable Commercial Product manufactured by Patheon, upon receipt and will give Patheon written notice of any visible Claim, on or before [***] days after receipt or, in the case of any Latent Defect or defect detected during Client's release testing, on or before [***] days after discovery by Client, but not after the expiration date of the Commercial Product. If Client fails to provide a Claim on or before the end of the [***] period, then the Commercial Product will be considered to have been accepted by Client on the [***] day. Patheon will have no liability for any deficiency for which it has not received notice on or before the [***]-day period. If the Parties do not agree as to whether a Claim exists, such dispute will be considered a Technical Dispute. Services will not be considered Deficient Services if Patheon Services complied with Performance Standards, and Patheon will have no obligation for any claims for non-conforming Commercial Product to the extent such non-conformance was caused by: [***]. If after a full investigation as set out in the Quality Agreement and this Section, it is determined that Patheon manufactured Commercial Product in accordance with the agreed Performance Standards, but a Batch or portion of Batch of Commercial Product is not released, Client will [***].

(c) **Determination of Deficiency.** Upon receipt of a claim for Deficient Services ("**Claim**"), Patheon will have the period specified in the Quality Agreement or as reasonably required for technical reasons, to advise Client by notice in writing whether it disagrees with the contents of the Claim. Any Claim with which Patheon disagrees will be considered a Technical Dispute and subject to Section 13.4 of the body of the MSA.

(d) **Shortages and Price.** Any dispute or claim related to the quantity of Commercial Product delivered or Price will be considered waived by Client if it has not been presented on or before [***] days of the date of the relevant invoice.

7.2 **Delays caused by Patheon:**

After [***] commercial batches have been produced by Patheon successfully, in the event that Patheon fails to deliver the Commercial Product by the agreed Release Date after a [***] grace period ("Delayed Product"), provided that such delay was not caused by Client including Client's negligence, wrongful actions, approval delays, Client Supplied Material delays or to a defect in the Client Supplied Materials, Patheon will pay or credit Client [***]% of the batch fee, with an increase of [***]% for every [***] days late, up to a max of [***]%. Client agrees to further use commercially reasonable efforts to work with Patheon to reduce issues which may cause delays.

7.3 **Commercial Product Recalls and Returns.**

(a) **Records and Notice.** The Parties will each maintain records in accordance with Applicable Laws, the Quality Agreement, its corporate policies, and as necessary to permit a Recall of any Commercial Product delivered to Client. Each Party will promptly notify the other of any information which might affect the marketability, safety, or efficacy of the Commercial Product. Recalls will be handled in accordance with the Quality Agreement. The decision to initiate a Recall of the Commercial Product or Bluebird Drug Product or to take some other corrective action, if any, will be made and implemented by Client.

(b) **Recalled Commercial Product or Bluebird Drug Product.** To the extent that a Recall results from, or arises from Deficient Services related to Commercial Product only, Patheon will be responsible for the reasonable documented out-of-pocket expenses of

Client for the Recall up to the limitation of liability in Section 12.7 of the body of the MSA and the Remedies provided in Section 12.5 shall be available to Client; provided however, that Patheon's liability for Excluded Materials will be as set forth in Section 10 of this Commercial Schedule. In all other circumstances, Client will be responsible for the cost and expenses associated with a Recall, including cost and expenses associated with a Recall of the Bluebird Drug Product which is not associated to Deficient Services.

7.4 Client will not dispose of Commercial Product for which it intends to assert a Claim against Patheon without Patheon's prior written authorization to do so. Patheon may instruct Client to return samples of or Batches of the Commercial Products that are the subject of a Claim to Patheon. If confirmed to be due to Deficient Services, Patheon will bear the cost of return and disposition of any such Commercial Product. In all other circumstances, Client will bear the cost of return and disposition, including all applicable fees for Commercial Services.

8. CO-OPERATION AND REGULATORY AFFAIRS.

8.1 **Regulatory Filings.**

(a) **Pharmacovigilance.** Client will be responsible, at its expense, for all pharmacovigilance obligations for the Commercial Product/Bluebird Drug Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including the cost of assistance required of Patheon under the Quality Agreement). Patheon agrees to cooperate reasonably with any request from Client in order to comply with its pharmacovigilance obligations, including reasonable requests for information or data.

(b) **No Patheon Responsibility.** If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the specific Commercial Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the Parties will discuss appropriate mutually acceptable actions. Patheon will not be obliged to undertake these activities or to pay for the fees or costs until the Parties reach agreement on scope and Fees for Patheon's assistance.

8.2 **Release**. The Parties agree that the release of the Commercial Product will not by itself indicate compliance by Patheon with its obligations relating to the Commercial Services. Nothing in this MSA will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Commercial Product will be released for shipment or Client's use. For clarity, Client will not release Commercial Product for individual sale or distribution, rather the Commercial Product will be used by Client in Bluebird Drug Product.

8.3 **Withdrawal on Completion**. On or before [***] days following completion or termination of the Commercial Services at the applicable Facility, Client will: (a) ensure that any regulatory filings relating to the Product are withdrawn or amended to remove all references to the Facility; and (b) provide to Patheon written confirmation of its compliance with this Section 8.3. If this time is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's best efforts, then Patheon may agree to extend the period based on the written reassurances of Client and agreement that Client will pay Patheon for any remaining Services provided.

9. WARRANTIES.

9.1 In addition to the warranties given under the body of the MSA, Client hereby further covenants, represents and warrants that:

(a) the Processing Instructions and specifications for the Commercial Product conforms to the current regulatory approvals, all applicable cGMPs and Applicable Laws related to the Bluebird Drug Product;

(b) the Commercial Product, if labelled and manufactured in accordance with the Processing Instructions and in compliance with applicable cGMPs and Applicable Laws (i) will only be used in Bluebird Drug Product which is lawfully sold and distributed in each jurisdiction in which Client markets the Bluebird Drug Product, and (ii) the Commercial Product, if used in a Bluebird Drug Product, will be in used in a manner consistent with the respective FDA approval of the Bluebird Drug Product; and

(c) Client has obtained and will maintain on a timely basis, any permits or other regulatory approvals if necessary, for the use of Commercial Product in a Bluebird Drug Product, Processing Instructions or specifications, including, without limitation, all marketing and post-marketing approvals, and any specific approvals referred to in the Quality Agreement.

8.2 Patheon hereby further covenants, represents and warrants that [***].

10. LIMITATION OF LIABILITY.

10.1 In accordance with Section 12.5 of the body of this MSA, at the time of Deficient Services Patheon will have no liability for Excluded Materials. Without limiting the foregoing, in no event will Patheon's liability for any Batch of Commercial Product exceed [***].

11. RIGHT TO CROSS-REFERENCE. Patheon hereby grants to Client, in connection with any Product and any intermediates, components, or derivatives of Product, a perpetual, irrevocable right to cross-reference Patheon's regulatory submissions and Facility approvals for the purpose of obtaining and maintaining regulatory approvals with respect to the foregoing anywhere in the world. Within [***] weeks after Client's written request, Patheon shall deliver to Client for filing with the U.S. Food and Drug Administration or any foreign Regulatory Authority designated by Client, such authorization letters as Client reasonably deems necessary for the foregoing purpose [***], subject to such modifications as may be required by Applicable Law; *provided, however,* that if Customer proposes any material modifications to such form, Patheon shall be entitled to [***]; and provided, further, that Client shall be responsible for all reasonable costs and expenses associated with its request for such cross reference, and for obtaining any notarization, legalization or apostille that may be required for filing any authorization letter with any foreign Regulatory Authority. For the avoidance of doubt, Patheon shall not be required to provide directly to Client any Patheon documents that are generally applicable to Patheon's business, such as Facility and equipment SOPs unless such documents are expressly requested by a relevant Regulatory Authority or are required by Applicable Law.

12. JSC. The Parties shall promptly establish and convene a joint steering committee (the "**JSC"**).

(a) ***Role***. The role of the JSC shall be the overall coordination and oversight of the Parties' activities under this Commercial Schedule in an advisory capacity only. The JSC shall work in good faith to determine strategies to improve manufacturing efficiency and to optimize costs for Services where appropriate. The JSC shall not have the power to take any action under this Commercial Schedule to interpret, amend or modify the MSA or this Commercial Schedule, or waive compliance therewith.

(b) ***Composition and Cadence*****.** The JSC shall consist of equal numbers of appropriate members of representatives from each Party. The JSC shall meet on a frequency as

agreed upon by the Parties. Meetings of the JSC shall be effective only if at least one representative of each Party is present or participating.

(c) ***Disputes*.** In the event of any conflict amongst the JSC members, the JSC shall discuss and attempt in good faith to resolve the conflict, provided that Client shall have control over matters relating to the objectives, direction and criteria of the Services, but at all times in accordance with this MSA and the applicable Project Agreement, subject at all time to compliance with Applicable Law.

Certain information marked as [***] has been excluded from this exhibit because it is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Exhibit 1
[***]

Exhibit 10.5

BLUEBIRD BIO, INC.

2023 INCENTIVE AWARD PLAN

(As amended and restated November 6, 2024)

ARTICLE I.
PURPOSE

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing these individuals with equity ownership opportunities.

ARTICLE II.
DEFINITIONS

As used in the Plan, the following words and phrases have the meanings specified below, unless the context clearly indicates otherwise:

2.1 "***Administrator***" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee. With reference to the Board's or a Committee's powers or authority under the Plan that have been delegated to one or more officers pursuant to Section 4.2, the term "Administrator" shall refer to such officer(s) unless and until such delegation has been revoked.

2.2 "***Applicable Law***" means any applicable law, including without limitation: (a) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (b) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether U.S. or non-U.S. federal, state or local; and (c) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.3 "***Award***" means an Option award, Stock Appreciation Right award, Restricted Stock award, Restricted Stock Unit award, Performance Bonus Award, Performance Stock Unit award, Dividend Equivalents award or Other Stock or Cash Based Award granted to a Participant under the Plan.

2.4 "***Award Agreement***" means an agreement evidencing an Award, which may be written or electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

2.5 "***Board***" means the Board of Directors of the Company.

2.6 "***Change in Control***" means the occurrence of any of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) directly or indirectly acquires beneficial ownership (within the meaning of Rules 13d-3 and 13d-5 under the Exchange Act) of the Company's securities possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; provided, however, that the following acquisitions shall not constitute a Change in Control: (i) any acquisition by the Company or any Subsidiary; (ii) any acquisition by an employee benefit plan maintained by the Company or any Subsidiary, (iii) any acquisition which complies with clauses (c)(i), (c)(ii) and (c)(iii) of this definition; or (iv) in respect of an Award held by a particular Participant, any acquisition by the Participant or any group of persons including the Participant (or any entity controlled by the Participant or any group of persons including the Participant);

(b) The Incumbent Directors cease for any reason to constitute a majority of the Board;

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination, (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "***Successor Entity***")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction;

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; and

(iii) after which at least a majority of the members of the board of directors (or the analogous governing body) of the Successor Entity were Board members at the time of the Board's approval of the execution of the initial agreement providing for such transaction; or

(d) The completion of a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or any portion of an Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b), (c) or (d) of this definition with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.7 "***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and all regulations, guidance, compliance programs and other interpretative authority issued thereunder.

2.8 "***Committee***" means one or more committees or subcommittees of the Board, which may include one or more Directors or executive officers of the Company, to the extent permitted by Applicable Law. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a "non-employee director" within the meaning of Rule 16b-3; however, a Committee member's failure to qualify as a "non-employee director" within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

2.9 "***Common Stock***" means the common stock of the Company.

2.10 "***Company***" means bluebird bio, Inc., a Delaware corporation, or any successor.

2.11 "***Consultant***" means any person, including any adviser, engaged by the Company or a Subsidiary to render services to such entity if the consultant or adviser: (a) renders bona fide services to the Company or a Subsidiary; (b) renders services not in connection with the offer or sale of securities in a capital-raising transaction and does not directly or indirectly promote or maintain a market for the Company's securities; and (c) is a natural person.

2.12 "***Designated Beneficiary***" means, if permitted by the Company, the beneficiary or beneficiaries the Participant designates, in a manner the Company determines, to receive amounts due or exercise the Participant's rights if the Participant dies. Without a Participant's effective designation, "Designated Beneficiary" will mean the Participant's estate or legal heirs.

2.13 "***Director***" means a Board member.

2.14 "***Disability***" means a permanent and total disability under Section 22(e)(3) of the Code.

2.15 "***Dividend Equivalents***" means a right granted to a Participant to receive the equivalent value (in cash or Shares) of dividends paid on a specified number of Shares. Such Dividend Equivalent shall be converted to cash or additional Shares, or a combination of cash and Shares, by such formula and at such time and subject to such limitations as may be determined by the Administrator.

2.16 "***DRO***" means a "domestic relations order" as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended, or the rules thereunder.

2.17 "***Effective Date***" has the meaning set forth in Section 11.3.

2.18 "***Employee***" means any employee of the Company or any of its Subsidiaries.

2.19 "***Equity Restructuring***" means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split (including a reverse stock split), spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

2.20 "***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended, and all regulations, guidance and other interpretative authority issued thereunder.

2.21 "***Fair Market Value***" means, as of any date, the value of a Share determined as follows: (a) if the Common Stock is listed on any established stock exchange, the value of a Share will be the closing sales price for a Share as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (b) if the Common Stock is not listed on an established stock exchange but is quoted on a national market or other quotation system, the value of a Share will be the closing sales price for a Share on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; or (iii) if the Common Stock is not listed on any established stock exchange or quoted on a national market or other quotation system, the value established by the Administrator in its sole discretion.

2.22 "***Full Value Award***" means any Award that is settled in Shares other than (a) an Option, (b) a Stock Appreciation Right or (c) any other Award for which a Participant pays the intrinsic value existing as of the date of grant (whether directly or by foregoing a right to receive a payment from the Company or any affiliate thereof).

2.23 "***Greater Than 10% Stockholder***" means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or any parent corporation or subsidiary corporation of the Company, as determined in accordance with Section 424(e) and (f) of the Code, respectively.

2.24 "***Incentive Stock Option***" means an Option that meets the requirements to qualify as an "incentive stock option" as defined in Section 422 of the Code.

2.25 "***Incumbent Directors***" means, for any period of 12 consecutive months, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in clause (a) or (c) of the Change in Control definition) whose election or nomination for election to the Board was approved by a vote of at least a majority (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for Director without objection to such nomination) of the Directors then still in office who either were Directors at the beginning of the 12-month period or whose election or nomination for election was previously so approved. No individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to Directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any person other than the Board shall be an Incumbent Director.

2.26 "***Non-Employee Director***" means a Director who is not an Employee.

2.27 "***Nonqualified Stock Option***" means an Option that is not an Incentive Stock Option.

2.28 "***Option***" means a right granted under Article VI to purchase a specified number of Shares at a specified price per Share during a specified time period. An Option may be either an Incentive Stock Option or a Nonqualified Stock Option.

2.29 "***Other Stock or Cash Based Awards***" means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.

2.30 "***Overall Share Limit***" means the sum of (a) 20,200,000 Shares plus (b) any Shares that are subject to Prior Plan Awards that become available for issuance under the Plan as Shares pursuant to Article V.

2.31 "***Participant***" means a Service Provider who has been granted an Award.

2.32 "***Performance Bonus Award***" has the meaning set forth in Section 8.3.

2.33 "***Performance Stock Unit***" means a right granted to a Participant pursuant to Section 8.1 and subject to Section 8.2, to receive Shares or an amount of cash or other consideration determined by the Administrator to be of equal value as of the settlement date, the payment of which is contingent upon achieving certain performance goals or other performance-based targets established by the Administrator.

2.34 "***Permitted Transferee***" means, with respect to a Participant, any "family member" of the Participant, as defined in the General Instructions to Form S-8 Registration Statement under the Securities Act (or any successor form thereto), or any other transferee specifically approved by the Administrator after taking into account Applicable Law.

2.35 "***Plan***" means this 2023 Incentive Award Plan, as amended and restated.

2.36 "***Prior Plan***" means the Company's 2013 Stock Option and Incentive Plan, as it may be amended from time to time.

2.37 "***Prior Plan Award***" means an award outstanding under the Prior Plan as of immediately prior to the Original Effective Date.

2.38 "***Restricted Stock***" means Shares awarded to a Participant under Article VII, subject to certain vesting conditions and other restrictions.

2.39 "***Restricted Stock Unit***" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date, subject to certain vesting conditions and other restrictions.

2.40 "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act, including any amendments thereto.

2.41 "***Section 409A***" means Section 409A of the Code.

2.42 "***Securities Act***" means the Securities Act of 1933, as amended, and all regulations, guidance and other interpretative authority issued thereunder.

2.43 "***Service Provider***" means an Employee, Consultant or Director.

2.44 "***Shares***" means shares of Common Stock.

2.45 "***Stock Appreciation Right***" or "***SAR***" means a right granted under Article VI to receive a payment equal to the excess of the Fair Market Value of a specified number of Shares on the date the right is exercised over the exercise price set forth in the applicable Award Agreement.

2.46 "***Subsidiary***" means any entity (other than the Company), whether U.S. or non-U.S., in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.47 "***Substitute Awards***" means Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company or other entity acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines.

2.48 "***Tax-Related Items***" means any U.S. and non-U.S. federal, state and/or local taxes (including, without limitation, income tax, social insurance contributions, fringe benefit tax, employment tax, stamp tax and any employer tax liability which has been transferred to a Participant) for which a Participant is liable in connection with Awards and/or Shares.

2.49 "***Termination of Service***" means:

(a) As to a Consultant, the time when the engagement of a Participant as a Consultant to the Company or a Subsidiary is terminated for any reason, including, without limitation, by resignation, discharge, death or retirement, but excluding terminations where the Consultant simultaneously commences or remains in employment or service with the Company or any Subsidiary.

(b) As to a Non-Employee Director, the time when a Participant who is a Non-Employee Director ceases to be a Director for any reason, including, without limitation, a termination by resignation, failure to be elected, death or retirement, but excluding terminations where the Participant simultaneously commences employment or service or remains in service with the Company or any Subsidiary.

(c) As to an Employee, the time when the employee-employer relationship between a Participant and the Company or any Subsidiary is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Participant simultaneously commences or remains in employment or service with the Company or any Subsidiary.

The Company, in its sole discretion, shall determine the effect of all matters and questions relating to any Termination of Service, including, without limitation, whether a Termination of Service has occurred, whether a Termination of Service resulted from a discharge for "cause" and all questions of whether particular leaves of absence constitute a Termination of Service. For purposes of the Plan, a Participant's employee-employer relationship or consultancy relationship shall be deemed to be terminated in the event that the Subsidiary employing or contracting with such Participant ceases to remain a Subsidiary following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off), even though the Participant may subsequently continue to perform services for that entity.

ARTICLE III.
ELIGIBILITY

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein. No Service Provider shall have any right to be granted an Award pursuant to the Plan and neither the Company nor the Administrator is obligated to treat Service Providers, Participants or any other persons uniformly.

ARTICLE IV.
ADMINISTRATION AND DELEGATION

4.1 Administration.

(a) The Plan is administered by the Administrator. The Administrator has authority to determine which Service Providers receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions, reconcile inconsistencies in the Plan or any Award and make all other determinations that it deems necessary or appropriate to administer the Plan and any Awards. The Administrator (and each member thereof) is entitled to, in good faith, rely or act upon any report or other information furnished to the Administrator or member thereof by any officer or other Employee, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan. The Administrator's determinations under the Plan are in its sole discretion and will be final, binding and conclusive on all persons having or claiming any interest in the Plan or any Award.

(b) Without limiting the foregoing, the Administrator has the exclusive power, authority and sole discretion to: (i) designate Participants; (ii) determine the type or types of Awards to be granted to each Participant; (iii) determine the number of Awards to be granted and the number of Shares to which an Award will relate; (iv) subject to the limitations in the Plan, determine the terms and conditions of any Award and related Award Agreement, including, but not limited to, the exercise price, grant price, purchase price, any performance criteria, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations, waivers or amendments thereof; (v) determine whether, to what extent, and under what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, or other property, or an Award may be cancelled, forfeited, or surrendered; and (vi) make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan.

4.2 Delegation of Authority. To the extent permitted by Applicable Law, the Board or any Committee may delegate any or all of its powers under the Plan to one or more Committees or officers of the Company or any of its Subsidiaries; provided, however, that in no event shall an officer of the Company or any of its Subsidiaries be delegated the authority to grant Awards to, or amend Awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act, or (b) officers of the Company or any of its Subsidiaries or Directors to whom authority to grant or amend Awards has been delegated hereunder. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation or that are otherwise included in the applicable organizational documents, and the Board or Committee, as applicable, may at

any time rescind the authority so delegated or appoint a new delegate. At all times, the delegate appointed under this Section 4.2 shall serve in such capacity at the pleasure of the Board or the Committee, as applicable, and the Board or the Committee may abolish any committee at any time and re-vest in itself any previously delegated authority. Further, regardless of any delegation, the Board or a Committee may, in its discretion, exercise any and all rights and duties as the Administrator under the Plan delegated thereby, except with respect to Awards that are required to be determined in the sole discretion of the Board or Committee under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

ARTICLE V.
STOCK AVAILABLE FOR AWARDS

5.1 Number of Shares. Subject to adjustment under Article IX and the terms of this Article V, Awards may be made under the Plan covering up to the Overall Share Limit. As of the Original Effective Date, the Company ceased granting awards under the Prior Plan; however, Prior Plan Awards will remain subject to the terms of the Prior Plan. Shares issued or delivered under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.

5.2 Share Recycling.

(a) If all or any part of an Award or Prior Plan Award expires, lapses or is terminated, converted into an award in respect of shares of another entity in connection with a spin-off or other similar event, exchanged or settled for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award or Prior Plan Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award or Prior Plan Award, the unused Shares covered by the Award or Prior Plan Award will, as applicable, become or again be available for Awards under the Plan. The payment of dividends or Dividend Equivalents in cash in conjunction with any outstanding Awards or Prior Plan Awards and any Awards that are settled in cash rather than by issuance of Shares shall not count against the Overall Share Limit.

(b) Notwithstanding anything in the Plan to the contrary, the following Shares shall not be available for future grants of Awards: (i) Shares tendered by a Participant or withheld by the Company in payment of the exercise price of an Option or any stock option granted under the Prior Plan; (ii) Shares tendered by a Participant or withheld by the Company to satisfy any tax withholding obligation with respect to an Award or any Prior Plan Award; (iii) Shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the Stock Appreciation Right or stock appreciation right granted under the Prior Plan on exercise; and (iv) Shares purchased on the open market with the cash proceeds from the exercise of Options or stock options granted under the Prior Plan.

5.3 Incentive Stock Option Limitations. Notwithstanding anything to the contrary herein, no more than 20,200,000 Shares (as adjusted to reflect any Equity Restructuring) may be issued pursuant to the exercise of Incentive Stock Options.

5.4 Substitute Awards. In connection with an entity's merger or consolidation with the Company or any Subsidiary or the Company's or any Subsidiary's acquisition of an entity's property or stock, the Administrator may grant Substitute Awards in respect of any options or other stock or stock-based awards granted before such merger or consolidation by such entity or its affiliate subject to Applicable Law. Substitute Awards may be granted on such terms and conditions as the Administrator deems appropriate, notwithstanding limitations on Awards in the Plan. Subject to Applicable Law, Substitute Awards will not count against the Overall Share Limit (nor shall Shares subject to a Substitute Award be added to the Shares available for Awards under the Plan as provided under Section 5.2 above), except that Shares acquired by exercise of substitute Incentive Stock Options will count against the maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under the Plan. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted

in contemplation of such acquisition or combination subject to Applicable Law, the shares available for grant pursuant to the terms of such pre-existing plan (as appropriately adjusted to reflect the transaction) may be used for Awards under the Plan and shall not count against the Overall Share Limit (and Shares subject to such Awards may again become available for Awards under the Plan as provided under Section 5.2 above); provided that Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not Service Providers prior to such acquisition or combination.

5.5 Non-Employee Director Award Limit. The maximum aggregate amount of cash and value of Awards (calculated based on grant date fair value determined in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) granted in any calendar year to any individual Non-Employee Director for their services as a Non-Employee Director shall not exceed $750,000 in the case of an incumbent Non-Employee Director; provided, however, that such maximum aggregate amount shall not exceed $1,000,000 in any calendar year for any individual Non-Employee Director in such Non-Employee Director's initial year of election or appointment; and provided, further, however, that fees paid by the Company on behalf of any Non-Employee Director in connection with regulatory compliance and any amounts paid to a Non-Employee Director as reimbursement of an expense shall not count against the foregoing limit. The Board may make exceptions to this limit for individual Non-Employee Directors in extraordinary circumstances, as the Board may determine in its discretion, provided that the Non-Employee Director receiving such additional compensation may not participate in the decision to award such compensation. For the avoidance of doubt, this limitation shall not apply to cash or Awards granted to a Non-Employee Director in his or her capacity as an advisor or consultant to the Company.

5.6 Minimum Award Vesting Limitations. Notwithstanding any other provision of the Plan to the contrary, but subject to Section 9.2, no Award (or portion thereof) granted under the Plan shall vest earlier than the first anniversary of the date the Award is granted and no Award Agreement shall reduce or eliminate such minimum vesting requirement; provided, however, that, notwithstanding the foregoing, the minimum vesting requirement of this Section 5.6 shall not apply to: (a) any Substitute Awards, (b) any Awards delivered in lieu of fully-vested cash-based Awards (or other fully-vested cash awards or payments), (c) any Awards to Non-Employee Directors for which the vesting period runs from the date of one annual meeting of the Company's stockholders to the next annual meeting of the Company's stockholders and which is at least 50 weeks after the immediately preceding year's annual meeting, or (d) any other Awards granted by the Administrator from time to time that result in the issuance of an aggregate of up to 5% of the Overall Share Limit. In addition, the Administrator may provide that such one-year vesting restrictions may lapse or be waived upon the Participant's Termination of Service and/or in connection with a Change in Control.

ARTICLE VI.
STOCK OPTIONS AND STOCK APPRECIATION RIGHTS

6.1 General. The Administrator may grant Options or Stock Appreciation Rights to one or more Service Providers, subject to such terms and conditions not inconsistent with the Plan as the Administrator shall determine. The Administrator will determine the number of Shares covered by each Option and Stock Appreciation Right, the exercise price of each Option and Stock Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Stock Appreciation Right. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying (a) the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by (b) the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose, and payable in cash, Shares valued at Fair Market Value on the date of exercise or a combination of the two as the Administrator may determine or provide in the Award Agreement.

6.2 Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. Subject to Section 6.7, the exercise price will

not be less than 100% of the Fair Market Value on the grant date of the Option or Stock Appreciation Right. Notwithstanding the foregoing, in the case of an Option or Stock Appreciation Right that is a Substitute Award, the exercise price per share of the Shares subject to such Option or Stock Appreciation Right, as applicable, may be less than the Fair Market Value per share on the date of grant; provided that the exercise price of any Substitute Award shall be determined in accordance with the applicable requirements of Sections 424 and 409A of the Code.

6.3 Duration of Options. Subject to Section 6.7, each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Stock Appreciation Right will not exceed ten years; provided, further, that, unless otherwise determined by the Administrator or specified in the Award Agreement, (a) no portion of an Option or Stock Appreciation Right which is unexercisable at a Participant's Termination of Service shall thereafter become exercisable and (b) the portion of an Option or Stock Appreciation Right that is unexercisable at a Participant's Termination of Service shall automatically expire on the date of such Termination of Service. In addition, in no event shall an Option or Stock Appreciation Right granted to an Employee who is a non-exempt employee for purposes of overtime pay under the U.S. Fair Labor Standards Act of 1938 be exercisable earlier than six months after its date of grant. Notwithstanding the foregoing, if the Participant, prior to the end of the term of an Option or Stock Appreciation Right, commits an act of "cause" (as determined by the Administrator), or violates any non-competition, non-solicitation or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company or any of its Subsidiaries, the right to exercise the Option or Stock Appreciation Right, as applicable, may be terminated by the Company and the Company may suspend the Participant's right to exercise the Option or Stock Appreciation Right when it reasonably believes that the Participant may have participated in any such act or violation.

6.4 Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company (or such other person or entity designated by the Administrator) a notice of exercise, in a form and manner the Company approves (which may be written, electronic or telephonic and may contain representations and warranties deemed advisable by the Administrator), signed or authenticated by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, (a) payment in full of the exercise price for the number of Shares for which the Option is exercised in a manner specified in Section 6.5 and (b) satisfaction in full of any withholding obligation for Tax-Related Items in a manner specified in Section 10.5.

6.5 No Fractional Shares. No fractional shares of Stock shall be issued or delivered pursuant to the Plan or any Award, and the Administrator shall determine whether cash, other securities or other property shall be paid or transferred in lieu of any fractional shares, or whether such fractional shares or any rights thereto shall be canceled, terminated or otherwise eliminated.

6.6 Payment Upon Exercise. The Administrator shall determine the methods by which payment of the exercise price of an Option shall be made, including, without limitation:

(a) Cash, check or wire transfer of immediately available funds; provided that the Company may limit the use of one of the foregoing methods if one or more of the methods below is permitted;

(b) If there is a public market for Shares at the time of exercise, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of a notice that the Participant has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise of the Option and that the broker has been directed to deliver promptly to the Company funds sufficient to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company an amount sufficient to pay the exercise price by cash, wire transfer of immediately available funds or check; provided that such amount is paid to the Company at such time as may be required by the Company;

(c) To the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value on the date of delivery;

(d) To the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(e) To the extent permitted by the Administrator, any combination of the above payment forms.

6.7 Additional Terms of Incentive Stock Options. The Administrator may grant Incentive Stock Options only to employees of the Company, any of its present or future parent or subsidiary corporations, as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. If an Incentive Stock Option is granted to a Greater Than 10% Stockholder, the exercise price will not be less than 110% of the Fair Market Value on the Option's grant date, and the term of the Option will not exceed five years. All Incentive Stock Options (and Award Agreements related thereto) will be subject to and construed consistently with Section 422 of the Code. By accepting an Incentive Stock Option, the Participant agrees to give prompt notice to the Company of dispositions or other transfers (other than in connection with a Change in Control) of Shares acquired under the Option made within the later of (a) two years from the grant date of the Option or (b) one year after the transfer of such Shares to the Participant, specifying the date of the disposition or other transfer and the amount the Participant realized, in cash, other property, assumption of indebtedness or other consideration, in such disposition or other transfer. Neither the Company nor the Administrator will be liable to a Participant, or any other party, if an Incentive Stock Option fails or ceases to qualify as an "incentive stock option" under Section 422 of the Code. Any Incentive Stock Option or portion thereof that fails to qualify as an "incentive stock option" under Section 422 of the Code for any reason, including becoming exercisable with respect to Shares having a fair market value exceeding the $100,000 limitation under Treasury Regulation Section 1.422-4, will be a Nonqualified Stock Option.

ARTICLE VII.
RESTRICTED STOCK; RESTRICTED STOCK UNITS

7.1 General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to forfeiture or the Company's right to repurchase all or part of the underlying Shares at their issue price or other stated or formula price from the Participant if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement, to Service Providers. The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock and Restricted Stock Units; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock and Restricted Stock Units to the extent required by Applicable Law. The Award Agreement for each Award of Restricted Stock and Restricted Stock Units shall set forth the terms and conditions not inconsistent with the Plan as the Administrator shall determine.

7.2 Restricted Stock.

(a) *Stockholder Rights*. Unless otherwise determined by the Administrator, each Participant holding Shares of Restricted Stock will be entitled to all the rights of a stockholder with respect to such Shares, subject to the restrictions in the Plan and the applicable Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares to the extent such dividends and other distributions have a record date that is on or after the date on which such Participant becomes the record holder of such Shares; provided, however, that with respect to a share of Restricted Stock subject to restrictions or vesting conditions, except in connection with a spin-off or other similar event as otherwise permitted under Section 9.2, dividends which are paid to Company stockholders prior to the removal of restrictions and satisfaction of vesting conditions shall only be paid to the Participant to the extent that the restrictions are subsequently removed and the vesting conditions are subsequently satisfied and the share of Restricted Stock vests.

(b) Stock Certificates. The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of Shares of Restricted Stock, together with a stock power endorsed in blank.

(c) Section 83(b) Election. If a Participant makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which such Participant would otherwise be taxable under Section 83(a) of the Code, such Participant shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service along with proof of the timely filing thereof.

7.3 Restricted Stock Units. The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, subject to compliance with Applicable Law. A Participant holding Restricted Stock Units will have only the rights of a general unsecured creditor of the Company (solely to the extent of any rights then applicable to Participant with respect to such Restricted Stock Units) until delivery of Shares, cash or other securities or property is made as specified in the applicable Award Agreement.

ARTICLE VIII.
OTHER TYPES OF AWARDS

8.1 General. The Administrator may grant Performance Stock Unit awards, Performance Bonus Awards, Dividend Equivalents or Other Stock or Cash Based Awards, to one or more Service Providers, in such amounts and subject to such terms and conditions not inconsistent with the Plan as the Administrator shall determine.

8.2 Performance Stock Unit Awards. Each Performance Stock Unit award shall be denominated in a number of Shares or in unit equivalents of Shares or units of value (including a dollar value of Shares) and may be linked to any one or more of performance or other specific criteria, including service to the Company or Subsidiaries, determined to be appropriate by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator. In making such determinations, the Administrator may consider (among such other factors as it deems relevant in light of the specific type of award) the contributions, responsibilities and other compensation of the particular Participant.

8.3 Performance Bonus Awards. Each right to receive a bonus granted under this Section 8.3 shall be denominated in the form of cash (but may be payable in cash, stock or a combination thereof) (a "***Performance Bonus Award***") and shall be payable upon the attainment of performance goals that are established by the Administrator and relate to one or more of performance or other specific criteria, including service to the Company or Subsidiaries, in each case on a specified date or dates or over any period or periods determined by the Administrator.

8.4 Dividends and Dividend Equivalents. If the Administrator provides, an Award (other than an Option or Stock Appreciation Right) may provide a Participant with the right to receive dividends or Dividend Equivalents. Dividend and Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Award with respect to which the dividends or Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement. Notwithstanding anything to the contrary herein, dividends and Dividend Equivalents with respect to an Award subject to vesting shall either (a) to the extent permitted by Applicable Law, not be paid or credited or (b) be accumulated and subject to vesting to the same extent as the related Award. Any such dividends and Dividend Equivalents shall be paid at such time as the Administrator shall specify in the applicable Award Agreement or as determined by the Administrator in the event not specified in such Award Agreement. In no event shall dividends or Dividend Equivalents be paid with respect to Options or Stock Appreciation Rights.

8.5 Other Stock or Cash Based Awards. Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive cash or Shares to be delivered in the future and annual or other periodic or long-term cash bonus awards (whether based on specified performance criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled, subject to compliance with Section 409A. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, as the Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Stock or Cash Based Award, including any purchase price, performance goal(s), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement. Except in connection with a spin-off or other similar event as otherwise permitted under Article IX, dividends that are scheduled to be paid prior to vesting of any Other Stock or Cash Based Award shall only be paid to the applicable Participant to the extent that the vesting conditions are subsequently satisfied and the Other Stock or Cash Based Award vests.

ARTICLE IX.
ADJUSTMENTS FOR CHANGES IN COMMON STOCK AND CERTAIN OTHER EVENTS

9.1 Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Article IX, the Administrator will equitably adjust the terms of the Plan and each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include (a) adjusting the number and type of securities subject to each outstanding Award or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article V hereof on the maximum number and kind of shares that may be issued); (b) adjusting the terms and conditions of (including the grant or exercise price), and the performance goals or other criteria included in, outstanding Awards; and (c) granting new Awards or making cash payments to Participants. The adjustments provided under this Section 9.1 will be nondiscretionary and final and binding on all interested parties, including the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

9.2 Corporate Transactions. In the event of any extraordinary dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, split-up, spin off, combination, amalgamation, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Law or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (i) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (ii) to facilitate such transaction or event or (iii) give effect to such changes in Applicable Law or accounting principles:

(a) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable, in each case as of the date of such cancellation; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(b) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all Shares (or other property) covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(c) To provide that such Award be assumed by the successor or survivor corporation or entity, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation or entity, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;

(d) To make adjustments in the number and type of Shares (or other securities or property) subject to outstanding Awards or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article V hereof on the maximum number and kind of shares which may be issued) or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards;

(e) To replace such Award with other rights or property selected by the Administrator; or

(f) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

9.3 Change in Control.

(a) Notwithstanding the provisions of Section 9.2, in the event that the successor corporation in a Change in Control refuses to assume or substitute for an Award , the Administrator shall cause such Award to become fully vested and, if applicable, exercisable immediately prior to the consummation of such transaction and all forfeiture restrictions on such Award to lapse and, to the extent unexercised upon the consummation of such transaction, to terminate in exchange for cash, rights or other property (and with respect to the portion of such Award subject to performance-based vesting, all performance criteria will be deemed achieved at the greater of (1) 100% of target levels and (2) actual achievement of the applicable performance criteria as of such Change in Control, unless specifically provided otherwise under the applicable Award Agreement or other written agreement between the Participant and the Company or any of its Subsidiaries, as applicable, or as otherwise determined by the Administrator). The Administrator shall notify the Participant of any Award that becomes exercisable pursuant to the preceding sentence that such Award shall be fully exercisable for a period of 15 days from the date of such notice, contingent upon the occurrence of the Change in Control, and such Award shall terminate upon the consummation of the Change in Control in accordance with the preceding sentence.

(b) For the purposes of this Section 9.3, an Award shall be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change in Control was not solely common stock of the successor corporation or its parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Award, for each Share subject to an Award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per-share consideration received by holders of Common Stock in the Change in Control.

9.4 Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock (including any Equity Restructuring or any securities offering or other similar transaction) or for reasons of administrative convenience or to facilitate compliance with any Applicable Law, the Company may refuse to permit the exercise or settlement of one or more Awards for such period of time as the Company may determine to be reasonably appropriate under the circumstances.

9.5 General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the

Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 9.1 above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant price or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (a) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (b) any merger, consolidation, spinoff, dissolution or liquidation of the Company or sale of Company assets or (c) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares.

ARTICLE X.
PROVISIONS APPLICABLE TO AWARDS

10.1 Transferability.

(a) No Award may be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a DRO, unless and until such Award has been exercised or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed. During the life of a Participant, Awards will be exercisable only by the Participant, unless it has been disposed of pursuant to a DRO. After the death of a Participant, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Award Agreement, be exercised by the Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then-Applicable Law of descent and distribution. References to a Participant, to the extent relevant in the context, will include references to a transferee approved by the Administrator.

(b) Notwithstanding Section 10.1(a), the Administrator, in its sole discretion, may determine to permit a Participant or a Permitted Transferee of such Participant to transfer an Award other than an Incentive Stock Option (unless such Incentive Stock Option is intended to become a Nonqualified Stock Option) to any one or more Permitted Transferees of such Participant, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee other than (A) to another Permitted Transferee of the applicable Participant or (B) by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Participant (other than the ability to further transfer the Award to any person other than another Permitted Transferee of the applicable Participant); (iii) the Participant (or transferring Permitted Transferee) and the receiving Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation, documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer; and (iv) any transfer of an Award to a Permitted Transferee shall be without consideration, except as required by Applicable Law. In addition, and further notwithstanding Section 10.1(a), the Administrator, in its sole discretion, may determine to permit a Participant to transfer Incentive Stock Options to a trust that constitutes a Permitted Transferee if, under Section 671 of the Code and other Applicable Law, the Participant is considered the sole beneficial owner of the Incentive Stock Option while it is held in the trust.

(c) Notwithstanding Section 10.1(a), if permitted by the Administrator, a Participant may, in the manner determined by the Administrator, designate a Designated Beneficiary. A Designated Beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Award Agreement applicable to the Participant and any additional restrictions deemed necessary or appropriate by the Administrator. If the Participant is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Participant's spouse or domestic partner, as applicable, as the Participant's Designated Beneficiary with respect to more than 50% of the Participant's interest in the Award shall not be effective without the prior written or electronic consent of the Participant's spouse or domestic partner. Subject to the foregoing, a

beneficiary designation may be changed or revoked by a Participant at any time; provided that the change or revocation is delivered in writing to the Administrator prior to the Participant's death.

10.2 Documentation. Each Award will be evidenced in an Award Agreement in such form as the Administrator determines in its discretion. Each Award may contain such terms and conditions as are determined by the Administrator in its sole discretion, to the extent not inconsistent with those set forth in the Plan.

10.3 Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

10.4 Changes in Participant's Status. The Administrator will determine how the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable. Except to the extent otherwise required by Applicable Law or expressly authorized by the Company or by the Company's written policy on leaves of absence, no service credit shall be given for vesting purposes for any period the Participant is on a leave of absence.

10.5 Withholding. Each Participant must pay the Company or a Subsidiary, as applicable, or make provision satisfactory to the Administrator for payment of, any Tax-Related Items to be withheld in connection with such Participant's Awards and/or Shares. At the Company's discretion and subject to any Company insider trading policy (including black-out periods), any withholding obligation for Tax-Related Items may be satisfied by (a) deducting an amount sufficient to satisfy such withholding obligation from any payment of any kind otherwise due to a Participant; (b) accepting a payment from the Participant in cash, by wire transfer of immediately available funds, or by check made payable to the order of the Company or a Subsidiary, as applicable; (c) accepting the delivery of Shares, including Shares delivered by attestation; (d) retaining Shares from an Award; (e) if there is a public market for Shares at the time the withholding obligation for Tax-Related Items is to be satisfied, selling Shares issued pursuant to an Award, either voluntarily by the Participant or mandatorily by the Company; (f) any other method of withholding determined by the Company and, to the extent required by Applicable Law or the Plan, approved by the Administrator; or (g) any combination of the foregoing payment forms. The amount withheld pursuant to any of the foregoing payment forms shall be determined by the Company and may be up to, but no greater than, the aggregate amount of such obligations based on the maximum statutory withholding rates in the applicable Participant's jurisdiction for all Tax-Related Items.

10.6 Amendment of Award. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, changing the exercise or settlement date, and converting an Incentive Stock Option to a Nonqualified Stock Option. The Participant's consent to such action will be required unless (a) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (b) the change is permitted under Article IX or pursuant to Section 11.6.

10.7 Prohibition on Repricing. Except pursuant to Article IX, the Administrator shall not, without the approval of the Company's stockholders, (a) amend any outstanding Option or Stock Appreciation Right to reduce its exercise price per Share or (b) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the exercise price of such Option or Stock Appreciation Right exceeds the Fair Market Value of the underlying Shares.

10.8 Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (a) all Award conditions have been met or removed to the Company's satisfaction, (b) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including, without limitation, any applicable securities laws and stock exchange or stock market rules and regulations, (c) any approvals from governmental agencies that the Company determines are necessary or advisable have been obtained, and (d) the Participant has

executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy Applicable Law. The inability or impracticability of the Company to obtain or maintain authority to issue or sell any securities from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained, and shall constitute circumstances in which the Administrator may determine to amend or cancel Awards pertaining to such Shares, with or without consideration to the Participant.

10.9 Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

ARTICLE XI.
MISCELLANEOUS

11.1 No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to commence or continue employment or any other relationship with the Company or a Subsidiary. The Company and its Subsidiaries expressly reserve the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement or other written agreement between the Participant and the Company or any Subsidiary.

11.2 No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Law requires, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares 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 share certificate or book entry to reference restrictions applicable to the Shares (including, without limitation, restrictions applicable to Restricted Stock).

11.3 Effective Date. The Plan originally became effective June 16, 2023 (the "***Original Effective Date***"). The Board approved the amended and restated Plan on September 12, 2024, subject to the approval of the Company's stockholders, and the amended and restated plan will become effective on the date it is approved by the Company's stockholders ("***Effective Date***"). No Incentive Stock Option may be granted pursuant to the Plan after the tenth anniversary of the date the amended and restated Plan was approved by the Board.

11.4 Amendment of Plan. The Administrator may amend, suspend or terminate the Plan at any time and from time to time; provided that (a) no amendment requiring stockholder approval to comply with Applicable Law shall be effective unless approved by the stockholders, and (b) no amendment, other than an increase to the Overall Share Limit or pursuant to Article IX or Section 11.6, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. No Awards may be granted under the Plan during any suspension period or after Plan termination. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as each in effect before such suspension or termination. The Administrator will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Law.

11.5 Provisions for Non-U.S. Participants. The Administrator may modify Awards granted to Participants who are nationals of a country other than the United States or employed or residing outside the United States, establish subplans or procedures under the Plan or take any other necessary or appropriate action to address Applicable Law, including (a) differences in laws, rules, regulations or customs of such jurisdictions with respect to tax, securities, currency, employee benefit or other matters, (b) listing and other requirements of any non-U.S. securities exchange, and (c) any necessary local governmental or regulatory exemptions or approvals.

11.6 Section 409A.

(a) *General*. The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (i) exempt this Plan or any Award from Section 409A, or (ii) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section 11.6 or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.

(b) *Separation from Service*. If an Award constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award upon a Participant's Termination of Service will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or after the Participant's Termination of Service. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms means a "separation from service."

(c) *Payments to Specified Employees*. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" required to be made under an Award to a "specified employee" (as defined under Section 409A and as the Administrator determines) due to such employee's "separation from service" will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such "separation from service" (or, if earlier, until the specified employee's death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award payable more than six months following the Participant's "separation from service" will be paid at the time or times the payments are otherwise scheduled to be made.

(d) *Separate Payments*. If an Award includes a "series of installment payments" within the meaning of Section 1.409A-2(b)(2)(iii) of Section 409A, the Participant's right to the series of installment payments will be treated as a right to a series of separate payments and not as a right to a single payment and, if an Award includes "dividend equivalents" within the meaning of Section 1.409A-3(e) of Section 409A, the Participant's right to receive the dividend equivalents will be treated separately from the right to other amounts under the Award.

11.7 Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as an Administrator, Director, officer or other Employee will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in such person's capacity as an Administrator, Director, officer or other Employee. The Company will indemnify and hold harmless each Director, officer or other Employee that has been or will be granted or delegated any duty or power relating to the Plan's administration or interpretation, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising from any act or omission concerning this Plan unless arising from such person's own fraud or bad faith; provided that such person gives the Company an opportunity, at its own expense, to handle and defend the same before undertaking to handle and defend it on such person's own behalf.

11.8 Data Privacy. As a condition for receiving 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 Section 11.8 by and among the Company and its Subsidiaries and affiliates exclusively for 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 the Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the "***Data***"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant's participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. 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 a recipient's country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 11.8 in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's sole discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section 11.8. For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

11.9 Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

11.10 Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary), the Plan will govern, unless such Award Agreement or other written agreement was approved by the Administrator and expressly provides that a specific provision of the Plan will not apply.

11.11 Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, without regard to the conflict of law rules thereof or of any other jurisdiction. By accepting an Award, each Participant irrevocably and unconditionally consents to submit, at the Company's discretion, to the exclusive jurisdiction of the courts of the State of Delaware and of the United States of America, in each case located in the State of Delaware, for any action arising out of or relating to the Plan (and agrees not to commence any litigation relating thereto except in such courts), and further agrees that service of any process, summons, notice or document by U.S. registered mail to the address contained in the records of the Company shall be effective service of process for any litigation brought against it in any such court. By accepting an Award, each Participant irrevocably and unconditionally waives any objection to the laying of venue of any litigation arising out of the Plan or Award hereunder in the courts of the State of Delaware or the United States of America, in each case located in the State of Delaware, and further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such litigation brought in any such court has been brought in an inconvenient forum. By accepting an Award, each Participant irrevocably and unconditionally waives, to the fullest extent permitted by Applicable Law, any and all rights to trial by jury in connection with any litigation arising out of or relating to the Plan or any Award hereunder.

11.12 Clawback Provisions. All Awards (including the gross amount of any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the

receipt or resale of any Shares underlying the Award) will be subject to recoupment by the Company to the extent required to comply with Applicable Law or any policy of the Company providing for the reimbursement of incentive compensation, whether or not such policy was in place at the time of grant of an Award.

11.13 Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

11.14 Conformity to Applicable Law. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Law. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in a manner intended to conform with Applicable Law. To the extent Applicable Law permits, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Law.

11.15 Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary, except as expressly provided in writing in such other plan or an agreement thereunder.

11.16 Unfunded Status of Awards. The Plan is intended to be an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Participant pursuant to an Award, nothing contained in the Plan or Award Agreement shall give the Participant any rights that are greater than those of a general creditor of the Company or any Subsidiary.

11.17 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

11.18 Prohibition on Executive Officer and Director Loans. Notwithstanding any other provision of the Plan to the contrary, no Participant who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

11.19 Broker-Assisted Sales. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section 10.5: (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all Participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company and its Directors, officers and other Employees harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

* * * * *

BLUEBIRD BIO, INC.
2023 INCENTIVE AWARD PLAN
STOCK OPTION GRANT NOTICE

bluebird bio, Inc., a Delaware corporation, (the "***Company***"), pursuant to its 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"), hereby grants to the holder listed below ("***Participant***"), an option to purchase the number of shares of the Company's Common Stock (the "***Shares***"), set forth below (the "***Option***"). This Option is subject to all of the terms and conditions set forth herein, as well as in the Plan and the Stock Option Agreement attached hereto as **Exhibit A** (the "***Stock Option Agreement***"), each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Stock Option Grant Notice (the "***Grant Notice***") and the Stock Option Agreement.

Participant:	[_____]
Grant Date:	[_____]
Vesting Commencement Date:	[_____]
Exercise Price per Share:	$[_____]
Total Exercise Price:	[_____]
Total Number of Shares Subject to the Option:	[_____]
Expiration Date:	[_____]
Vesting Schedule:	[_____]

Type of Option: [__] Incentive Stock Option [__] Nonqualified Stock Option

If the Company uses an electronic capitalization table system (such as Shareworks, Carta or Equity Edge) and the fields in this Grant Notice are blank or the information is otherwise provided in a different format electronically, the blank fields and other information will be deemed to come from the electronic capitalization system and is considered part of this Grant Notice. In addition, the Company's signature below shall be deemed to have occurred by the Company's input of the Option in such electronic capitalization table system and Participant's signature below shall be deemed to have occurred by Participant's online acceptance of the Option through such electronic capitalization table system.

By Participant's acceptance of the Option through the online acceptance procedure established by the Company or by signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Stock Option Agreement and this Grant Notice. Participant has reviewed the Plan, the Stock Option Agreement and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, the Stock Option Agreement and this Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Stock Option Agreement or this Grant Notice.

BLUEBIRD BIO, INC.:

By:
Print Name:
Title:
Address:

PARTICIPANT:

By:
Print Name:

Address:

EXHIBIT A
TO STOCK OPTION GRANT NOTICE

STOCK OPTION AGREEMENT

Pursuant to the Stock Option Grant Notice (the "***Grant Notice***") to which this Stock Option Agreement (this "***Agreement***") is attached, bluebird bio, Inc., a Delaware corporation (the "***Company***"), has granted to Participant an Option under the Company's 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"), to purchase the number of Shares indicated in the Grant Notice.

ARTICLE 1.

GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions of the Plan which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.

GRANT OF OPTION

2.1 Grant of Option. In consideration of Participant's past and/or continued employment with or service to the Company or any Subsidiary and for other good and valuable consideration, effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"), the Company irrevocably grants to Participant the Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement, subject to adjustments as provided in Article IX of the Plan. Unless designated as a Nonqualified Stock Option in the Grant Notice, the Option shall be an Incentive Stock Option to the maximum extent permitted by law.

2.2 Exercise Price. The exercise price of the Shares subject to the Option shall be as set forth in the Grant Notice, without commission or other charge; *provided*, *however*, that the exercise price per share of the Shares subject to the Option shall not be less than 100% of the Fair Market Value of a Share on the Grant Date. Notwithstanding the foregoing, if this Option is designated as an Incentive Stock Option and Participant is a Greater Than 10% Stockholder as of the Grant Date, the exercise price per share of the Shares subject to the Option shall not be less than 110% of the Fair Market Value of a Share on the Grant Date.

ARTICLE 3.

PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to this Section 3.1 and Sections 3.2, 3.3, 5.11 and 5.17 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) No portion of the Option which has not become vested and exercisable at the date of Participant's Termination of Service shall thereafter become vested and exercisable, except as may be otherwise provided by the Administrator or as set forth in a written agreement between the Company (or any Subsidiary that is the employer of Participant) and Participant.

(c) Notwithstanding Section 3.1(a) hereof and the Grant Notice, but subject to Section 3.1(b) hereof, in the event of a Change in Control the Option shall be treated pursuant to Sections 9.2 and 9.3 of the Plan.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice, which shall in no event be more than ten years from the Grant Date;

(b) If this Option is designated as an Incentive Stock Option and Participant, at the time the Option was granted, was a Greater Than 10% Stockholder, the expiration of five years from the Grant Date;

(c) The expiration of three months from the date of Participant's Termination of Service, unless such termination occurs by reason of Participant's death or Disability or Cause;

(d) The expiration of one year from the date of Participant's Termination of Service by reason of Participant's death or Disability; or

(e) Participant's Termination of Service for Cause. For purposes hereof, "***Cause***" shall mean, unless otherwise provided in an employment or service agreement between the Company and Participant, a determination by the Administrator that Participant shall be dismissed as a result of (i) Participant's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any of the Company's current or prospective customers, suppliers vendors or other third parties with which such entity does business; (ii) Participant's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) Participant's failure to perform his assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, after written notice given to Participant by the Company; (iv) the Participant's gross negligence, willful misconduct or insubordination with respect to the Company or any affiliate of the Company; or (v) Participant's violation of any provision of any agreement(s) between Participant and the Company relating to noncompetition, nondisclosure and/or assignment of inventions.

3.4 Special Tax Consequences. Participant acknowledges that, to the extent that the aggregate Fair Market Value (determined as of the time the Option is granted) of all Shares with respect to which Incentive Stock Options, including the Option (if applicable), are exercisable for the first time by Participant in any calendar year exceeds $100,000, the Option and such other options shall be Nonqualified Stock Options to the extent necessary to comply with the limitations imposed by Section 422(d) of the Code. Participant further acknowledges that the rule set forth in the preceding sentence shall be applied by taking the Option and other "incentive stock options" into account in the order in which they were granted, as determined under Section 422(d) of the Code and the Treasury Regulations thereunder. Participant also acknowledges that an Incentive Stock Option exercised more than three months after Participant's Termination of Employment, other than by reason of death or Disability, will be taxed as a Nonqualified Stock Option.

3.5 Tax Indemnity.

(a) Participant agrees to hold harmless, indemnify and keep indemnified the Company, any Subsidiary and Participant's employing company, if different, from and against any liability for or obligation to pay any Tax-Related Items that are attributable to (1) the grant or exercise of, or any benefit derived by Participant from, the Option, (2) the acquisition by Participant of the Shares on exercise of the Option or (3) the disposal of any Shares.

(b) The Option cannot be exercised until Participant has made such arrangements as the Company may require for the satisfaction of any Tax-Related Items that may arise in connection with the exercise of the Option or the acquisition of the Shares by Participant. The Company shall not be required to issue, allot or transfer Shares until Participant has satisfied this obligation.

(c) Participant hereby acknowledges that the Company (i) makes no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option and (ii) does not commit to and is under no obligation to structure the terms of the grant or any aspect of any Award, including the Option, to reduce or eliminate Participant's liability for Tax-Related Items or achieve any particular tax result. Furthermore, if Participant becomes subject to tax in more than one jurisdiction between the date of grant of an Award, including the Option, and the date of any relevant taxable event, Participant acknowledges that the Company may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

ARTICLE 4.

EXERCISE OF OPTION

4.1 Person Eligible to Exercise. Except as provided in Section 5.3 hereof, during the lifetime of Participant, only Participant may exercise the Option or any portion thereof, unless it has been disposed of pursuant to a DRO. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by the deceased Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then applicable laws of descent and distribution.

4.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof. However, the Option shall not be exercisable with respect to fractional Shares.

4.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company; for the avoidance of doubt, delivery shall include electronic delivery), during regular business hours, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof:

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator. The notice shall be signed by Participant or other person then entitled to exercise the Option or such portion of the Option;

(b) The receipt by the Company of full payment for the Shares with respect to which the Option or portion thereof is exercised, including payment of any applicable Tax-Related Items, which shall be made by deduction from other compensation payable to Participant or in such other form of consideration permitted under Section 4.4 hereof that is acceptable to the Company;

(c) Any other written representations or documents as may be required in the Administrator's sole discretion to evidence compliance with the Securities Act, the Exchange Act or any other Applicable Law; and

(d) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Company shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

4.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of Shares (including, without limitation, Shares otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof; or

(c) Other legal consideration acceptable to the Administrator (including, without limitation, through the delivery of a notice that Participant has placed a market sell order with a broker with respect to Shares then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale).

4.5 Conditions to Issuance of Shares. The Shares deliverable upon the exercise of the Option, or any portion thereof, may be either previously authorized but unissued Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any Shares purchased upon the exercise of the Option or portion thereof prior to fulfillment of all of the conditions in Section 10.8 of the Plan and the following conditions:

(a) The continuation of such Shares to listing on all stock exchanges on which such Shares are then listed;

(b) The completion of any registration or other qualification of such Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or of any other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state or federal governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable;

(d) The receipt by the Company of full payment for such Shares, including payment of any applicable Tax-Related Items, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Administrator may from time to time establish for reasons of administrative convenience.

4.6 Rights as Stockholder. The holder of the Option shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any Shares purchasable upon the exercise of any part of the Option unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE 5.

OTHER PROVISIONS

5.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Administrator or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the Option.

5.2 Whole Shares. The Option may only be exercised for whole Shares.

5.3 Transferability. The Option shall be subject to the restrictions on transferability set forth in Section 10.1 of the Plan.

5.4 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences as a result of the grant, vesting or exercise of the Option, or with the purchase or disposition of the Shares subject to the Option. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of such Shares and that Participant is not relying on the Company for any tax advice.

5.5 Binding Agreement. Subject to the limitation on the transferability of the Option contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the Option in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

5.7 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.7, either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to Participant shall, if Participant is then deceased, be given to the person entitled to exercise his or her Option pursuant to Section 4.1 hereof by written notice under this Section 5.7. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

5.10 Conformity to Applicable Law. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any other Applicable Law. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to such Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

5.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of Participant, unless such action is necessary to ensure or facilitate compliance with Applicable Law, as determined by the Administrator.

5.12 Successors and Assigns. The Company may assign any of its rights and delegate any of its obligations under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 5.3 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

5.13 Notification of Disposition. If this Option is designated as an Incentive Stock Option, Participant shall give prompt notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or transfer is made (a) within two years from the Grant Date with respect to such Shares or (b) within one year after the transfer of such Shares to Participant. 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 Participant in such disposition or other transfer.

5.14 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, then the Plan, the Option and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.15 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to commence or continue to serve as an Employee or other Service Provider or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise by Applicable Law or in a written agreement between the Company or a Subsidiary (as applicable) and Participant.

5.16 Entire Agreement. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto, if any) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof, provided that the Option shall be subject to any accelerated vesting provisions in any written agreement between Participant and the Company (or any Subsidiary that is the employer of Participant) or a Company plan pursuant to which Participant participates, in each case, in accordance with the terms therein.

5.17 Section 409A. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "***Section 409A***"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the Option (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate either for the Option to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.18 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company and its Subsidiaries with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

* * * * *

BLUEBIRD BIO, INC.
2023 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT AWARD GRANT NOTICE

bluebird bio, Inc., a Delaware corporation, (the "***Company***"), pursuant to its 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"), hereby grants to the holder listed below ("***Participant***"), an award of restricted stock units ("***Restricted Stock Units***" or "***RSUs***"). Each vested RSU represents the right to receive, in accordance with the Restricted Stock Unit Award Agreement attached hereto as **Exhibit A** (the "***Agreement***"), one share of Common Stock ("***Share***"). This award of RSUs is subject to all of the terms and conditions set forth herein and in the Agreement and the Plan, each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and the Agreement.

Participant:	[_____]
Grant Date:	[_____]
Total Number of RSUs:	[_____]
Vesting Commencement Date:	[_____]
Vesting Schedule:	[_____]
Termination of Service:	Except as otherwise provided by the Administrator, if Participant experiences a Termination of Service, all RSUs that have not become vested on or prior to the date of such Termination of Service will thereupon be automatically forfeited by Participant without payment of any consideration therefor.

If the Company uses an electronic capitalization table system (such as Shareworks, Carta or Equity Edge) and the fields in this Grant Notice are blank or the information is otherwise provided in a different format electronically, the blank fields and other information will be deemed to come from the electronic capitalization system and is considered part of this Grant Notice. In addition, the Company's signature below shall be deemed to have occurred by the Company's input of the RSUs in such electronic capitalization table system and Participant's signature below shall be deemed to have occurred by Participant's online acceptance of the RSUs through such electronic capitalization table system.

By Participant's acceptance of the RSUs through the online acceptance procedure established by the Company or by signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. Participant has reviewed the Plan, the Agreement and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, the Agreement and this Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Agreement or this Grant Notice. In addition, by signing below, Participant also agrees that the Company, in its sole discretion, may satisfy any withholding obligations in accordance with Section 2.5(b) of the Agreement by (i) withholding Shares otherwise issuable to Participant upon settlement of the RSUs, (ii) instructing a broker on Participant's behalf to sell Shares otherwise issuable to Participant upon settlement of the RSUs and submit the proceeds of such sale to the Company, or (iii) using any other method permitted by Section 2.5(b) of the Agreement or the Plan.

BLUEBIRD BIO, INC.:

By:
Print Name:
Title:
Address:

PARTICIPANT:

By:
Print Name:

Address:

EXHIBIT A
TO RESTRICTED STOCK UNIT AWARD GRANT NOTICE

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") to which this Restricted Stock Unit Award Agreement (this "***Agreement***") is attached, bluebird bio, Inc., a Delaware corporation (the "***Company***"), has granted to Participant the number of restricted stock units ("***Restricted Stock Units***" or "***RSUs***") set forth in the Grant Notice under the Company's 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"). Each RSU represents the right to receive one share of Common Stock (a "***Share***") upon vesting.

ARTICLE 1.

GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions of the Plan, which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.

GRANT OF RESTRICTED STOCK UNITS

2.1 Grant of RSUs. Pursuant to the Grant Notice and upon the terms and conditions set forth in the Plan and this Agreement, effective as of the Grant Date set forth in the Grant Notice, the Company hereby grants to Participant an award of RSUs under the Plan in consideration of Participant's past and/or continued employment with or service to the Company or any Subsidiary and for other good and valuable consideration.

2.2 Unsecured Obligation to RSUs. Unless and until the RSUs have vested in the manner set forth in Article 2 hereof, Participant will have no right to receive Common Stock under any such RSUs. Prior to actual payment of any vested RSUs, such RSUs will represent an unsecured obligation of the Company, payable (if at all) only from the general assets of the Company.

2.3 Vesting Schedule. Subject to Section 2.4 hereof, the RSUs shall vest and become nonforfeitable with respect to the applicable portion thereof according to the vesting schedule set forth in the Grant Notice (rounding down to the nearest whole Share). Notwithstanding the foregoing and the Grant Notice, but subject to Section 2.4 hereof, in the event of a Change in Control, the RSUs shall be treated pursuant to Sections 9.2 and 9.3 of the Plan.

2.4 Forfeiture, Termination and Cancellation upon Termination of Service. Notwithstanding any contrary provision of this Agreement or the Plan, except as otherwise provided by the Administrator, upon Participant's Termination of Service for any or no reason, all RSUs which have not vested prior to or in connection with such Termination of Service shall thereupon automatically be forfeited, terminated and cancelled as of the applicable termination date without payment of any consideration by the Company, and Participant, or Participant's beneficiary or personal representative, as the case may be, shall have no further rights hereunder. No portion of the RSUs which has not become vested as of the date on which Participant incurs a Termination of Service shall thereafter become vested, except as may otherwise be provided by the Administrator or as set forth in a written agreement between the Company (or any Subsidiary that is the employer of Participant) and Participant.

2.5 Issuance of Common Stock upon Vesting; Withholding.

(a) As soon as administratively practicable following the vesting of any RSUs pursuant to Section 2.3 hereof, but in no event later than March 15 of the year after the year of vesting (for the avoidance of doubt, this deadline is intended to comply with the "short term deferral" exemption from Section 409A of the Code), the Company shall deliver to Participant (or any transferee permitted under Section 3.2 hereof) a number of Shares equal to the number of RSUs subject to this Award that vest on the applicable vesting date. Notwithstanding the foregoing, in the event Shares are not issued pursuant to Section 10.8 of the Plan, the Shares shall be issued pursuant to the preceding sentence as soon as administratively practicable after the Administrator determines that Shares can again be issued in accordance with such Section.

(b) As set forth in Section 10.5 of the Plan, the Company shall have the authority and the right to deduct or withhold, or to require Participant to remit to the Company, an amount sufficient to satisfy all applicable Tax-Related Items required by law to be withheld with respect to any taxable event arising in connection with the RSUs, using any method determined by the Company and permitted under Section 10.5 of the Plan. The Company shall not be obligated to deliver any Shares to Participant or Participant's legal representative unless and until Participant or Participant's legal representative shall have paid or otherwise satisfied in full the amount of all Tax-Related Items applicable to the taxable income of Participant resulting from the grant or vesting of the RSUs or the issuance of Shares.

2.6 Conditions to Delivery of Shares. The Shares deliverable hereunder may be either previously authorized but unissued Shares, treasury Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue Shares deliverable hereunder prior to fulfillment of the conditions set forth in Section 10.8 of the Plan.

2.7 Rights as Stockholder. The holder of the RSUs shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of the RSUs and any Shares underlying the RSUs and deliverable hereunder unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE 3.

OTHER PROVISIONS

3.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Administrator or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the RSUs.

3.2 Transferability. The RSUs shall be subject to the restrictions on transferability set forth in Section 10.1 of the Plan.

3.3 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences in connection with the RSUs granted pursuant to this Agreement (and the Shares issuable with respect thereto). Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the RSUs and the issuance of Shares with respect thereto and that Participant is not relying on the Company for any tax advice.

3.4 Binding Agreement. Subject to the limitation on the transferability of the RSUs contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

3.5 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the RSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

3.6 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.6, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

3.7 Participant's Representations. If the Shares issuable hereunder have not been registered under the Securities Act or any applicable state laws on an effective registration statement at the time of such issuance, Participant shall, if required by the Company, concurrently with such issuance, make such written representations as are deemed necessary or appropriate by the Company or its counsel.

3.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

3.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

3.10 Conformity to Applicable Law. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any other Applicable Law. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the RSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

3.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of Participant, unless such action is necessary to ensure or facilitate compliance with Applicable Law, as determined by the Administrator.

3.12 Successors and Assigns. The Company may assign any of its rights and delegate any of its obligations under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 3.2 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

3.13 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, then the Plan, the RSUs and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

3.14 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to commence or continue to serve as an Employee or other Service Provider or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise by Applicable Law or in a written agreement between the Company or a Subsidiary (as applicable) and Participant.

3.15 Entire Agreement. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto, if any) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof, provided that the RSUs shall be subject to any accelerated vesting provisions in any written agreement between Participant and the Company (or any Subsidiary that is the employer of Participant) or a Company plan pursuant to which Participant participates, in each case, in accordance with the terms therein.

3.16 Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "***Section 409A***"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

3.17 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company and its Subsidiaries with respect to amounts credited and benefits payable, if any, with respect to the RSUs, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to RSUs, as and when payable hereunder.

* * * * *

BLUEBIRD BIO, INC.
2023 INCENTIVE AWARD PLAN
STOCK OPTION GRANT NOTICE FOR NON-EMPLOYEE DIRECTORS

bluebird bio, Inc., a Delaware corporation, (the "***Company***"), pursuant to its 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"), hereby grants to the holder listed below ("***Participant***"), an option to purchase the number of shares of the Company's Common Stock (the "***Shares***"), set forth below (the "***Option***"). This Option is subject to all of the terms and conditions set forth herein, as well as in the Plan and the Stock Option Agreement for Non-Employee Directors attached hereto as **Exhibit A** (the "***Stock Option Agreement***"), each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Stock Option Grant Notice for Non-Employee Directors (the "***Grant Notice***") and the Stock Option Agreement.

Participant:	[_____]
Grant Date:	[_____]
Vesting Commencement Date:	[_____]
Exercise Price per Share:	$[_____]
Total Exercise Price:	[_____]
Total Number of Shares Subject to the Option:	[_____]
Expiration Date:	[_____]
Vesting Schedule:	[_____]

Type of Option: Nonqualified Stock Option

If the Company uses an electronic capitalization table system (such as Shareworks, Carta or Equity Edge) and the fields in this Grant Notice are blank or the information is otherwise provided in a different format electronically, the blank fields and other information will be deemed to come from the electronic capitalization system and is considered part of this Grant Notice. In addition, the Company's signature below shall be deemed to have occurred by the Company's input of the Option in such electronic capitalization table system and Participant's signature below shall be deemed to have occurred by Participant's online acceptance of the Option through such electronic capitalization table system.

By Participant's acceptance of the Option through the online acceptance procedure established by the Company or by signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Stock Option Agreement and this Grant Notice. Participant has reviewed the Plan, the Stock Option Agreement and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, the Stock Option Agreement and this Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Stock Option Agreement or this Grant Notice.

[*Signature Page Follows*]

BLUEBIRD BIO, INC.:

By:
Print Name:
Title:
Address:

PARTICIPANT:

By:
Print Name:

Address:

EXHIBIT A
TO STOCK OPTION GRANT NOTICE FOR NON-EMPLOYEE DIRECTORS

STOCK OPTION AGREEMENT FOR NON-EMPLOYEE DIRECTORS

Pursuant to the Stock Option Grant Notice for Non-Employee Directors (the "***Grant Notice***") to which this Stock Option Agreement for Non-Employee Directors (this "***Agreement***") is attached, bluebird bio, Inc., a Delaware corporation (the "***Company***"), has granted to Participant an Option under the Company's 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"), to purchase the number of Shares indicated in the Grant Notice.

ARTICLE 1.

GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions of the Plan which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.

GRANT OF OPTION

2.1 Grant of Option. In consideration of Participant's past and/or continued service to the Company or any Subsidiary and for other good and valuable consideration, effective as of the Grant Date set forth in the Grant Notice (the "***Grant Date***"), the Company irrevocably grants to Participant the Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement, subject to adjustments as provided in Article IX of the Plan. This Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

2.2 Exercise Price. The exercise price of the Shares subject to the Option shall be as set forth in the Grant Notice, without commission or other charge; *provided*, *however*, that the exercise price per share of the Shares subject to the Option shall not be less than 100% of the Fair Market Value of a Share on the Grant Date.

ARTICLE 3.

PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to this Section 3.1 and Sections 3.2, 3.3, 5.11 and 5.17 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) No portion of the Option which has not become vested and exercisable at the date of Participant's Termination of Service shall thereafter become vested and exercisable, except as may be otherwise provided by the Administrator or as set forth in a written agreement between the Company and Participant.

(c) Notwithstanding Section 3.1(a) hereof and the Grant Notice, but subject to Section 3.1(b) hereof, in the event of a Change in Control the Option shall be treated pursuant to Sections 9.2 and 9.3 of the Plan.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice, which shall in no event be more than ten years from the Grant Date;

(b) The expiration of six months from the date of Participant's Termination of Service, unless such termination occurs by reason of Participant's death or Disability or Cause;

(c) The expiration of one year from the date of Participant's Termination of Service by reason of Participant's death or Disability; or

(d) Participant's Termination of Service for Cause. For purposes hereof, "***Cause***" shall mean, unless otherwise provided in an employment or service agreement between the Company and Participant, a determination by the Administrator that Participant shall be dismissed as a result of (i) Participant's dishonest statements or acts with respect to the Company or any affiliate of the Company, or any of the Company's current or prospective customers, suppliers vendors or other third parties with which such entity does business; (ii) Participant's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) Participant's failure to perform his assigned duties and responsibilities to the reasonable satisfaction of the Company which failure continues, in the reasonable judgment of the Company, after written notice given to Participant by the Company; (iv) the Participant's gross negligence, willful misconduct or insubordination with respect to the Company or any affiliate of the Company; or (v) Participant's violation of any provision of any agreement(s) between Participant and the Company relating to noncompetition, nondisclosure and/or assignment of inventions.

3.4 Tax Indemnity.

(a) Participant agrees to hold harmless, indemnify and keep indemnified the Company and any Subsidiary, if different, from and against any liability for or obligation to pay any Tax-Related Items that are attributable to (1) the grant or exercise of, or any benefit derived by Participant from, the Option, (2) the acquisition by Participant of the Shares on exercise of the Option or (3) the disposal of any Shares.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Participant hereby acknowledges that the Company (i) makes no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option and (ii) does not commit to and is under no obligation to structure the terms of the grant or any aspect of any Award, including the Option, to reduce or eliminate Participant's liability for Tax-Related Items or achieve any particular tax result. Furthermore, if Participant becomes subject to tax in more than one jurisdiction between the date of grant of an Award, including the Option, and the date of any relevant taxable event, Participant acknowledges that the Company may be required to account for Tax-Related Items in more than one jurisdiction.

ARTICLE 4.

EXERCISE OF OPTION

4.1 Person Eligible to Exercise. Except as provided in Section 5.3 hereof, during the lifetime of Participant, only Participant may exercise the Option or any portion thereof, unless it has been disposed of pursuant to a DRO. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by the deceased Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then applicable laws of descent and distribution.

4.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof. However, the Option shall not be exercisable with respect to fractional Shares.

4.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company; for the avoidance of doubt, delivery shall include electronic delivery), during regular business hours, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof:

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator. The notice shall be signed by Participant or other person then entitled to exercise the Option or such portion of the Option;

(b) The receipt by the Company of full payment for the Shares with respect to which the Option or portion thereof is exercised, including payment of any applicable Tax-Related Items, which shall be made by deduction from other compensation payable to Participant or in such other form of consideration permitted under Section 4.4 hereof that is acceptable to the Company;

(c) Any other written representations or documents as may be required in the Administrator's sole discretion to evidence compliance with the Securities Act, the Exchange Act or any other Applicable Law; and

(d) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Company shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

4.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of Shares (including, without limitation, Shares otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof; or

(c) Other legal consideration acceptable to the Administrator (including, without limitation, through the delivery of a notice that Participant has placed a market sell order with a broker

with respect to Shares then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale).

4.5 Conditions to Issuance of Shares. The Shares deliverable upon the exercise of the Option, or any portion thereof, may be either previously authorized but unissued Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any Shares purchased upon the exercise of the Option or portion thereof prior to fulfillment of all of the conditions in Section 10.8 of the Plan and the following conditions:

(a) The continuation of such Shares to listing on all stock exchanges on which such Shares are then listed;

(b) The completion of any registration or other qualification of such Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or of any other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state or federal governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable;

(d) The receipt by the Company of full payment for such Shares, including payment of any applicable Tax-Related Items, if and as applicable, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Administrator may from time to time establish for reasons of administrative convenience.

4.6 Rights as Stockholder. The holder of the Option shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any Shares purchasable upon the exercise of any part of the Option unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE 5.

OTHER PROVISIONS

5.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Administrator or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the Option.

5.2 Whole Shares. The Option may only be exercised for whole Shares.

5.3 Transferability. The Option shall be subject to the restrictions on transferability set forth in Section 10.1 of the Plan.

5.4 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences as a result of the grant, vesting or exercise of the Option, or with the purchase or disposition of the Shares subject to the Option. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of such Shares and that Participant is not relying on the Company for any tax advice.

5.5 Binding Agreement. Subject to the limitation on the transferability of the Option contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the Option in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

5.7 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.7, either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to Participant shall, if Participant is then deceased, be given to the person entitled to exercise his or her Option pursuant to Section 4.1 hereof by written notice under this Section 5.7. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

5.10 Conformity to Applicable Law. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any other Applicable Law. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to such Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

5.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of Participant, unless such action is necessary to ensure or facilitate compliance with Applicable Law, as determined by the Administrator.

5.12 Successors and Assigns. The Company may assign any of its rights and delegate any of its obligations under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 5.3 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

5.13 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, then the Plan, the Option and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the

Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.14 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to commence or continue to serve as a Service Provider or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise by Applicable Law or in a written agreement between the Company or a Subsidiary (as applicable) and Participant.

5.15 Entire Agreement. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto, if any) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof, provided that the Option shall be subject to any accelerated vesting provisions in any written agreement between Participant and the Company or a Company plan pursuant to which Participant participates, in each case, in accordance with the terms therein.

5.16 Section 409A. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "***Section 409A***"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the Option (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate either for the Option to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.17 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company and its Subsidiaries with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

* * * * *

BLUEBIRD BIO, INC.
2023 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT AWARD GRANT NOTICE FOR NON-EMPLOYEE DIRECTORS

bluebird bio, Inc., a Delaware corporation, (the "***Company***"), pursuant to its 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"), hereby grants to the holder listed below ("***Participant***"), an award of restricted stock units ("***Restricted Stock Units***" or "***RSUs***"). Each vested RSU represents the right to receive, in accordance with the Restricted Stock Unit Award Agreement for Non-Employee Directors attached hereto as **Exhibit A** (the "***Agreement***"), one share of Common Stock ("***Share***"). This award of RSUs is subject to all of the terms and conditions set forth herein and in the Agreement and the Plan, each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Restricted Stock Unit Award Grant Notice for Non-Employee Directors (the "***Grant Notice***") and the Agreement.

Participant:	[_____]
Grant Date:	[_____]
Total Number of RSUs:	[_____]
Vesting Commencement Date:	[_____]
Vesting Schedule:	[_____]
Termination of Service:	Except as otherwise provided by the Administrator, if Participant experiences a Termination of Service, all RSUs that have not become vested on or prior to the date of such Termination of Service will thereupon be automatically forfeited by Participant without payment of any consideration therefor.

If the Company uses an electronic capitalization table system (such as Shareworks, Carta or Equity Edge) and the fields in this Grant Notice are blank or the information is otherwise provided in a different format electronically, the blank fields and other information will be deemed to come from the electronic capitalization system and is considered part of this Grant Notice. In addition, the Company's signature below shall be deemed to have occurred by the Company's input of the RSUs in such electronic capitalization table system and Participant's signature below shall be deemed to have occurred by Participant's online acceptance of the RSUs through such electronic capitalization table system.

By Participant's acceptance of the RSUs through the online acceptance procedure established by the Company or by signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. Participant has reviewed the Plan, the Agreement and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, the Agreement and this Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Agreement or this Grant Notice.

BLUEBIRD BIO, INC.:	**PARTICIPANT:**
By:	By:
Print Name:	Print Name:
Title:	
Address:	Address:

EXHIBIT A
TO RESTRICTED STOCK UNIT AWARD GRANT NOTICE FOR NON-EMPLOYEE DIRECTORS

RESTRICTED STOCK UNIT AWARD AGREEMENT FOR NON-EMPLOYEE DIRECTORS

Pursuant to the Restricted Stock Unit Award Grant Notice for Non-Employee Directors (the "***Grant Notice***") to which this Restricted Stock Unit Award Agreement for Non-Employee Directors (this "***Agreement***") is attached, bluebird bio, Inc., a Delaware corporation (the "***Company***"), has granted to Participant the number of restricted stock units ("***Restricted Stock Units***" or "***RSUs***") set forth in the Grant Notice under the Company's 2023 Incentive Award Plan, as may be amended from time to time (the "***Plan***"). Each RSU represents the right to receive one share of Common Stock (a "***Share***") upon vesting.

ARTICLE 1.

GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions of the Plan, which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.

GRANT OF RESTRICTED STOCK UNITS

2.1 Grant of RSUs. Pursuant to the Grant Notice and upon the terms and conditions set forth in the Plan and this Agreement, effective as of the Grant Date set forth in the Grant Notice, the Company hereby grants to Participant an award of RSUs under the Plan in consideration of Participant's past and/or continued service to the Company or any Subsidiary and for other good and valuable consideration.

2.2 Unsecured Obligation to RSUs. Unless and until the RSUs have vested in the manner set forth in Article 2 hereof, Participant will have no right to receive Common Stock under any such RSUs. Prior to actual payment of any vested RSUs, such RSUs will represent an unsecured obligation of the Company, payable (if at all) only from the general assets of the Company.

2.3 Vesting Schedule. Subject to Section 2.4 hereof, the RSUs shall vest and become nonforfeitable with respect to the applicable portion thereof according to the vesting schedule set forth in the Grant Notice (rounding down to the nearest whole Share). Notwithstanding the foregoing and the Grant Notice, but subject to Section 2.4 hereof, in the event of a Change in Control, the RSUs shall be treated pursuant to Sections 9.2 and 9.3 of the Plan.

2.4 Forfeiture, Termination and Cancellation upon Termination of Service. Notwithstanding any contrary provision of this Agreement or the Plan, except as otherwise provided by the Administrator, upon Participant's Termination of Service for any or no reason, all RSUs which have not vested prior to or in connection with such Termination of Service shall thereupon automatically be forfeited, terminated and cancelled as of the applicable termination date without payment of any consideration by the Company, and Participant, or Participant's beneficiary or personal representative, as the case may be, shall have no further rights hereunder. No portion of the RSUs which has not become vested as of the date on which Participant incurs a Termination of Service shall thereafter become vested, except as may otherwise be provided by the Administrator or as set forth in a written agreement between the Company and Participant.

2.5 Issuance of Common Stock upon Vesting; Withholding.

(a) As soon as administratively practicable following the vesting of any RSUs pursuant to Section 2.3 hereof, but in no event later than March 15 of the year after the year of vesting (for the avoidance of doubt, this deadline is intended to comply with the "short term deferral" exemption from Section 409A of the Code), the Company shall deliver to Participant (or any transferee permitted under Section 3.2 hereof) a number of Shares equal to the number of RSUs subject to this Award that vest on the applicable vesting date. Notwithstanding the foregoing, in the event Shares are not issued pursuant to Section 10.8 of the Plan, the Shares shall be issued pursuant to the preceding sentence as soon as administratively practicable after the Administrator determines that Shares can again be issued in accordance with such Section.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the award, vesting or payment of the RSUs or the subsequent sale of Shares. The Company and its Subsidiaries do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

2.6 Conditions to Delivery of Shares. The Shares deliverable hereunder may be either previously authorized but unissued Shares, treasury Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue Shares deliverable hereunder prior to fulfillment of the conditions set forth in Section 10.8 of the Plan.

2.7 Rights as Stockholder. The holder of the RSUs shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of the RSUs and any Shares underlying the RSUs and deliverable hereunder unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE 3.

OTHER PROVISIONS

3.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Administrator or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the RSUs.

3.2 Transferability. The RSUs shall be subject to the restrictions on transferability set forth in Section 10.1 of the Plan.

3.3 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences in connection with the RSUs granted pursuant to this Agreement (and the Shares issuable with respect thereto). Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the RSUs and the issuance of Shares with respect thereto and that Participant is not relying on the Company for any tax advice.

3.4 Binding Agreement. Subject to the limitation on the transferability of the RSUs contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

3.5 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the RSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

3.6 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.6, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

3.7 Participant's Representations. If the Shares issuable hereunder have not been registered under the Securities Act or any applicable state laws on an effective registration statement at the time of such issuance, Participant shall, if required by the Company, concurrently with such issuance, make such written representations as are deemed necessary or appropriate by the Company or its counsel.

3.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

3.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

3.10 Conformity to Applicable Law. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any other Applicable Law. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the RSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

3.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of Participant, unless such action is necessary to ensure or facilitate compliance with Applicable Law, as determined by the Administrator.

3.12 Successors and Assigns. The Company may assign any of its rights and delegate any of its obligations under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 3.2 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

3.13 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, then the Plan, the RSUs and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

3.14 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to commence or continue to serve as a Service Provider or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise by Applicable Law or in a written agreement between the Company or a Subsidiary (as applicable) and Participant.

3.15 Entire Agreement. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto, if any) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof, provided that the RSUs shall be subject to any accelerated vesting provisions in any written agreement between Participant and the Company or a Company plan pursuant to which Participant participates, in each case, in accordance with the terms therein.

3.16 Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "***Section 409A***"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

3.17 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company and its Subsidiaries with respect to amounts credited and benefits payable, if any, with respect to the RSUs, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to RSUs, as and when payable hereunder.

* * * * *

PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT UNDER THE BLUEBIRD BIO, INC. 2023 INCENTIVE AWARD PLAN

Name of Grantee: _____
Target Number of PSUs subject to Award: _____
Date of Grant: _____

Pursuant to the bluebird bio, Inc. 2023 Incentive Award Plan (as may be amended from time to time, the "Plan"), bluebird bio, Inc. (the "Company") hereby grants on the date set forth above (the "Date of Grant") an award (the "Award") of a target number (the "Target Award") of Performance-Based Restricted Stock Units (the "PSUs") listed above to the Grantee named above. Each PSU shall relate to one share of Common Stock, par value $0.01 per share (the "Stock"), of the Company, each as earned, vested and paid as set forth in this Performance-Based Restricted Stock Unit Agreement (the "Agreement"), subject to the terms and conditions set forth in this Agreement and the Plan.

1. Restrictions on Transfer of Award. This Award shall be subject to the restrictions on transferability set forth in Section 10.1 of the Plan.

2. Earning and Vesting of PSUs. The PSUs shall be eligible to become Earned PSUs (as defined in Exhibit A) and vested in accordance with the terms and conditions of Exhibit A hereto.

3. Termination of Employment. If the Grantee's service with the Company and its Subsidiaries terminates for any reason (including without limitation death or disability) prior to the Vesting Date (as defined in Exhibit A), any PSUs that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested PSUs.

4. Issuance of Shares of Stock. As soon as practicable following the Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of PSUs that have earned and vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares. Notwithstanding the foregoing, in the event shares of Stock cannot be issued pursuant to Section 10.8 of the Plan, such shares shall be issued pursuant to the preceding sentence as soon as administratively practicable after the Administrator determines that Shares can again be issued in accordance with such Section.

5. Incorporation of the Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 4.1 of the Plan and the adjustment, modification and termination provisions set forth in the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding. As set forth in Section 10.5 of the Plan, the Company shall have the authority and the right to deduct or withhold, or to require the Grantee to remit to the Company, an amount sufficient to satisfy all applicable federal, state and local taxes required by law to be withheld with respect to any taxable event arising in connection with this Award. By accepting this Award, the Grantee understands and agrees that the Company, on the Grantee's behalf, shall instruct the Company's broker, transfer agent or stock plan administrator, as applicable (the "Agent"), to (1) sell, at the then-applicable market price, that number of shares of Stock issued upon the vesting or settlement of the PSUs as necessary to satisfy any applicable statutory federal, state and local withholding obligations required

with respect to any taxable event arising in connection with the PSUs and all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto, and (2) to pay the cash proceeds of such sale(s) to the Company, with such sales to occur on or as soon as Agent determines is reasonably practicable after the date on which the applicable tax withholding obligation arises (a "Sell to Cover"). The Company shall then make a cash payment equal to the required tax withholding from the cash proceeds of such sale(s) directly to the appropriate taxing authorities. The Company shall not be obligated to deliver any shares of Stock to the Grantee or the Grantee's legal representative unless and until the Grantee or the Grantee's legal representative shall have paid or otherwise satisfied in full the amount of all federal, state and local taxes applicable to the taxable income of the Grantee resulting from the grant or vesting of the PSUs Units or the issuance of shares of Stock.

7. Section 409A of the Code. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Grantee or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

8. No Obligation to Continue Employment. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee in employment or service and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the employment or service of the Grantee at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with Applicable Law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

12. Conformity to Securities Laws. The Grantee acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any other Applicable Law. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the PSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

13. Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Award in any material way without the prior written consent of the Grantee.

14. Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 1 hereof, this Agreement shall be binding upon the Grantee and his or her heirs, executors, administrators, successors and assigns.

15. Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if the Grantee is subject to Section 16 of the Exchange Act, then the Plan, the PSUs and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

[Signature page follows.]

bluebird bio, Inc.
By: _____
Name: _____
Title: _____

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, including, without limitation, the Sell to Cover. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____
Grantee's Signature

Grantee's name and address

_____
_____
_____

EXHIBIT A

1. General. The PSUs will be eligible to be earned and vest subject to the terms and conditions of this Exhibit A based on achievement of the Company's Total Shareholder Return ("TSR") measured against the TSRs of the companies selected by the Compensation Committee and set forth on Exhibit B hereto, which comprise the peer group (the "Peer Group") for purposes of this Agreement (each company in the Peer Group is referred to as a "Peer Group Member").

2. Definitions. The terms set forth below, as used in this Exhibit A, shall have the following meanings:

    a. "Median TSR of Peer Group" shall mean the median value of the series comprising the TSR of each of the Peer Group Members for the Performance Period; *provided* that:

        i. In the event a bankruptcy proceeding is commenced during the Performance Period with respect to any Peer Group Member, or if at any time during the Performance Period a Peer Group Member is liquidated, such company shall be treated as having a TSR of negative one hundred (-100%) for the Performance Period;

        ii. In the event that a merger, acquisition or business combination of a Peer Group Member by or with another Peer Group Member is consummated during the Performance Period, then the entity that survives as a result of such merger, acquisition, or business combination will be considered a Peer Group Member for the Performance Period;

        iii. In the event that a merger, acquisition or business combination of a Peer Group Member by or with an entity that is not Peer Group Member is consummated during the Performance Period, and such Peer Group Member is the entity that survives as a result of such merger, acquisition, or business combination, then such Peer Group Member will continue to be considered a Peer Group Member for the Performance Period; and

        iv. In the event that (a) a Peer Group Member ceases to be a publicly-traded company, or (b) a merger, acquisition or business combination of a Peer Group Member by or with an entity that is not Peer Group Member is consummated during the Performance Period, and such Peer Group Member is not the entity that survives as a result of such merger, acquisition, or business combination, then such Peer Group Member shall be removed and treated as if it had never been in the Peer Group for the Performance Period.

    b. "Performance Period" shall mean the period from the Performance Period Start Date through the Performance Period End Date.

    c. "Performance Period End Date" shall mean the earlier of (i) [____] and (ii) a Change in Control.

    d. "Performance Period Start Date" shall mean [____].

    e. "Total Shareholder Return" shall mean the change in value expressed as a percentage of a given dollar amount invested in a company's most widely publicly traded stock

over the Performance Period, taking into account both stock price appreciation (or depreciation) and the reinvestment of dividends (including the cash value of non-cash dividends) in such stock of the company. The twenty (20) trading-day average closing price of shares of Stock and the stock of the companies in the Peer Group (i.e., the average closing prices over the period of twenty (20) trading days immediately prior to the Performance Period Start Date and the average closing prices over the period of the final twenty (20) trading days ending on the Performance Period End Date) will be used to value shares of Stock and the stock of the Peer Group Member. The twenty (20) trading-day average prices will also be adjusted for dividends, assuming dividends are reinvested. Dividend reinvestment will be calculated using the closing price of a share of Stock or the stock of the applicable Peer Group Member on the ex- dividend date or, if no trades were reported on such date, the most recent preceding date for which a trade was reported. All spinoffs or share-based dividends will be assumed to be sold on the issue date and reinvested in the issuing company that same date.

3. Earning and Vesting of PSUs.

   a. The number of PSUs, if any, that are earned and vested following the completion of the Performance Period based on the achievement of the Company's TSR shall be equal to the Target Award multiplied by the "Percentage of PSUs Earned" set forth in the table below opposite the applicable Threshold, Target or Maximum level of performance based on the Company's TSR compared to the Median TSR of the Peer Group.

The Company's TSR Compared to the Median TSR of the Peer Group	**Percentage of PSUs Earned**
Below Threshold: Company TSR is more than 2500 basis points below the Median TSR of the Peer Group	0%
Threshold: Company TSR is 2500 basis points below the Median TSR of the Peer Group	50%
Target: Company TSR equals the Median TSR of the Peer Group	100%
Maximum: Company TSR is 5000 basis points or more above the Median TSR of the Peer Group	200%

   If the difference between the Company TSR and the Median TSR of the Peer Group falls between Threshold and Target or between Target and Maximum, the Percentage of PSUs Earned shall be interpolated on a straight-line basis.

4. Treatment of PSUs on a Change in Control. Notwithstanding the forgoing, in the event that a Change in Control occurs before the Performance Period End Date while the Grantee is in the continuous services of the Company, upon the occurrence of the Change in Control, the

Grantee shall earn and be vested a number of PSUs equal to the greater of (i) the number of PSUs determined under Section 3 of this Exhibit as if the date of the Change in Control were the last day of the Performance Period, or (ii) the number of PSUs subject to the Target Award.

5. Determination by the Compensation Committee. Not later than sixty (60) days following the completion of the Performance Period, the Compensation Committee shall determine and certify the level of achievement with respect to the Company's TSR performance and the number of PSUs, if any, that are earned and vested in accordance with the forgoing. Any PSUs that are earned hereunder are referred to as "Earned PSUs" and the date when the Committee certifies the number of the Earned PSUs is referred to as the "Vesting Date." Any PSUs that fail to become earned on the Vesting Date shall be immediately forfeited for no consideration as of such date. Any Earned PSUs shall be rounded down to the nearest whole number of shares of Stock and any fractional Earned PSUs shall be disregarded. All determinations under this Exhibit A shall be made by the Compensation Committee and will be final and binding on the Grantee.

EXHIBIT B

Peer Group

AlloVir
Atara Biotherapeutics
Beam Therapeutics
Coherus BioSciences
Editas Medicine
FibroGen
Fulcrum Therapeutics
G1 Therapeutics
Inovio Pharmaceuticals
Intercept Pharmaceuticals
Karyopharm Therapeutics
Marinus Pharmaceuticals
Orchard Therapeutics
Precigen
REGENXBIO
Rhythm Pharmaceuticals
Sangamo Therapeutics
Sorrento Therapeutics
Travere Therapeutics
UniQure

Exhibit 31.1

CERTIFICATIONS

I, Andrew Obenshain, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of bluebird bio, 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: November 14, 2024

By: /s/ Andrew Obenshain

Andrew Obenshain
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, O. James Sterling, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of bluebird bio, 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: November 14, 2024

By: /s/ O. James Sterling

O. James Sterling
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of bluebird bio, Inc. (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his 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: November 14, 2024

By: /s/ Andrew Obenshain

Andrew Obenshain
President, Chief Executive Officer and Director
(Principal Executive Officer and Duly Authorized Signer)

Date: November 14, 2024

By: /s/ O. James Sterling

O. James Sterling
Chief Financial Officer
(Principal Financial Officer, Principal Accounting Officer and Duly Authorized Signer)