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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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: 001-39045

IGM Biosciences, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**77-0349194**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
325 E. Middlefield Road Mountain View, CA	**94043**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 965-7873

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, par value $0.01 per share	IGMS	The Nasdaq Global Select Market

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

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

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

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

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

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

As of August 7, 2024, the registrant had 33,931,686 shares of common stock, $0.01 par value per share, and 25,386,983 shares of non-voting common stock, $0.01 par value per share, outstanding.

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Special Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would,” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about: the therapeutic applications for our IgM antibodies; the advantages of the properties of our IgM bispecific antibodies; the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our discovery programs; our ability to utilize our IgM antibody platform to generate and advance additional product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; the commercializing of our product candidates, if approved; whether, and for how long, we will rely on third parties to manufacture our product candidates for preclinical and clinical testing and to package, label, store and distribute our investigational product candidates; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; potential business disruptions affecting drug discovery, our preclinical studies or the initiation, patient enrollment, development and operation of our clinical trials; the sufficiency of our backup to our master cell banks; expectations regarding our collaboration agreement with Genzyme Corporation, a wholly owned subsidiary of Sanofi (Sanofi), including all financial aspects of the collaboration, the potential benefits and results of the collaboration, as well as plans and objectives with respect to the collaboration; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our expectations regarding the impact of macroeconomic conditions, such as inflation, supply chain disruptions and economic volatility, on our business; our expectations regarding the impact of health epidemics, such as the COVID-19 pandemic, and other catastrophic events on our business; our anticipated use of our existing resources; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash, cash equivalents, and marketable securities to fund our future operating expenses and capital expenditure requirements; our expectations regarding the impact of recently issued accounting standards; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified professionals; the implementation of our business model, strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our IgM platform, product candidates and discovery programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; and the ability of our clinical trials to demonstrate the safety and efficacy of our product candidates, and other positive results.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties, and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, or otherwise.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

IGM Biosciences, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 66,974	$ 112,520
Restricted cash	289	592
Marketable securities	189,407	225,157
Prepaid expenses and other current assets	9,348	9,328
Total current assets	266,018	347,597
Property, plant and equipment, net	36,012	38,232
Operating lease right-of-use assets	33,040	35,773
Other non-current assets	1,431	1,809
Total assets	$ 336,501	$ 423,411
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,259	$ 1,326
Accrued liabilities	26,461	31,544
Lease liabilities	5,937	5,834
Deferred revenue	1,998	3,777
Total current liabilities	37,655	42,481
Lease liabilities, non-current	33,436	34,672
Deferred revenue, non-current	143,052	143,024
Total liabilities	214,143	220,177
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 200,000,000 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, $0.01 par value; 1,000,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 33,852,584 and 33,180,749 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	338	331
Non-voting common stock, $0.01 par value; 200,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 25,386,983 and 25,500,383 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	254	255
Additional paid-in-capital	1,040,921	1,023,739
Accumulated other comprehensive (loss) income	(195)	151
Accumulated deficit	(918,960)	(821,242)
Total stockholders' equity	122,358	203,234
Total liabilities and stockholders' equity	$ 336,501	$ 423,411

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

IGM Biosciences, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 1,254	$ 448	$ 1,751	$ 970
Operating expenses:				
Research and development	41,962	55,673	85,777	106,567
General and administrative	10,649	12,983	21,187	25,985
Total operating expenses	52,611	68,656	106,964	132,552
Loss from operations	(51,357)	(68,208)	(105,213)	(131,582)
Other income (expense):				
Interest income	3,455	3,894	7,495	8,066
Other expense	—	—	—	(20)
Total other income (expense)	3,455	3,894	7,495	8,046
Loss before income tax expense	(47,902)	(64,314)	(97,718)	(123,536)
Income tax expense	—	(109)	—	(196)
Net loss	$ (47,902)	$ (64,423)	$ (97,718)	$ (123,732)
Net loss per share, basic and diluted	$ (0.79)	$ (1.43)	$ (1.62)	$ (2.76)
Weighted-average common shares outstanding, basic and diluted	60,434,161	45,122,900	60,274,285	44,796,644

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

IGM Biosciences, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	$ (47,902)	$ (64,423)	$ (97,718)	$ (123,732)
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable securities	(67)	(105)	(346)	249
Comprehensive loss	$ (47,969)	$ (64,528)	$ (98,064)	$ (123,483)

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

IGM Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Non-Voting Common Stock		Additional Paid-In-	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balance—December 31, 2023	33,180,749	$ 331	25,500,383	$ 255	$ 1,023,739	$ 151	$ (821,242)	$ 203,234
Conversion of non-voting common stock into voting common stock	113,400	1	(113,400)	(1)	—	—	—	—
Exercise of stock options, net of shares withheld for taxes and exercise costs	113,314	1	—	—	191	—	—	192
Issuance of common stock for vested restricted stock units	156,439	2	—	—	(2)	—	—	—
Unrealized loss on marketable securities	—	—	—	—	—	(279)	—	(279)
Stock-based compensation expense	—	—	—	—	7,922	—	—	7,922
Net loss	—	—	—	—	—	—	(49,816)	(49,816)
Balance—March 31, 2024	33,563,902	$ 335	25,386,983	$ 254	$ 1,031,850	$ (128)	$ (871,058)	$ 161,253
Exercise of stock options, net of shares withheld for taxes and exercise costs	76,339	1	—	—	63	—	—	64
Issuance of common stock for vested restricted stock units	96,550	1	—	—	(1)	—	—	—
Purchases under employee stock purchase plan	115,793	1	—	—	581	—	—	582
Unrealized loss on marketable securities	—	—	—	—	—	(67)	—	(67)
Stock-based compensation expense	—	—	—	—	8,428	—	—	8,428
Net loss	—	—	—	—	—	—	(47,902)	(47,902)
Balance—June 30, 2024	33,852,584	$ 338	25,386,983	$ 254	$ 1,040,921	$ (195)	$ (918,960)	$ 122,358

IGM Biosciences, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Non-Voting Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance—December 31, 2022	29,394,436	$ 294	13,687,883	$ 137	$ 862,359	$ (701)	$ (574,826)	$ 287,263
Exercise of stock options	40,774	—	—	—	75	—	—	75
Issuance of common stock for vested restricted stock units	64,863	1	—	—	(1)	—	—	—
Unrealized gain on marketable securities	—	—	—	—	—	354	—	354
Stock-based compensation expense	—	—	—	—	11,047	—	—	11,047
Net loss	—	—	—	—	—	—	(59,309)	(59,309)
Balance—March 31, 2023	29,500,073	$ 295	13,687,883	$ 137	$ 873,480	$ (347)	$ (634,135)	$ 239,430
Issuance of common stock in connection with public offering and private placement, net of offering costs	3,187,500	32	6,187,500	62	68,297	—	—	68,391
Exercise of stock options	10,788	—	—	—	14	—	—	14
Issuance of common stock for vested restricted stock units	81,136	1	—	—	(1)	—	—	—
Purchases under employee stock purchase plan	84,559	1	—	—	990	—	—	991
Unrealized loss on marketable securities	—	—	—	—	—	(105)	—	(105)
Stock-based compensation expense	—	—	—	—	14,309	—	—	14,309
Net loss	—	—	—	—	—	—	(64,423)	(64,423)
Balance—June 30, 2023	32,864,056	$ 329	19,875,383	$ 199	$ 957,089	$ (452)	$ (698,558)	$ 258,607

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

IGM Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (97,718)	$ (123,732)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,452	3,837
Stock-based compensation expense	16,350	25,356
Purchase of net discount on marketable securities	2,262	3,361
Net accretion of discounts on marketable securities	(4,106)	(4,799)
Non-cash lease expense	2,850	2,668
Other	(1)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	458	(3,657)
Other non-current assets	378	(116)
Accounts payable	1,846	1,000
Accrued liabilities	(3,561)	(5,805)
Lease liabilities, net	(1,250)	(1,245)
Deferred revenue	(1,751)	(970)
Net cash used in operating activities	(79,791)	(104,102)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(3,698)	(7,850)
Purchases of marketable securities	(117,027)	(165,691)
Proceeds from maturities and sales of marketable securities	153,868	237,040
Proceeds from sales of property, plant and equipment	32	—
Net cash provided by investing activities	33,175	63,499
Cash flows from financing activities:		
Proceeds from exercise of stock options	257	89
Proceeds from purchases under the employee stock purchase plan	582	991
Proceeds from issuance of common stock in public offering and private placement, net of offering costs	—	68,947
Payment of deferred offering costs	(71)	—
Payment of employee taxes and exercise costs for shares withheld	(1)	—
Net cash provided by financing activities	767	70,027
Net (decrease) increase in cash, cash equivalents, and restricted cash	(45,849)	29,424
Cash, cash equivalents, and restricted cash		
Beginning of period	113,112	121,920
End of period	$ 67,263	$ 151,344
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 66,974	$ 150,702
Restricted cash	289	642
Cash, cash equivalents, and restricted cash	$ 67,263	$ 151,344
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets recognized in exchange for lease obligations	$ 117	$ 1,490
Unpaid amounts related to purchase of property, plant and equipment	$ 973	$ 2,334
Unpaid amounts related to offering costs for public offering and private placement	$ —	$ 476

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

Note 1. Organization

Description of the Business

IGM Biosciences, Inc. (the Company) was incorporated in the state of Delaware in August 1993 under the name Palingen, Inc. and the name was subsequently changed to IGM Biosciences, Inc. in 2010. The Company's headquarters are in Mountain View, California. IGM Biosciences, Inc. is a biotechnology company engaged in the development of IgM antibody therapeutics for the treatment of cancer and autoimmune and inflammatory diseases.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP), as defined by the Financial Accounting Standards Board (FASB), and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2023 has been derived from the audited financial statements at that date but does not include all of the information required by GAAP for complete financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments which are necessary for a fair statement of the Company's financial information. The interim results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other interim period or for any other future year.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2024.

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $919.0 million as of June 30, 2024. As of June 30, 2024, the Company had cash, cash equivalents, and marketable securities of $256.4 million. Management believes that the existing financial resources are sufficient to continue operating activities at least one year past the issuance date of these condensed consolidated financial statements. The Company has historically financed its operations primarily through the sale of common stock and pre-funded warrants in its public offerings and private placement, the sale of convertible preferred stock and issuance of unsecured promissory notes in private placements, and funding received from our collaboration partners. To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any product revenue since inception. Management expects operating losses to continue and increase for the foreseeable future, as the Company progresses its planned research and development activities for its product candidates. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed below. While the Company has been able to raise multiple rounds of financing, there can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to raise sufficient capital when needed or generate sufficient cash flow from operations would impact the ability to pursue business strategies and could require the Company to delay, scale back or discontinue one or more product development programs, or other aspects of the Company's business objectives.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Such management estimates include, but are not limited to, those related to revenue recognition, marketable securities, manufacturing accruals, accrued research and development expenses, stock-based compensation, operating lease right-of-use (ROU) assets and liabilities, income tax uncertainties and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates. The most significant estimates and assumptions that management considers in the preparation of our financial statements relate to revenue recognition, accrued research and development costs, and leases.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing engineered IgM antibodies for the treatment of cancer and autoimmune and inflammatory diseases. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States of America.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company invests in money market funds, U.S. treasury securities, corporate bonds, commercial paper, and U.S. government agency securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents, and restricted cash, and bond issuers to the extent recorded on the balance sheets. The Company's investment policy limits investments to high credit quality securities issued by the U.S. government and its agencies, highly rated banks, and corporate issuers, subject to certain concentration limits and restrictions on maturities. The Company has not experienced any material losses on its deposits of cash, cash equivalents, and marketable securities.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, the Company's early stages of clinical drug development; uncertainties related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; the Company's ability to advance product candidates into, and successfully complete, clinical trials on the timelines it projects; the Company's ability to adequately demonstrate sufficient safety and efficacy of its product candidates; the Company's ability to enroll patients in its ongoing and future clinical trials; the Company's ability to successfully manufacture and supply its product candidates for clinical trials; the occurrence of any event or circumstance that could give rise to the termination of the Company's collaborations with third parties; the Company's ability to obtain additional capital to finance its operations; uncertainties related to the projections of the size of patient populations suffering from the diseases the Company is targeting; the Company's ability to obtain, maintain, and protect its intellectual property rights; developments relating to the Company's competitors and its industry, including competing product candidates and therapies; general economic and market conditions; and other risks and uncertainties, including those more fully described in the "Risk Factors" section of this Quarterly Report on Form 10-Q.

The Company's product candidates will require approvals from the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash and cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds, commercial paper, U.S. treasury securities, and U.S. government agency securities and are stated at fair value. Restricted cash consists of the remaining unused portion of a grant received from a non-profit organization which the Company will continue to utilize as it incurs expenses for services performed under the grant agreement.

Marketable Securities

The Company's marketable securities have been classified and accounted for as available-for-sale securities. Fixed income securities consist of U.S. treasury securities, U.S. government agency securities, corporate bonds, and commercial paper. The specific identification method is used to determine the cost basis of fixed income securities sold. These securities are recorded on the condensed consolidated balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive loss. The cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income (expense). All available-for-sale securities are considered available to support current operations and are classified as current assets. The Company presents any credit losses identified as an allowance rather than as a reduction in the amortized cost of the available-for-sale securities.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value and recognized in other income (expense) in the condensed consolidated statements of operations. If neither criteria is met, the Company evaluates whether the decline in fair value is related to credit-related factors or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. Credit-related impairment losses, limited by the amount that the fair value is less than the amortized cost basis, are recorded through an allowance for credit losses in other income (expense).

Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit factors are recognized in accumulated other comprehensive income (loss), net of tax as a separate component of stockholders' equity, along with unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in other income (expense) in the condensed consolidated statements of operations.

For purposes of identifying and measuring credit-related impairments, the Company's policy is to exclude applicable accrued interest from both the fair value and amortized cost basis of the related security. The Company has elected to write-off uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent. The accrued interest write-off will be recorded by reversing interest income. Accrued interest receivable is recorded to prepaid expenses and other current assets on the condensed consolidated balance sheets.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are depreciated using the straight-line method over the shorter of the lease term or the estimated useful economic lives of the related assets. Assets are held in construction in progress until placed in service, upon which date, we begin to depreciate these assets.

Upon retirement or sale of the assets, the cost and related accumulated depreciation and amortization are removed from the condensed consolidated balance sheets and the resulting gain or loss are recorded to the condensed consolidated statements of operations. Repairs and maintenance are charged to the condensed consolidated statements of operations as incurred.

Leases

The Company determines if an arrangement is a lease at inception. In addition, the Company determines whether leases meet the classification criteria of a finance or operating lease at the lease commencement date considering: (1) whether the lease transfers ownership of the underlying asset to the lessee at the end of the lease term, (2) whether the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (3) whether the lease term is for a major part of the remaining economic life of the underlying asset, (4) whether the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset, and (5) whether the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of June 30, 2024, the Company's lease population consisted of real estate leases and the Company did not have finance leases.

Operating leases are included in operating lease ROU assets and lease liabilities in the Company's condensed consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. The Company determines the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to the Company.

The determination of the Company's incremental borrowing rate requires management judgment including the development of a synthetic credit rating and cost of debt as the Company currently does not carry any debt. The Company believes that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Operating lease cost is recognized on a straight-line basis over the expected lease term. Variable lease costs represent payments that are dependent on usage, a rate or index. Variable lease cost primarily relates to common area maintenance charges. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on the Company's condensed consolidated balance sheets.

Impairment of Long-Lived Assets

The Company evaluates the carrying amount of its long-lived assets, such as property and equipment, whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. There were no impairments of long-lived assets for the three and six months ended June 30, 2024 and 2023.

Fair Value Measurement

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the condensed consolidated financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market

participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Financial instruments classified within Level 2 of the fair value hierarchy are valued based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers.

Revenue Recognition

For arrangements or transactions between participants determined to be within the scope of Accounting Standard Codification (ASC) Topic 606, "Revenue from Contracts with Customers" (Topic 606) the Company performs the following steps to determine the appropriate amount of revenue to be recognized as the Company fulfills its obligations: (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 has entered into and may enter into additional collaboration agreements in the future under which it may obtain upfront payments, milestone payments, royalty payments, profit sharing, and other fees. Promises under these arrangements may include intellectual property licenses, research and development services, and the participation in joint committees.

At contract inception, the Company assesses the goods or services promised and enforceable in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. In assessing whether a promised good or service is distinct, and therefore a performance obligation, the Company considers factors such as the nature of the research, stage of development of the targets, manufacturing and commercialization capabilities of the customer and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, the Company combines that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. Promised goods and services that are not material in the context of the contract are not considered performance obligations. Additional goods or services that are exercisable at a customer's discretion, including substitution rights, are assessed to determine if they provide a material right to the customer and if so, they are considered performance obligations.

The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Non-refundable upfront payments are considered fixed consideration and included in the transaction price.

If an arrangement includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. The Company includes the amount of estimated variable consideration, including milestones, in the transaction price to the extent that it is probable that a significant reversal of cumulative revenue recognized will not occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and if the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations based on the relative standalone selling prices (SSP), unless the consideration is variable and meets the criteria to be allocated entirely to one or more, but not all, performance obligations in the contract. The relative SSP for each deliverable is estimated using objective evidence if it is available. If SSP is not directly observable the Company estimates the SSP at an amount that would result in the allocation of the transaction price in an amount that depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to the customer, using methods such as the expected cost plus margin approach. Once the transaction price has been allocated to a performance obligation using the applicable methodology, it is not subject to reassessment for subsequent changes in standalone selling prices.

Collaboration revenue is recognized when, or as, the Company satisfies a performance obligation. The Company recognizes revenue over time by measuring the progress toward complete satisfaction of the relevant performance obligation using an appropriate input method based on the nature of the good or service promised to the customer. After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, including variable consideration, estimating the standalone selling prices of identified performance obligations, and applying the input method for revenue recognition, including the estimated budgets for each performance obligation.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's condensed consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in the Company's condensed consolidated balance sheets. If the Company expects to have an unconditional right to receive consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

Contract modifications occur when the price and /or scope of an arrangement changes. If the modification consists of adding new distinct goods or services in exchange for consideration that reflects standalone selling prices of these goods and services, the modification is accounted for as a separate contract with the customer. Otherwise, if the remaining goods and services are distinct from those previously provided, the existing contract is considered terminated, and the remaining consideration is allocated to the remaining goods and services as if this was a newly signed contract. If the remaining goods and services are not distinct from those previously provided, the effects of the modification are accounted for in a manner similar to the effect of a change in the estimated measure of progress, with cumulative catch-up in revenue recorded at the time of the modification. If some of the remaining goods and services are distinct from those previously provided and others are not, the Company applies principles consistent with the objectives of the modification guidance to account for the effects of the modification.

Collaborative Arrangements

The Company analyzes its agreements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (Topic 808). These assessments are performed throughout the life of the arrangements based on changes in the responsibilities of all parties in the arrangement.

Research and Development Expenses

The Company expenses research and development costs as they are incurred. Research and development expenses consist primarily of: (i) personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in the Company's research and development functions; (ii) fees paid to third parties such as contractors, consultants and contract research organizations (CROs) for conducting clinical trials, and other costs related to clinical and preclinical testing; (iii) costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as contract manufacturing organizations (CMOs), and other vendors; (iv) costs related to the preparation of regulatory submissions; (v) expenses related to laboratory supplies and services; (vi) fees under license agreements where no alternative future use exists; and (vii) depreciation of equipment and facilities expenses.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, CROs and CMOs. The Company's contracts with CROs generally include pass-through fees such as laboratory supplies and services, regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The Company's contracts with the CMOs generally include fees such as initiation fees, reservation fees, verification run costs, materials and reagents expenses, taxes, etc. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients

enrolled, the rate of patient enrollment and the actual services performed, may vary from the Company's estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations. Through June 30, 2024, there have been no material differences from the Company's estimated accrued research and development expenses to actual expenses.

Acquired In-Process Research and Development Expenses

The Company has entered into agreements (see Note 5 – License Agreements) with third parties to acquire the rights to develop and potentially commercialize certain products. Such agreements generally require an initial payment by the Company when the contract is executed. The purchase of license rights for use in research and development activities, including product development, are expensed as incurred and are classified as research and development expense. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the technology and achieves a certain sales volume. In accordance with ASC Topic 730, *Research and Development* (Topic 730), expenditures for research and development, including upfront licensing fees and milestone payments associated with products not yet been approved by the FDA, are charged to research and development expense as incurred. Future contract milestone and/or royalty payments will be recognized as expense after the achievement of the milestone and the corresponding milestone payment is legally due.

Stock-Based Compensation

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees, non-employees and directors based on estimated grant-date fair values. The Company uses the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period. The grant date fair value of restricted stock units is estimated based on the closing stock price of the Company's common stock on the date of grant. The grant date fair value of stock options granted to employees and directors is estimated using the Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur. The fair value of each purchase right under the employee stock purchase plan (ESPP) is estimated at the beginning of the offering period using the Black-Scholes option pricing model and recorded as expense over the service period using the straight-line method.

Income Taxes

The Company accounts for income taxes using the liability method, whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance when it is more likely than not that some portion, or all of the Company's deferred tax assets will not be realized.

The Company accounts for income tax contingencies using a benefit recognition model. If it considers that a tax position is more likely than not to be sustained upon audit, based solely on the technical merits of the position, it recognizes the benefit. The Company measures the benefit by determining the amount that is greater than 50% likely of being realized upon settlement, presuming that the tax position is examined by the appropriate taxing authority that has full knowledge of all relevant information. The Company is subject to taxation in the United States federal jurisdiction, and various state jurisdictions. The net operating loss and research and development credit carryforwards that are available for utilization in future years may be subject to examination by federal and state tax authorities. The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. As of June 30, 2024, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties.

Comprehensive Loss

Comprehensive loss represents the net loss for the period and other comprehensive loss. Other comprehensive loss reflects certain gains and losses that are recorded as a component of stockholders' equity and are not reflected in the condensed consolidated statements of operations. The Company's other comprehensive loss consists of changes in unrealized gains and losses on available-for-sale securities.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock (including non-voting common stock and pre-funded warrants) outstanding during the period, without consideration for all other common stock equivalents. Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Recently Issued Accounting Pronouncements

In October 2023, the FASB issued Accounting Standards Update (ASU) 2023-06, *Disclosure Improvements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*, which will impact various disclosure areas.

The amendments in ASU 2023-06 will be effective on the date the related disclosures are removed from Regulation S-X or Regulation S-K by the SEC, and will no longer be effective if the SEC has not removed the applicable disclosure requirement by June 30, 2027. The Company is currently evaluating the impacts of this standard on its related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)*, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. This ASU is effective for fiscal years beginning after December 15, 2023 and is applicable to public entities, including those that have a single reportable segment. Early adoption is permitted. The Company is currently evaluating the impacts of this standard on its condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which amends the guidance in ASC 740, Income Taxes. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Entities are permitted to early adopt the standard for annual financial statements that have not yet been issued or made available for issuance. Adoption is permitted either prospectively or retrospectively. The Company will adopt this ASU on a prospective basis. The Company is currently evaluating the impact of this standard but does not expect any material impacts on its condensed consolidated financial statements and related disclosures.

Note 3. Fair Value Measurement

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The following tables set forth the fair value of the Company's financial assets, which consist of cash equivalents and marketable securities measured and recognized at fair value (in thousands):

		June 30, 2024			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 28,413	$ —	$ —	$ 28,413
U.S. government agency securities	Level 2	7,391	—	—	7,391
Commercial paper	Level 2	26,875	—	(14)	26,861
Marketable securities:					
U.S. treasury securities	Level 1	133,549	1	(119)	133,431
Corporate bonds	Level 2	17,286	—	(27)	17,259
Commercial paper	Level 2	24,549	—	(17)	24,532
U.S. government agency securities	Level 2	14,204	—	(19)	14,185
Total		$ 252,267	$ 1	$ (196)	$ 252,072

		December 31, 2023			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 21,458	$ —	$ —	$ 21,458
U.S. treasury securities	Level 1	25,896	2	—	25,898
Commercial paper	Level 2	54,427	—	(27)	54,400
U.S. government agency securities	Level 2	4,951	1	—	4,952
Marketable securities:					
U.S. treasury securities	Level 1	182,289	214	(14)	182,489
Corporate bonds	Level 2	13,986	—	(8)	13,978
Commercial paper	Level 2	20,216	—	(17)	20,199
U.S. government agency securities	Level 2	8,491	11	(11)	8,491
Total		$ 331,714	$ 228	$ (77)	$ 331,865

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Levels 1, 2 and 3 during the three and six months ended June 30, 2024 and 2023. As of June 30, 2024 and December 31, 2023, there were no financial instruments classified as Level 3.

The following table summarizes the available-for-sale securities in an unrealized loss position for which an allowance for credit losses has not been recorded as of June 30, 2024 and December 31, 2023, aggregated by major security type and length of time in a continuous unrealized loss position:

	June 30, 2024					
	Less than 12 months		Greater than 12 months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. treasury securities	$ 108,065	$ (118)	$ 1,497	$ (1)	$ 109,562	$ (119)
Corporate bonds	17,259	(27)	—	—	17,259	(27)
Commercial paper	51,393	(31)	—	—	51,393	(31)
U.S. government agency securities	21,576	(19)	—	—	21,576	(19)
Total	$ 198,293	$ (195)	$ 1,497	$ (1)	$ 199,790	$ (196)

	December 31, 2023					
	Less than 12 months		Greater than 12 months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. treasury securities	$ 28,137	$ (14)	$ —	$ —	$ 28,137	$ (14)
Corporate bonds	13,978	(8)	—	—	13,978	(8)
Commercial paper	74,599	(44)	—	—	74,599	(44)
U.S. government agency securities	4,771	(11)	—	—	4,771	(11)
Total	$ 121,485	$ (77)	$ —	$ —	$ 121,485	$ (77)

As of June 30, 2024 and December 31, 2023, the Company held 55 and 35 debt securities, respectively, with an unrealized loss position. The Company evaluated its securities for credit losses and considered the decline in market value to be primarily attributable to current economic and market conditions and not to a credit loss or other factors. Additionally, the Company does not intend to sell the securities in an unrealized loss position and does not expect it will be required to sell the securities before recovery of the unamortized cost basis. As of June 30, 2024 and December 31, 2023, an allowance for credit losses has not been recognized. Given the Company's intent and ability to hold such securities until recovery, and the lack of significant change in credit risk of these investments, it does not consider these marketable securities impaired as of June 30, 2024 and December 31, 2023.

There were no realized gains or losses on marketable securities for the three and six months ended June 30, 2024 and 2023. Interest on marketable securities is included in interest income. As of June 30, 2024 and December 31, 2023, the Company had accrued interest receivable of $0.9 million and $0.8 million, respectively, which was included in prepaid expenses and other current assets on the condensed consolidated balance sheets.

The following table summarizes the contractual maturities of the Company’s cash equivalents and marketable securities as of June 30, 2024 and December 31, 2023 at estimated fair value (in thousands):

	June 30, 2024	December 31, 2023
Due in less than one year	$ 239,955	$ 312,554
Due in more than one year	12,117	19,311
Total	$ 252,072	$ 331,865

Note 4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued research and development materials and services	$ 16,740	$ 14,625
Accrued professional services	1,381	3,147
Accrued compensation	7,249	13,527
Other	1,091	245
Total accrued liabilities	$ 26,461	$ 31,544

Note 5. License Agreements

The Company enters into arrangements to in-license research and development technology rights with third parties relating to its clinical and pre-clinical programs and product candidates. These arrangements may include non-refundable, upfront payments, payments for options to acquire additional rights relating to its product candidates, as well as contingent obligations for potential development, regulatory and commercial performance milestone payments, and royalty payments. The Company's obligation to make payments for contingent obligations is contingent upon the respective milestones being achieved as well as its continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. The activities under these license agreements are performed with no guarantee of either technological or commercial success.

During the three and six months ended June 30, 2024, the Company recorded no license fees and $0.6 million, respectively, of research and development expenses in our condensed consolidated statements of operations related to license agreements, and $0.2 million and $0.5 million, for the three and six months ended June 30, 2023.

As of June 30, 2024, the Company's license agreements for technologies optioned by the Company, including the Medivir agreement described below, included potential future payments for development, regulatory, and sales milestones totaling approximately $361.9 million plus royalties on net sales that range from single digits to mid-teens. No milestones were achieved or deemed probable as of June 30, 2024.

Medivir Agreement

In January 2021, the Company entered into an exclusive license agreement with Medivir AB (Medivir) through which the Company received global, exclusive development and commercialization rights for birinapant, a clinical-stage Second Mitochondrial-derived Activator of Caspases (SMAC) mimetic. Under the terms of the agreement, the Company made an upfront payment of $1.0 million upon signing the agreement, and made an additional $1.5 million payment in November 2021 due to the Company's initiation of a Phase 1 clinical trial of aplitabart in combination with birinapant. Under the terms of the agreement, should birinapant be successfully developed and approved, the Company would be obligated to make additional milestone payments up to a total of approximately $348.5 million, plus tiered royalties from the mid-single digits up to mid-teens on net sales. No milestones were achieved or deemed probable as of June 30, 2024.

Note 6. Stockholders' Equity

Common Stock and Non-Voting Common Stock

As of June 30, 2024 and December 31, 2023, the Company's certificate of incorporation authorized the Company to issue 1,200,000,00 shares of common stock (including 200,000,000 shares of non-voting common stock) and 200,000,000 shares of preferred stock, at a par value of $0.01 per share. Each share of common stock (excluding non-voting common stock) is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Company's Board of Directors, subject to prior rights of the preferred stockholders. As of June 30, 2024 and December 31, 2023, no dividends have been declared.

The Company had reserved common stock, on an as-converted basis, for future issuance as follows:

	June 30, 2024	December 31, 2023
Stock options, issued and outstanding	7,525,626	6,766,340
Restricted stock units	1,707,599	658,792
Stock options and restricted stock units, future issuance	3,623,814	3,536,312
Employee stock purchase plan, available for future grants	1,821,195	1,376,988
Pre-funded warrants	1,334,332	1,334,332
Total	16,012,566	13,672,764

Pre-Funded Warrants

In December 2020, the Company issued pre-funded warrants to purchase up to 1,334,332 shares of common stock in an underwritten public offering at the offering price of the common stock, less the $0.01 per share exercise price of each warrant and were issued to two separate related party affiliates. The pre-funded warrants were recorded as a component of stockholders' equity within additional paid-in-capital and will expire on the date any such warrant is exercised in full.

Subject to applicable law, upon exercise of a pre-funded warrant, a holder may elect to receive the same number of shares of non-voting common stock as the shares of common stock for which the pre-funded warrant is exercisable, provided that (i) at the time of such election there is a sufficient number of authorized but unissued and otherwise unreserved shares of non-voting common stock and (ii) the Company consents to such election.

The outstanding pre-funded warrants to purchase shares of common stock are exercisable at any time after their original issuance. However, the Company may not affect the exercise of any pre-funded warrants, and a holder will not be entitled to exercise any portion of any pre-funded warrants that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of the Company's common stock beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of the Company's securities beneficially owned by such holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of the Company's securities outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder of a pre-funded warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to the Company. As of June 30, 2024, no shares underlying the pre-funded warrants had been exercised. All of the outstanding pre-funded warrants are included in the weighted-average number of shares of common stock used to calculate basic net loss per share attributable to common stockholders (see Note 10 – Net Loss Per Share Attributable to Common Stockholders).

Note 7. Sanofi Agreement

In March 2022, the Company entered into a global collaboration and license agreement (the Sanofi Agreement) with Genzyme Corporation, a wholly owned subsidiary of Sanofi (Sanofi), which became effective in May 2022. Under the terms of the Sanofi Agreement, the Company agreed to generate, develop, manufacture and commercialize IgM antibodies directed to six primary targets, three of which were oncology targets and three of which were immunology targets.

In April 2024, Sanofi exercised its right to terminate the oncology collaboration targets effective June 2024. As a result of this termination, the Company has no further obligations to conduct research and development activities for such terminated targets and Sanofi retains no substitution rights for such terminated targets, pursuant to the terms of the agreement, and the collaboration will now focus exclusively on the immunology collaboration targets. The termination of the oncology targets will not affect any rights and obligations under the Sanofi Agreement with respect to the immunology targets.

For each immunology target collaboration program, the Company will continue to lead research and development activities, and assume related costs, through the completion of the first Phase 1 clinical trials for up to two candidates directed to each immunology target, after which Sanofi will be responsible for all future development and commercialization activities and related costs, in exchange for up to $1.065 billion in aggregate development, regulatory and commercial milestones per immunology target. Following the completion of the first Phase 1 clinical trials for each immunology target, Sanofi will be responsible for subsequent development activities, commercialization efforts, and related costs. The Company is eligible to receive tiered high single-digit to low-teen royalties on global net sales for licensed products related to immunology targets, subject to certain reductions and offsets.

Subject to earlier expiration in certain circumstances, the Sanofi Agreement expires on a licensed product-by-licensed product and country-by-country basis until the expiration of the applicable profit and loss share term or royalty term, as the case may be. Sanofi has the right to terminate the Sanofi Agreement on a collaboration target-by-collaboration target basis or country-by-country basis with or without cause, upon specified prior notice.

At the inception of the Sanofi Agreement, the Company identified promised goods and services, which consisted of the granting of intellectual property licenses and the performance of specified research, development and other various activities. The Company determined that for each of the six targets, the identified promised goods and services were not distinct from each other on a target-by-target basis. The licenses, considered to be functional intellectual property, were determined to not be capable of being distinct due to the specialized nature of the research, development, and other activities to be provided by the Company. Accordingly, the promised goods and services were combined together as one single performance obligation, on a target-by-target basis. The Company determined that the underlying promised goods and services for each of the six targets were both capable of being distinct and distinct within the context of the contract from each of the other targets. Therefore, the Company concluded that there were six performance obligations in the Sanofi Agreement, one for each target, that were comprised of the underlying promised goods and services. Other components and options within the Sanofi Agreement were determined to not provide Sanofi with free or discounted goods or services and therefore did not constitute a material right or were deemed immaterial in the context of the contract.

To determine the transaction price, the Company evaluates all the payments to be received during the duration of the contract. In May 2022, the Company received a $150.0 million upfront payment as part of the Sanofi Agreement. Additionally, in April 2022, Sanofi purchased non-voting common stock in connection with the Company's public common stock offering. The Company concluded that at inception and as of June 30, 2024, the transaction price was $150.0 million and was comprised solely of the fixed non-refundable upfront payment. No consideration received from Sanofi as part of the April 2022 offering was deemed necessary to include in the transaction price as Sanofi purchased the shares at the same offering price as the other participating investors.

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

At the inception of the Sanofi Agreement, the Company allocated the transaction price based on the estimated SSP of each of the six performance obligations. The Company determined the SSP for each of the six performance obligations based on the estimated costs to complete the underlying activities of each performance obligation and included factors such as forecasted internal costs, estimated third-party expenditures, development timelines and scenarios, probability of target failures and selection of substitute targets, and program-specific factors. These estimated cost forecasts were based on observable data for both market and entity specific factors, such as considering the actual and expected costs of the Company's existing research and development programs and adjusting for factors specific to the targets identified.

The Company recognizes revenue using an input method of costs incurred as a percentage of total estimated costs for each of the performance obligations under the contract. Costs consist primarily of internal personnel costs and third-party contract expenses related to the programs of the Sanofi Agreement. The cumulative effect of revisions to estimated costs to complete the Company's performance obligations is recorded in the period in which changes are identified and amounts can be reasonably estimated.

The Company determined that Sanofi's exercise of its right to terminate the oncology collaboration targets in April 2024 was a contract modification because it changed the scope of the contract by reducing the number of performance obligations under the agreement. The remaining performance obligations relating to the three immunology collaboration targets are not distinct from themselves before and after the contract modification occurred; however, they are distinct from the terminated oncology target performance obligations. As a result, the Company allocated the unrecognized transaction price to the three remaining performance obligations based on their relative estimated SSP and calculated a cumulative catch-up adjustment of $0.8 million which was recognized as collaboration revenue during the three months ended June 30, 2024.

For the three and six months ended June 30, 2024, the Company recognized collaboration revenue related to the Sanofi Agreement of $1.3 million and $1.8 million, respectively, and $0.4 million and $1.0 million for the three and six months ended June 30, 2023. As of June 30, 2024 and December 31, 2023, $145.1 million and $146.8 million were recorded as deferred revenue related to the Sanofi Agreement, respectively, of which $2.0 million and $3.8 million, respectively, were classified as current, on the condensed consolidated balance sheets. The deferred revenue is expected to be recognized over the research and development period of the programs through the completion of Phase 1 clinical trials.

Contract Balances from Customer Contract

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

The following tables present changes in the Company's customer contract liabilities for the periods presented (in thousands):

Six Months Ended June 30, 2024	December 31, 2023	Additions	Deductions	June 30, 2024
Contract liabilities:				
Deferred revenue	$ 146,801	$ —	$ (1,751)	$ 145,050

Six Months Ended June 30, 2023	December 31, 2022	Additions	Deductions	June 30, 2023
Contract liabilities:				
Deferred revenue	$ 148,931	$ —	$ (970)	$ 147,961

The Company had no customer contract assets during the three and six months ended June 30, 2024 and 2023.

Note 8. Stock-Based Compensation

The 2018 Omnibus Incentive Plan (the 2018 Plan) provides for an increase in the number of shares reserved for issuance on the first day of each fiscal year equal to the least of (i) 8,768,800 shares, (ii) 4% of the Company's common stock and non-voting common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Company's Board of Directors. As a result of this provision, on January 1, 2024 and 2023, an additional 2,347,245 and 1,723,292 shares, respectively, became available for issuance under the 2018 Plan. As of June 30, 2024, the 2018 Plan had 3,623,814 shares of common stock available for future issuance.

Total stock-based compensation expense related to the Company's equity incentive plan and employee stock purchase plan was recorded in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 4,807	$ 8,248	$ 9,169	$ 14,687
General and administrative	3,621	6,061	7,181	10,669
Total stock-based compensation expense	$ 8,428	$ 14,309	$ 16,350	$ 25,356

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2024		2023		2024		2023	
	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value	Grants	Weighted Average Grant Date Fair Value
Stock options	29,805	$ 7.44	1,475,238	$ 9.92	1,552,298	$ 7.82	1,726,338	$ 10.92
Restricted stock units	35,474	$ 8.53	697,236	$ 12.43	1,400,817	$ 9.89	716,450	$ 12.63

Note 9. Restructuring Charges

On December 5, 2023, the Company committed to a strategic refocusing (Strategic Refocusing) and suspended clinical development activities for certain product candidates in several indications and reduced its workforce by approximately 22%, with headcount reductions substantially completed by December 31, 2023 and fully completed by March 31, 2024.

In connection with the Strategic Refocusing, the Company recognized no restructuring charges and $0.2 million in restructuring charges during the three and six months ended June 30, 2024, respectively. The Company recognized $1.8 million in restructuring charges during the three months ended December 31, 2023, which were primarily related to severance and one-time termination payments of $3.7 million and partially offset by a $1.9 million reversal of previously recognized non-cash stock-based compensation expense. All severance and one-time termination payments had been paid by March 31, 2024.

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

	Beginning Balance December 31, 2023	Charges	Payments	Ending Balance June 30, 2024
Accrued severance	$ 2,397	$ —	$ (2,397)	$ —
Accrued contract termination costs	—	107	(107)	—
Total accrued restructuring liability	$ 2,397	$ 107	$ (2,504)	$ —

Note 10. Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock and pre-funded warrants outstanding for the period. Shares of common stock into which the pre-funded warrants may be exercised are

considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

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

	June 30,	
	2024	2023
Stock options	7,525,626	7,390,547
Estimated shares issuable under the employee stock purchase plan	86,292	59,616
Unvested restricted stock units	1,707,599	958,121
Total	9,319,517	8,408,284

Note 11. Subsequent Events

On July 19, 2024, the Company completed an exchange of stock options for new restricted stock units (RSUs). The Company offered eligible employees with outstanding option awards that had an exercise price equal to or greater than $17.70 per share and granted on or prior to March 1, 2023, the opportunity to exchange those options for a number of RSUs with an aggregate fair value for financial accounting purposes substantially similar to the aggregate fair value of the options surrendered, subject to a 2-for-1 exchange ratio floor. The RSUs vest 50% on either the 1-year anniversary or 18-months after the exchange date and then quarterly thereafter over a total vesting period of two to three years, depending on the vesting status of the exchanged options. The Company accepted for exchange eligible options to purchase a total of 1,583,305 shares of the Company's common stock, which were cancelled in exchange for RSUs representing 657,427 shares of the Company's common stock.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a clinical-stage biotechnology company pioneering the development of IgM antibodies for the treatment of cancer and autoimmune and inflammatory diseases. IgM antibodies have inherent properties that we believe may enable them to bind more strongly to targets on the surface of cells than comparable IgG antibodies. We have created a proprietary IgM antibody technology platform that we believe is particularly well suited for developing receptor cross-linking agonists and bispecific T cell engaging antibodies. Among our product candidates currently in or planned to enter clinical testing are:

- Aplitabart: An IgM antibody targeting Death Receptor 5 (DR5) proteins, currently being evaluated in multiple Phase 1 combination trials, including randomized and single-arm combination trials for the treatment of colorectal cancer.
- Imvotamab: A bispecific T cell engaging IgM antibody targeting CD20 and CD3 proteins, currently being evaluated in three Phase 1 clinical trials in autoimmune diseases, including severe systemic lupus erythematosus (SLE), severe rheumatoid arthritis (RA), and myositis.
- IGM-2644: A bispecific T cell engaging IgM antibody targeting CD38 and CD3 proteins, currently planned for evaluation in a Phase 1 clinical trial in autoimmune disease.

Our clinical development priorities are (i) treating colorectal cancer using IgM DR5 agonist antibodies and (ii) treating autoimmune diseases using IgM T cell engager antibodies. In December 2023, we announced we are deprioritizing all hematologic oncology clinical development as well as the clinical development of our targeted cytokine product candidate (Strategic Refocusing).

We believe that we have the most advanced research and development program focused on therapeutic IgM antibodies. We have created a portfolio of patents and patent applications, know-how and trade secrets directed to our platform technology, product candidates and manufacturing capabilities, and we retain worldwide commercial rights to all of our product candidates, other than those being developed in partnership with Sanofi S.A. (Sanofi) and the intellectual property related thereto.

Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in-house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have primarily focused on the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform. We do not have any products approved for sale, and we have not generated any revenue from product sales.

We have incurred significant net losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $97.7 million and $123.7 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $919.0 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities.

We expect our expenses and capital requirements will increase in connection with our ongoing activities as we:

- advance the development of our clinical-stage and other product candidates;
- expand our pipeline of IgM antibody product candidates;
- continue to invest in our IgM antibody technology platform;
- build out and expand our in-house manufacturing capabilities;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know-how;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out;

- implement operational, financial and management information systems; and
- attract, hire and retain additional clinical, scientific, management and administrative personnel.

We plan to continue to use third-party service providers, including contract research organizations (CROs) and contract manufacturing organizations (CMOs), to carry out our preclinical and clinical development and manufacture and supply some of our preclinical and clinical materials to be used during the development of our product candidates.

Since inception, we have funded our operations primarily from the sale of voting and non-voting common stock and pre-funded warrants in our public offerings and a private placement, the sale of convertible preferred stock and the issuance of unsecured promissory notes in private placements, and payments from our collaboration partners.

Recent Developments

In April 2024, we announced that our exclusive global collaboration and license agreement (the Sanofi Agreement) with Genzyme Corporation, a wholly owned subsidiary of Sanofi to create and develop IgM agonist antibodies will now focus exclusively on immunology targets (the Sanofi Refocusing). In connection with the Sanofi Refocusing, Sanofi exercised their right to terminate the oncology collaboration targets effective June 2024. We have retained global rights to our proprietary technology related to the oncology targets nominated by Sanofi under the collaboration, but as a result of this termination we have no further obligation to conduct research and development activities for the oncology targets.

For each of the three Sanofi designated immunology targets, we will continue to lead research and development activities and assume related costs through the completion of a Phase 1 clinical trial, after which Sanofi will be responsible for all subsequent development activities, commercialization efforts, and related costs. We will be eligible to receive up to $1.065 billion in aggregate development, regulatory and commercial milestones per each immunology target as well as tiered high single-digit to low-teen royalties on global net sales.

Components of Results of Operations

Revenue

We have recognized collaboration revenue pursuant to the Sanofi Agreement and expect to continue to recognize revenue in the future to the extent we satisfy our performance obligations under the Sanofi Agreement, including the generation, development, manufacturing and commercialization of IgM antibodies. We may also be entitled to receive payments pursuant to the Sanofi Agreement upon achievement of specified development, regulatory and commercial milestones, which will cause us to recognize additional revenue. As the recognition of future collaboration revenue will be based on costs incurred to date relative to total estimated costs at completion and the uncertainty of when the events underlying various milestones or target terminations are resolved, we expect our collaboration revenue will fluctuate from period to period.

To date, we have not generated any revenue from the sale of products and do not expect to generate any revenue from the sale of products in the near future.

Operating Expenses

Research and Development

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

Direct expenses consisting of:

- Fees paid to third parties such as consultants, contractors and CROs, for conducting clinical trials, and other costs related to preclinical and clinical testing;
- Costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as CMOs and other vendors;
- Costs related to the preparation of regulatory submissions;
- Expenses related to laboratory supplies and services; and
- Fees under license agreements where no alternative future use exists.

Indirect expenses consisting of:

- Personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in our research and development functions; and
- Depreciation of equipment and facilities expenses.

We expense research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. All direct research and development expenses are tracked by stage of development. We do not track our indirect research and development costs by product candidate or program.

We expect our research and development expenses to increase for the foreseeable future as we continue to invest in research and development activities to advance our product candidates and our clinical programs, expand our product candidate pipeline and continue to build out and expand our in-house manufacturing capabilities. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. To the extent that we initiate additional clinical development activities for our product candidates, as well as advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses for personnel in our executive, finance, corporate and other administrative functions, intellectual property, facilities and other allocated expenses, other expenses for outside professional services, including legal, human resources, audit and accounting services, and insurance costs. Personnel-related expenses consist of salaries, benefits, recruiting costs, and stock-based compensation. We expect our general and administrative expenses to increase as we increase our headcount to support our continued and expanding research activities and development of product candidates in the areas of cancer and autoimmune and inflammatory diseases, and as a result of operating as a public company, including compliance with the rules and regulations of the Securities and Exchange Commission (SEC) and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Interest Income

Interest income includes interest income earned on our cash, cash equivalents, marketable securities, and restricted cash and non-cash interest income related to accretion of the discount on marketable securities.

Results of Operations

Comparison of Three Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023, together with the changes in those items in dollars:

	Three Months Ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Collaboration revenue	$ 1,254	$ 448	$ 806
Operating expenses:			
Research and development	41,962	55,673	(13,711)
General and administrative	10,649	12,983	(2,334)
Total operating expenses	52,611	68,656	(16,045)
Loss from operations	(51,357)	(68,208)	16,851
Other income:			
Interest income	3,455	3,894	(439)
Total other income	3,455	3,894	(439)
Loss before income tax expense	(47,902)	(64,314)	16,412
Income tax expense	—	(109)	109
Net loss	$ (47,902)	$ (64,423)	$ 16,521

Collaboration Revenue

Collaboration revenue was $1.3 million and $0.4 million for the three months ended June 30, 2024 and 2023, respectively and relates solely to revenue generated from the Sanofi Agreement. The increase of $0.8 million in collaboration revenue is primarily attributable to the cumulative catch-up adjustment of $0.8 million related to the Sanofi Refocusing. Please refer to Note 7 – Sanofi Agreement to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional revenue recognition disclosures.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated:

	Three Months Ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Direct expenses			
Clinical stage programs [(1)]	$ 13,027	$ 17,063	$ (4,036)
Preclinical stage programs	5,394	9,539	(4,145)
Indirect expenses			
Personnel-related	16,907	22,641	(5,734)
Depreciation and facilities	6,634	6,430	204
Total research and development expenses	$ 41,962	$ 55,673	$ (13,711)

(1) The three months ended June 30, 2024 and 2023 include direct expenses related to our active and completed clinical programs and related preclinical costs prior to trial initiation.

Research and development expenses were $42.0 million and $55.7 million for the three months ended June 30, 2024 and 2023, respectively. The decrease of $13.7 million was primarily driven by lower personnel expense and preclinical and clinical stage program expenses.

- Clinical stage direct program expenses decreased by $4.0 million, primarily driven by the wind down of deprioritized clinical programs, including imvotamab in oncology, IGM-7354, and IGM-2644 in oncology.
- Preclinical stage program expenses decreased by $4.1 million, primarily driven by a decrease in research related activities and professional services as a result of the Strategic Refocusing.
- Personnel-related expenses decreased by $5.7 million due to the Strategic Refocusing.
- Depreciation and facilities expenses increased by $0.2 million, primarily due to additional equipment and infrastructure.

General and Administrative Expenses

General and administrative expenses were $10.6 million and $13.0 million for the three months ended June 30, 2024 and 2023, respectively. The decrease of $2.4 million was primarily driven by lower personnel costs due to reduced headcount.

Interest Income

Interest income was $3.5 million and $3.9 million for the three months ended June 30, 2024 and 2023, respectively. The decrease of approximately $0.4 million was primarily due to lower invested capital during the three months ended June 30, 2024.

Comparison of Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023, together with the changes in those items in dollars:

	Six Months Ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Collaboration revenue	$ 1,751	$ 970	$ 781
Operating expenses:			
Research and development	85,777	106,567	(20,790)
General and administrative	21,187	25,985	(4,798)
Total operating expenses	106,964	132,552	(25,588)
Loss from operations	(105,213)	(131,582)	26,369
Other income (expense):			
Interest income	7,495	8,066	(571)
Other expense	—	(20)	20
Total other income (expense)	7,495	8,046	(551)
Loss before income tax expense	(97,718)	(123,536)	25,818
Income tax expense	—	(196)	196
Net loss	$ (97,718)	$ (123,732)	$ 26,014

Collaboration Revenue

Collaboration revenue was $1.8 million and $1.0 million for the six months ended June 30, 2024 and 2023, respectively and relates solely to revenue generated from the Sanofi Agreement. The increase of $0.8 million and total revenue generated is primarily attributable to the cumulative catch-up adjustment of $0.8 million related to the Sanofi Refocusing. Please refer to Note 7 – Sanofi Agreement to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional revenue recognition disclosures.

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated:

	Six Months Ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Direct expenses			
Clinical stage programs [(1)]	$ 27,396	$ 32,368	$ (4,972)
Preclinical stage programs	12,102	19,188	(7,086)
Indirect expenses			
Personnel-related	33,405	43,252	(9,847)
Depreciation and facilities	12,874	11,759	1,115
Total research and development expenses	$ 85,777	$ 106,567	$ (20,790)

(1) The six months ended June 30, 2024 and 2023 include direct expenses related to our active and completed clinical programs and related preclinical costs prior to trial initiation.

Research and development expenses were $85.8 million and $106.6 million for the six months ended June 30, 2024 and 2023, respectively. The decrease of $20.8 million was primarily driven by lower personnel, preclinical stage and clinical stage program expenses, partially offset by higher depreciation and facilities expenses.

- Clinical stage direct program expenses decreased by $5.0 million, primarily driven by the wind down of deprioritized clinical programs, including imvotamab in oncology, IGM-7354, and IGM-2644, partially offset by the advancement of Phase 1 clinical trials for imvotamab in autoimmune diseases.
- Preclinical stage program expenses decreased by $7.1 million, primarily driven by a decrease in research related activities and professional services as a result of the Strategic Refocusing.
- Personnel-related expenses decreased by $9.8 million due to the Strategic Refocusing.

- Depreciation and facilities expenses increased by $1.1 million, primarily due to additional equipment and infrastructure.

General and Administrative Expenses

General and administrative expenses were $21.2 million and $26.0 million for the six months ended June 30, 2024 and 2023, respectively. The decrease of $4.8 million was primarily driven by lower personnel costs due to reduced headcount.

Interest Income

Interest income was $7.5 million and $8.1 million for the six months ended June 30, 2024 and 2023, respectively. The decrease of approximately $0.6 million was primarily due to lower invested capital during the six months ended June 30, 2024.

Liquidity and Capital Resources

Sources of Liquidity

We are a clinical-stage biotechnology company with limited operating history, and due to our significant research and development expenditures, we have generated operating losses since our inception and have not generated any revenue from the sale of any products. We expect to continue incurring significant expenses and operating losses for the foreseeable future as we continue our research and development of our product candidates.

Since our inception and through June 30, 2024, we have funded our operations primarily through the sale of common stock and pre-funded warrants in our public offerings and private placement, the sale of convertible preferred stock and the issuance of unsecured promissory notes in private placements, and payments from our collaboration partners. We maintain a shelf registration statement with the SEC for the potential offering, issuance and sale by us of our common stock, non-voting common stock, debt securities, preferred stock, and certain other securities from time to time in one or more offerings.

As of June 30, 2024, we had cash, cash equivalents, and marketable securities of $256.4 million and an accumulated deficit of $919.0 million. Our material cash requirements include our operating expenses, which consist primarily of research and development expenditures related to our programs and related personnel costs, as well as our operating leases.

We believe that our cash, cash equivalents, and marketable securities will be sufficient to fund our planned operations for at least one year past the issuance date of the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. Our assessment of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves numerous risks and uncertainties.

Future Funding Requirements

We will continue to require additional funding in order to complete development of our product candidates and commercialize our products, if approved. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. The timing and amount of our future funding requirements depends on many factors, including the following:

- the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates, including building out and expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and cost of capital expenditures to support our research, development and manufacturing efforts;
- the number and characteristics of other product candidates that we pursue;
- the costs, timing and outcome of seeking and obtaining U.S. Food and Drug Administration (FDA) and non-U.S. regulatory approvals;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;

- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements to which we are a party or into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the impact of macroeconomic conditions, including inflation, supply chain disruptions and volatility in the capital markets, on our business, financial condition and results of operations;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If we require additional financing, we may not be able to obtain such financing on acceptable terms, or at all. If we raise additional capital by issuing equity or equity-linked securities, our stockholders may experience dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. If we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Failure to raise sufficient capital when needed or generate sufficient cash flow from operations, would impact our ability to pursue our business strategies and could require us to delay, scale back or discontinue one or more of our product development programs, or other aspects of our business objectives.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
(in thousands)	**2024**	**2023**
Net cash, cash equivalents, and restricted cash (used in) provided by:		
Operating activities	$ (79,791)	$ (104,102)
Investing activities	33,175	63,499
Financing activities	767	70,027
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (45,849)	$ 29,424

Cash Used in Operating Activities

For the six months ended June 30, 2024, net cash used in operating activities was $79.8 million, which consisted primarily of a net loss of $97.7 million and a net change of $3.9 million in our net operating assets and liabilities, partially offset by $21.8 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a decrease in net liabilities of $4.7 million mainly driven by the reduction of deferred revenue from the recognition of collaboration revenue and payments related to operating leases. The non-cash charges primarily consisted of stock-based compensation of $16.4 million, depreciation expense of $4.5 million and lease expense of $2.9 million, offset by the net change in discounts purchased and accretion on marketable securities of $1.8 million.

For the six months ended June 30, 2023, net cash used in operating activities was $104.1 million, which consisted primarily of a net loss of $123.7 million and a net change of $10.8 million in our net operating assets and liabilities, partially offset by $30.4 million in non-cash charges. The net change in our operating assets and liabilities was primarily due to a decrease in net liabilities of $7.0 million due to the timing of payments related to clinical trials and compensation costs. The non-cash charges primarily consisted of stock-based compensation of $25.4 million, depreciation expense of $3.8 million and lease expense of $2.7 million, offset by net discount purchased and accretion on marketable securities of $1.4 million.

Cash Provided by Investing Activities

For the six months ended June 30, 2024, net cash provided by investing activities was $33.2 million, which primarily consisted of $153.9 million in maturities of marketable securities, partially offset by $117.0 million in purchases of marketable securities and $3.7 million in purchases of property, plant, and equipment.

For the six months ended June 30, 2023, net cash provided by investing activities was $63.5 million, which consisted of $237.0 million in maturities and sales of marketable securities, partially offset by $165.7 million in purchases of marketable securities and $7.9 million in purchases of property, plant, and equipment.

Cash Provided by Financing Activities

For the six months ended June 30, 2024, net cash provided by financing activities was $0.8 million, which consisted primarily of $0.6 million in proceeds from purchases under the employee stock purchase plan and $0.3 million in proceeds from the exercise of stock options.

For the six months ended June 30, 2023, net cash provided by financing activities was $70.0 million, which consisted of $68.9 million in proceeds from the issuance of common stock in public offering and concurrent private placement net of payments of offering costs, $1.0 million in proceeds from purchases under the employee stock purchase plan, and $0.1 million due to proceeds from the exercise of stock options.

Contractual Obligations and Commitments

We have entered into leases for offices, laboratory, and manufacturing facilities in Mountain View, California, which includes our headquarters and main offices. Additionally, we have entered into a lease for office and laboratory space in Doylestown, Pennsylvania. As of June 30, 2024, future minimum lease commitments under these leases were $59.9 million.

In addition, we enter into agreements in the normal course of business with CROs, CMOs and other vendors for research and development services for operating purposes, which are generally cancelable upon written notice.

For product candidates that are currently in various research and development stages, we may be obligated to make up to $361.9 million of future development, regulatory, and commercial milestone and royalty payments associated with the optioned technologies in our license agreements. Payments under these agreements generally become due and payable upon achievement of certain milestones. The achievement of these milestones was not probable and payment was not required as of June 30, 2024, as such, contingencies have not been recorded in our condensed consolidated financial statements. Amounts related to contingent milestone payments are not yet considered contractual obligations as they are contingent on the successful achievement of certain milestones. See Note 5 – License Agreements to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

Please refer to Note 2 – Summary of Significant Accounting Policies to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional disclosures around recently issued accounting pronouncements.

Critical Accounting Policies and Use of Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses, and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities, and equity and the amount of revenues and expenses, which are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

Our critical accounting policies are described in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates” in our Annual Report on Form 10-K filed with the SEC on March 7, 2024 and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the six months ended June 30, 2024, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K filed with the SEC on March 7, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our principal executive officer and principal financial officer, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of such date our disclosure controls and procedures were effective at a reasonable assurance level (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

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

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, 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.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, growth prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report, and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

Risk Factor Summary

Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following:

- We are early in our development efforts and all of our product candidates are in preclinical development or early stage clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and commercialize one or more of our product candidates, our business will be materially adversely affected and we may never generate any product revenue.
- The use of engineered IgM antibodies is a novel and unproven therapeutic approach, and our development of our product candidates and our discovery programs may never lead to a marketable product.

- Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval.

- If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

- If we experience delays or difficulties in the enrollment of patients in clinical trials, including because of competition for patients, we will be unable to complete these trials on a timely basis, if at all.

- Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public for any indication.

- We face significant competition from entities that have developed or may develop product candidates for the treatment of diseases that we are initially targeting, including companies developing novel treatments and technology platforms. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

- The manufacturing of our product candidates is complex. We and our third-party manufacturers have encountered and may continue to encounter difficulties in the production of our product candidates, and supply chain shortages have limited and may continue to limit our access to raw materials and other supplies. If we continue to encounter any such difficulties, our ability to manufacture drug substances or supply our product candidates for preclinical studies or clinical trials or, if approved, for commercial sale, could be further delayed or halted entirely.

- We may not be successful in our efforts to use and expand our IgM platform to build a pipeline of product candidates.

- We face risks related to health epidemics and other outbreaks, such as COVID-19, which could significantly disrupt our business operations or otherwise result in material adverse impact to us.

- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

- Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

- We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations.

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

- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Risks Related to Our Business and the Development and Commercialization of Our Product Candidates

We are early in our development efforts and all of our product candidates are in preclinical development or early stage clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and commercialize one or more of our product candidates, our business will be materially adversely affected and we may never generate any product revenue.

We are early in our development efforts and have not yet completed the development of any of our product candidates. As a result, we are not currently permitted to market or sell any of our product candidates in any country, and we may never be able to do so in the future. We have a limited number of product candidates and discovery programs, all of which are in preclinical development or early stage clinical development and we have not received marketing approval for any of our product candidates. Our product candidates

will require clinical development, evaluation of preclinical, clinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales, if ever. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals. Our ability to generate product revenue and achieve and sustain profitability depends on, among other things, obtaining regulatory approvals for our product candidates. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following:

- completing process development, manufacturing and formulation activities;
- initiating, enrolling patients in and completing clinical trials of product candidates on a timely basis;
- developing and maintaining adequate manufacturing capabilities either by ourselves or in connection with third-party manufacturers; and
- demonstrating with substantial evidence the efficacy, safety and tolerability of product candidates to the satisfaction of the FDA or any comparable foreign regulatory authority for marketing approval.

Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to develop product candidates at all, and our business will be materially adversely affected.

The use of engineered IgM antibodies is a novel and unproven therapeutic approach and our development of our product candidates and our discovery programs may never lead to a marketable product.

Our product candidates are based on engineered IgM antibody approaches that differ from current antibody therapies and are unproven. Our IgM antibodies ultimately may not be as safe or effective as IgG antibodies that have been approved or may in the future be approved by the FDA. Further, we are not aware of any therapeutic IgM antibodies that have been approved by the FDA. The scientific evidence to support the feasibility of developing our product candidates and discovery programs is both preliminary and limited. We may ultimately discover that our product candidates and discovery programs do not possess some of the properties that are necessary for therapeutic efficacy, and we may also discover that they do not possess those characteristics that we believe may be helpful for therapeutic effectiveness, including stronger binding that increases efficacy. Our IgM antibodies may also have significant undesirable characteristics, such as immunogenicity, which would limit their ability to be developed as effective and safe therapeutics. In addition, we may discover that our IgM antibodies are not as safe as IgG antibodies.

We may not succeed in demonstrating safety and efficacy of these product candidates or discovery programs in clinical trials, notwithstanding results in preclinical studies. As a result, we may never succeed in developing a marketable product. We may discover that the half-life, tissue distribution or other pharmacodynamic or pharmacokinetic characteristics of our IgM antibodies render them unsuitable for the therapeutic applications we have chosen or otherwise non-competitive with IgG antibodies. We may also experience manufacturing, formulation or stability problems with one or more of our IgM antibodies which may render them unsuitable for use as therapeutic drug products.

The FDA has limited experience with IgM antibody-based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, the FDA may require us to provide additional data to support our regulatory applications. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be subject to post-marketing testing requirements to maintain regulatory approval. In addition, upon obtaining any marketing approvals, we may have difficulty in establishing the necessary sales and marketing capabilities to gain market acceptance.

Moreover, advancing our product candidates and our discovery programs as novel products creates other significant challenges for us, including educating medical personnel regarding a novel class of engineered antibody therapeutics and their potential efficacy and safety benefits, as well as the challenges of incorporating our product candidates, if approved, into treatment regimens.

If any of our product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, and it may prove to be difficult or impossible to finance the further development of such pipeline. Any of these events would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive and difficult to design and implement. Clinical testing can take many years to complete, and its ultimate outcome is uncertain.

A failure of one or more clinical trials can occur at any stage of the process. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, any of which could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any regulatory approvals we may have obtained. Recently, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA where the law is ambiguous. This Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision on us or the pharmaceutical industry in general.

Interim, preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, preliminary or topline data from clinical trials. Interim 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. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Interim or preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, preliminary or topline data and final data could significantly harm our reputation and business prospects. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

Moreover, preliminary, interim and topline data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on study, patient enrollment continues or as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we can complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approval.

We have obtained, and where appropriate in the future may seek, approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as Fast Track designation and Breakthrough Therapy

designation, orphan drug designation, or accelerated approval. Even if we receive accelerated approval from the FDA or comparable regulatory authorities, if our confirmatory clinical trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such other regulatory authorities may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates from the FDA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, 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, additional post-approval confirmatory clinical trials to verify and describe the drug's clinical benefit. If such post-approval clinical trials fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. Further, in December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. In March 2023, the FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent the FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.

Prior to seeking accelerated approval, we may seek feedback from the FDA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a Biologics License Application (BLA) for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., Fast Track designation, Breakthrough Therapy designation or orphan drug designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further clinical trials prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. For example, because of supply chain constraints and staffing issues at one of our CMOs, we had to postpone the filing date of our IND application for one of our clinical candidates. We also experienced questions from the FDA on issues related to starting dose and sequencing of healthy volunteers and patients, delivery device and non-drug substance formulation components that delayed our original plans to advance IGM-6268, a former clinical candidate, into the clinic. The commencement or completion of our clinical trials could be substantially delayed or prevented by many factors, including:

- further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate or combination agents for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board (IRB) approval to conduct a clinical trial at a prospective site;
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment by us or our CROs;
- our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- the inability to produce or obtain sufficient quantities of a product candidate to complete clinical trials;
- inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the impact of, and delays related to, health epidemics such as the COVID-19 pandemic; and
- the need to suspend, repeat or terminate clinical trials as a result of non-compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic partners that have responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us.

Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

If we experience delays or difficulties in the enrollment of patients in clinical trials, including because of competition for patients, we will be unable to complete these trials on a timely basis, if at all.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including supply chain disruptions, staffing shortages and other business and economic disruptions resulting from geopolitical actions, including war and terrorism, natural disasters, including earthquakes, typhoons, floods and fires, as well as other disruptions resulting from the impact of public health factors, including the COVID-19 pandemic, business disruptions of our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until completion of treatment and adequate follow-up. The enrollment of patients depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of subjects to clinical sites and ability of subjects to travel to clinical trial sites;
- continued enrollment of prospective patients by clinical trial sites;
- efforts to facilitate timely enrollment;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- patient referral practices of physicians;
- ability to obtain and maintain patient consents;
- ability to monitor patients adequately during and after treatment;
- risk that enrolled subjects will drop out before completion;
- clinicians' and patients' perceptions as to the potential advantages and disadvantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- inability to enroll, or delay in enrollment of, patients due to outbreaks and public health crises, such as the COVID-19 pandemic.

In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. Moreover, because our product candidates represent a departure from existing cancer treatments, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, IgG antibody therapy or CAR-T treatment, rather than enroll patients in our clinical trials.

Our inability to enroll sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. If we are unable to enroll a sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for such product candidates and our business will be harmed. Even if we can enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public for any indication.

All of our product candidates and discovery programs are in preclinical development or early stage clinical development, and not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from our product candidates could arise at any time during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. Of our product candidates in active development, we have only disclosed early safety data in humans from Phase 1 clinical trials, and our preclinical and discovery programs have not been tested on humans at all. For example, we are encouraged by the safety profile of imvotamab and the relatively low rate of cytokine release syndrome (CRS) observed in our previous clinical trial; however, we may see cases of serious CRS in patients in future clinical trials, which may delay our clinical testing of imvotamab or delay or prevent marketing approval in the future.

In our preclinical studies, we may observe undesirable characteristics of our product candidates. This may prevent us from advancing them into clinical trials, delay these trials or limit the extent of these trials. Despite our preclinical data, toxicity observations in clinical testing, if they occur, may limit our ability to develop our product candidates or may constitute a dose limiting toxicity.

The results of ongoing or future clinical trials may also show that our product candidates and/or our discovery programs may cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable foreign regulatory authorities, or result in marketing approval from the FDA or comparable foreign regulatory authorities with restrictive label warnings or for limited patient populations, or result in potential product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication.

Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, limit the patient population who can use the product or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products.

We face significant competition from entities that have developed or may develop product candidates for the treatment of diseases that we are initially targeting, including companies developing novel treatments and technology platforms. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The development and commercialization of drugs and therapeutic biologics is highly competitive and subject to rapid and significant technological change. We are currently developing biotherapeutics that will compete with other drugs and therapies that currently exist or are being developed in the segments of the pharmaceutical, biotechnology and other related markets that develop oncology treatments. Product candidates we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been

approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do.

There are many companies developing or marketing treatments for cancer, including most major pharmaceutical and biotechnology companies, as well as many smaller biotechnology companies. These treatments consist both of small molecule drug products as well as biologics that work by using antibody therapeutic platforms to address specific cancer targets.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (*e.g.*, T cell engagers), adoptive cellular therapies (*e.g.*, CAR-T), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin and targeted cancer vaccines. We are aware of other companies with competing products or product candidates that target the same proteins, including CD20, DR5, and CD38, or that utilize similar mechanisms, as our product candidates in clinical or preclinical development.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than the products that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

The manufacturing of our product candidates is complex. We and our third-party manufacturers have encountered and may continue to encounter difficulties in the production of our product candidates, and supply chain shortages have limited and may continue to limit our access to raw materials and other supplies. If we continue to encounter any such difficulties, our ability to manufacture drug substance or supply our product candidates for preclinical studies or clinical trials or, if approved, for commercial sale, could be further delayed or halted entirely.

We have spent significant resources to date on developing our current manufacturing processes and know-how to produce sufficient yields and optimize functionality in conjunction with our contract manufacturers. In 2021, we completed construction and began to operate a good manufacturing practice (cGMP) manufacturing facility for the manufacture of clinical trial drug materials. We may construct additional manufacturing facilities to produce commercial supply for any approved products. We will need to scale our manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient yields needed to advance all of our product candidates and discovery programs in preclinical studies and clinical trials and currently rely on our third-party manufacturers for the majority of our product candidate production. Accordingly, we may be required to make significant further investments to expand our manufacturing facilities in the future, and our efforts to scale our internal manufacturing capabilities may not succeed.

Also, historically IgM antibodies have been particularly difficult to manufacture and CMOs have limited experience in the manufacturing of IgM antibodies. The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, difficulties in scaling the production process and shipping issues. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. For example, because of supply chain constraints and staffing issues at one of our CMOs, we previously had to adjust the anticipated filing date of our IND application for one of our clinical candidates. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, and we could be subject to sanctions, restrictions on the product candidate or on the manufacturing facilities, product liability claims or other adverse consequences, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. Any interruption in the supply of clinical drug product from any cause could adversely affect the timing, enrollment and scope of our ongoing clinical trials.

All of our engineered antibodies are manufactured by culturing cells from a master cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP. It is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks, and we may fail to have adequate backup should any particular cell bank be lost in a catastrophic event. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts and the use of engineered IgM antibodies is a novel therapeutic approach. Failure to develop our own manufacturing capacity may hamper our ability to further process improvement, maintain quality control, limit our reliance on contract manufacturers and protect our trade secrets and other intellectual property.

We may not be successful in our efforts to use and expand our IgM platform to build a pipeline of product candidates.

A key element of our strategy is to leverage our IgM platform to expand our pipeline of antibody product candidates. Although our research and development efforts to date have resulted in a pipeline of product candidates, we may not be able to develop product candidates that are safe and effective. In addition, although we expect that our IgM platform will allow us to continue to develop a steady stream of product candidates, we may not prove to be successful at doing so. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, be competitive with alternatives, or otherwise achieve market acceptance. If we do not successfully develop and begin to commercialize product candidates, we will not be able to generate any product revenue, which would adversely affect business.

We may expend our limited resources to pursue product candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our programs, we must focus our programs on specific product candidates and indications and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or indications may not lead to the development of any viable commercial product and may divert resources away from better opportunities. For example, in December 2023, we committed to a strategic refocusing (Strategic Refocusing), pursuant to which we suspended clinical development activities for certain product candidates. This decision or potential future decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the oncology or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, fail to recoup our research and development and other investments in the clinical programs we have selected, be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We face risks related to health epidemics and other outbreaks, such as COVID-19, which could significantly disrupt our operations or otherwise result in material adverse impacts to us.

Our business could be adversely impacted by the effects of health epidemics and other outbreaks, including:

- delays or difficulties in enrolling and retaining patients in our ongoing and planned clinical trials, and incurrence of additional costs as a result of any preclinical study and clinical trial delays and adjustments;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- shutdowns or continued business disruptions experienced by suppliers and other third parties with whom we conduct business;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;

- interruption or delays of key clinical trial activities, such as clinical trial site monitoring and collecting sufficient clinical data, patient safety considerations or limitations on travel imposed or recommended by federal or state governments, employers and others;
- other limitations on resources that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people or government restrictions;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research or to support manufacturing activities of our business and that of our suppliers or contractors;
- changes in clinical site policies and procedures for conducting clinical trials during the pandemic;
- changes in regulations as part of a response to health epidemics or other outbreaks which may require us to change the ways in which our clinical trials are conducted and incur unexpected costs, or require us to discontinue the clinical trials altogether; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors.

On May 11, 2023, the federal government ended the COVID-19 public health emergency, which ended a number of temporary changes made to federally funded programs, although some continue to be in effect. The extent to which any health epidemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of a particular virus and its variants and the actions to contain it or treat its impact, among others.

Material changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

The design or execution of our clinical trials may not support regulatory approval.

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in potential future Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. Failure to successfully obtain regulatory approval could have a material adverse impact on our business and financial performance.

Even if any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive price and otherwise will be accepted in the market. The antibodies we are developing use relatively new technologies. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our technologies, and the medical community and third-party payors may not accept and use, or provide favorable reimbursement for, any product candidates developed by us. The commercial success of our product candidates will depend upon their acceptance among physicians, patients, the medical community and third-party payors. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- limitations or warnings contained in the approved labeling for our product candidates;
- changes in the standard of care for the targeted indications for our product candidates;
- the clinical indications for which any product candidate is approved;
- lack of significant adverse side effects;
- the effectiveness of sales and marketing efforts;
- availability and extent of coverage and adequate reimbursement, as well as pricing, by managed care plans and other third-party payors, including government authorities;
- patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payors;
- timing of market introduction of our product candidate as well as competitive products;
- the potential and perceived advantages of our product candidate over alternative treatments;
- the degree of cost-effectiveness of our product candidate;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which any product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second or third-line therapy for particular indications;
- whether our product candidate can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidate or favorable publicity about competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the approval of other new therapies for the same indications;
- relative convenience and ease of administration of our product candidates; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and third-party payors, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We may be unsuccessful, in obtaining or may be unable to maintain the benefits associated with, orphan drug designation for current or future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We may elect to seek Orphan Drug Designation for certain indications for our product candidates. 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.

Generally, if a product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time. There are also limited circumstances where the FDA may reduce the seven-year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Historically, development of IgM antibodies has been limited by difficulties in recombinant expression and manufacture of these antibodies; therefore, the FDA may determine that we cannot assure the availability of sufficient quantities of our product candidates to the extent necessary to support marketing exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. However, in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and approval standards. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If reimbursement is not available or is not sufficient for our products, it is less likely that our products will be widely used.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Third-party payors, such as government healthcare programs, private health insurers and health maintenance organizations, decide which drugs they will cover and establish the level of reimbursement for such drugs. One third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. We cannot be certain that coverage and reimbursement will be available or adequate for any products that we develop. If coverage and adequate reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates, if approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary

according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future change to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors, including both government-funded and private payors, for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We focus our product candidate development on therapeutic IgM antibodies. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new developments, such as the development of vaccines or new therapeutics, may change the estimated incidence or prevalence of the diseases targeted by our programs. The number of patients may turn out to be lower than expected. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. The FDA often approves new cancer therapies only for use after one or more other treatments have failed. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy or surgery, is sometimes adequate to treat the patient. If first-line therapy proves unsuccessful, second-line therapies, such as additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these therapies, may be administered. Third- or fourth-line therapies may include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We have in the past sought approval through clinical testing for certain product candidates for patients who have failed one or more approved treatments, and may do so again in the future. Even if we obtain regulatory approval and significant market share for such product candidates, because the potential target population may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. In addition, there is no guarantee that any of our product candidates, even if approved, would be approved as a particular line of treatment. In addition, even if any of our product candidates were approved for a particular line of treatment, we would likely have to conduct additional clinical trials prior to gaining approval as an earlier line of treatment.

Development of product candidates in combination with other therapies could expose us to additional risks.

Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which will result in significant additional expense.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product.

For any approved product, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMP and current good clinical practices (cGCP) for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- adverse publicity, fines, warning letters or holds on clinical trials;
- refusal by the FDA, EMA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off-label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the FDA's or comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability.

If any product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and we will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for any future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny, including investigations by the FDA and other regulators of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls, a change in the indications for which they may be used or suspension or withdrawal of marketing approvals;
- loss of revenue;

- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

We may need to have in place increased product liability coverage if and when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

Our product candidates, for which we intend to seek approval, may face competition sooner than anticipated.

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of biosimilar products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." Under this statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, efficacy and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for a referenced product may be reduced to seven years.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly those in the European Union, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates, if approved, and affect the prices we may obtain.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change healthcare systems in ways that could affect our ability to sell any of our product candidates profitably, if such product candidates are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. 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, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as

well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- The demand for our product candidates, if approved;
- Our ability to set a price that we believe is fair for our products;
- Our ability to obtain coverage and reimbursement approval for a product;
- Our ability to generate revenue and achieve or maintain profitability;
- The level of taxes that we are required to pay; and
- The availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

In March 2010, the ACA was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry. Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price (AMP), for most branded and generic drugs, respectively;
- Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- requirement that applicable manufacturers and group purchasing organizations report annually to the Centers for Medicare & Medicaid Services (CMS), information regarding certain payments and other transfers of value given to physicians and teaching hospitals, and any ownership or investment interest that physicians, or their immediate family members, have in their company;
- a requirement that manufacturers and authorized distributors of applicable drugs annually report information related to samples provided to practitioners;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- 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
- establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there remain judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments will remain in effect through 2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several

Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various pharmaceutical companies have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. With the Supreme Court's recent decision that overturned the *Chevron* doctrine, the IRA as well as other administration decisions of HHS, including those of the CMS, may be subject to increased litigation and judicial scrutiny. The full impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the IRA, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Uncertainties created by the IRA and other cost containment measures may negatively impact potential investments, company valuation, royalty-based earnings, mergers and acquisitions in our industry. Further, many states have proposed or enacted legislation and administrative actions that seek to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate, if approved, is prescribed or used. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

In the European Union similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products and third-party payors' reimbursement policies might adversely affect our ability to sell any future products profitably.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-approval testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC

and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including delays or disruptions due to the health epidemics, travel restrictions, staffing shortages, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown or disruption occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions and provide feedback on our clinical development plans, which could have a material adverse effect on our business and our anticipated timelines. Further, in our operations as a public company, future government shutdowns or other disruptions to normal operations could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business may be subject to risks associated with conducting business internationally. Some of our clinical trial sites as well as some of our suppliers and collaborators, are located outside of the United States. We may also enter into additional non-U.S markets. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes, including price controls;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing foreign operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war (such as the ongoing conflict between Russia and Ukraine) and terrorism, natural disasters, or public health emergencies such as the COVID-19 pandemic.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Our business and current and future relationships with customers and third-party payors in the United States and elsewhere will be subject, directly or indirectly, to applicable federal and state anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our current and future arrangements with

healthcare professionals, principal investigators, consultants, customers, and third-party payors and other entities may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research on product candidates and market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens on behalf of the government, through civil whistleblower, or qui tam actions, and the federal civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities, among other things, for knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government;

- HIPAA, which among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to 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 payor (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;

- HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that create, receive, maintain or transmit individually health information for or on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to "payments or other transfers of value" made to covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, and information regarding ownership and investment interests held by physicians (as defined above) and their immediate family members. The information reported annually is publicly available on a searchable website;

- analogous state and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information relating to pricing and marketing information; and

- state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have

actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be

eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.

We have incurred significant losses since our inception. Our net loss for the six months ended June 30, 2024 was $97.7 million. As of June 30, 2024, our accumulated deficit was approximately $919.0 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. Historically we have financed our operations primarily through the sale of equity and debt securities as well as funding received from our collaboration partners. We do not generate any revenue from product sales and our product candidates will require substantial additional investment before they may provide us with any revenue, if ever.

The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate product revenue or achieve profitability. For example, our expenses could increase if we are required by the FDA to perform clinical trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in-house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have exclusively related to the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform. We are still in the early stages of developing our product candidates, and we have not completed development of any product candidate. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Our ability to generate revenue and achieve profitability depends in large part on our ability, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenue from sales of products for the foreseeable future.

To generate product revenue and become and remain profitable, we must succeed in developing and commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including:

- successfully completing preclinical and clinical development of our product candidates in a timely manner;
- obtaining regulatory approval for such product candidates in a timely manner;
- satisfying any post-marketing approval commitments required by applicable regulatory authorities;

- developing an efficient, scalable and compliant manufacturing process for such product candidates, including expanding and maintaining manufacturing operations, commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale;
- successfully launching commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- maintaining a continued acceptable safety profile following any marketing approval;
- achieving commercial acceptance of such product candidates as viable treatment options by patients, the medical community and third-party payors;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio, including our licensed intellectual property;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and
- attracting, hiring and retaining qualified personnel.

We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations.

All of our product candidates and discovery programs are in preclinical development or early stage clinical development. Developing drug products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates, which will increase our expenses. We will continue to require additional funding to complete the development and commercialization of our product candidates, to continue to advance our discovery programs, to expand our manufacturing facilities and to satisfy additional costs that we have incurred and expect to continue to incur in connection with operating as a public company. Such funding may not be available on acceptable terms or at all.

As of June 30, 2024, we had $256.4 million in cash, cash equivalents, and marketable securities. We believe that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least one year past the issuance date of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Our estimate as to how long we expect our cash, cash equivalents, and marketable securities to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. In addition, because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

- the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates, including expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and cost of capital expenditures to support our research, development and manufacturing efforts;
- the number and characteristics of other product candidates that we pursue;
- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;

- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the impact of macroeconomic conditions, including inflation, supply chain disruption and volatility in the capital markets, on our business, financial condition and results of operations;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate enough product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through one or more public and private equity offerings, debt financings and strategic partnerships. We do not have any committed external source of funds. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our clinical or discovery programs or our business operations.

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

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, ongoing armed conflicts have created volatility in the capital markets and are expected to have further global economic consequences. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

At June 30, 2024, we had $256.4 million of cash, cash equivalents, and marketable securities. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since June 30, 2024, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and general economic downturn.

Risks Related to Managing Our Growth and Operations

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

We are highly dependent on the business, research and development and clinical expertise of our senior management team, key employees and other highly qualified managerial, scientific, and medical personnel. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The loss of the services provided by any of our senior management team, other key employees and other scientific and medical advisors, and any inability to find suitable replacements, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing, and sales and marketing personnel, and we face significant competition for experienced personnel. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills

and experience required to successfully develop, gain regulatory approval of and commercialize products. Intense competition for attracting key skill sets may limit our ability to retain and motivate these key personnel on acceptable terms.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. This high cost of living will increase the difficulty of attracting experienced personnel to our company, and we may be required to expend significant financial resources in our employee recruitment and retention efforts. Additionally, the U.S. has recently experienced historically high levels of inflation and an acute workforce shortage generally, which has created a hyper-competitive wage environment that may increase our operating costs. Any changes in our compensation structure, workforce reductions (including the reduction in force we announced in December 2023 in connection with the Strategic Refocusing), or other cost reduction efforts may be negatively received by employees and result in attrition or recruiting difficulties. Moreover, there can be no assurance that any initiatives we take to improve employee retention will be successful in achieving their objectives, including the exchange of employee stock options for new restricted stock units completed in July 2024.

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

We will need to grow our organization, and we may experience difficulty in managing this growth, which could disrupt our operations.

As of June 30, 2024, we had 204 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. Additionally, as our product candidates and discovery programs enter and advance through preclinical studies and any clinical trials, we will need to expand our research, development, manufacturing, regulatory and sales and marketing capabilities or contract with other organizations to provide these capabilities for us. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity amongst remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates and discovery programs. In December 2023, we announced a reduction in our workforce by approximately 22% as part of our commitment to the Strategic Refocusing. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend on our ability to effectively expand our organization and manage any future growth.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we or our CROs may collect, store, and otherwise process sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by us. We manage and maintain our applications and data by utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. We face multiple risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls over these risks.

The secure storage, maintenance, transmission, and other processing of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure and that of any service provider we may use, whether they rely on our network and systems or their own to render service, may be vulnerable to cybersecurity attacks by hackers or viruses, ransomware or other malicious code, or breaches or incidents due to employee error, or malfeasance, other disruptions, or other causes. While we have not experienced cyber incidents that have been determined to be material in the past, either individually or in the aggregate, we and our third-party providers have experienced cyberattacks in the past. For example, in

December 2023, an unidentified actor briefly gained unauthorized access to an employee account. We promptly detected and responded to the incident and terminated the unauthorized access. We engaged cybersecurity and other specialists to assist in the response to the incident. The unauthorized actor did access certain company information, but the incident did not adversely impact our operations.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), viruses, worms, and other malicious code, ransomware and other malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, software bugs, server malfunctions, software or hardware failures, loss, corruption and other unavailability of data or other information technology assets, adware, telecommunications failures, natural disasters, and other similar threats. Geopolitical tensions and conflicts such as the Russia-Ukraine and Israel-Hamas wars may increase the cybersecurity risks faced by us and the third parties on which we rely.

Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may reduce or alleviate negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products/services) or the third-party information technology systems that support us and our services.

Any such breach or interruption could compromise our networks and systems and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss, unavailability, or other unauthorized processing of information, or the perception that it has occurred, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), the EU General Data Protection Regulation (EU GDPR) and UK General Data Protection Regulation (UK GDPR), mandatory notification and reporting obligations, additional regulatory oversight, significant regulatory penalties and remediation expenses. There is no guarantee that we can protect our systems from breaches or incidents or the information in or processed by such systems from compromise. Unauthorized access to, or loss, unavailability, corruption, dissemination, or other processing of information or any mechanical failure of our or our third-party service providers' information technology systems could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. We and the third parties upon which we rely may face difficulties or delays in identifying and responding to any actual or perceived breach or incident. We may be required to expend significant amounts to address security risks, whether in connection with an actual or perceived breach or incident or otherwise.

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

We are subject to stringent and changing obligations related to privacy, data protection and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

Our data processing activities subject us to numerous obligations relating to privacy, data protection and data security, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. The interpretation and application of consumer, health-related and data protection laws in the United States, the European Union, and elsewhere are often uncertain, contradictory and in flux. For example, the California Consumer Privacy Act (the CCPA), which went into effect on January 1, 2020, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Aspects of the CCPA, and its interpretation and enforcement remain uncertain. The effects of this legislation potentially are far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA has been amended on multiple occasions, and it is unclear whether it will be further amended.

In addition, California voters recently passed the California Privacy Rights Act (CPRA), which modified the CCPA significantly as of January 1, 2023, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. In addition, several states within the United States have enacted or proposed data privacy laws. For example, Colorado, Connecticut, Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia, have enacted similar legislation. Although the CCPA and many similar state statutes include exemptions for certain clinical trials data, these laws may increase our compliance costs and potential liability with respect to other personal information we collect or otherwise process. Further, other states have enacted laws that cover certain aspects of the collection, use, disclosure, and/or other processing of health information, such as Washington's My Health, My Data Act, which, among other things, provides a private right of action. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our practices, or for this to be perceived to be the case. Such interpretation and application could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these laws and regulations relating to privacy, data protection and data security vary between states, may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to privacy, data protection and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing the personal data of individuals. These laws, regulations, and standards can create complex, demanding compliance obligations, and they carry substantial penalties for noncompliance. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. The UK GDPR has a similar penalty regime. Further, individuals may initiate litigation related to our processing of their personal data. Our efforts to comply with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Further, because the interpretation and application of many laws and regulations relating to privacy, security, and data protection, along with mandatory industry standards, are uncertain, it is possible that these laws, regulations and standards, or contractual obligations to which we are or may become subject, may be interpreted and applied in a manner that is inconsistent with our existing or future data management practices. Any failure or perceived failure by us to comply with our posted privacy policies, our privacy-related obligations to users or other third parties, or any other legal obligations or regulatory requirements relating to privacy, data protection or data security, may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us or public censure and could result in significant liability, cause harm to our brand and reputation, and otherwise materially and adversely affect our reputation and business.

Furthermore, the loss, corruption, or unavailability of clinical trial data from ongoing, completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

Our operations are vulnerable to interruption by catastrophic events, which could harm our business and financial condition.

Our operations, and those of our CROs, clinical trial sites, suppliers, regulators, and other third parties with whom we engage, could be subject to natural disasters, power outages, telecommunications failures, failures or breaches of information technology systems, epidemics, pandemics, and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of

the third parties with whom we engage, including the suppliers, CROs, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

All of our operations are located in Mountain View, California and Doylestown, Pennsylvania, with our corporate headquarters in Mountain View, California. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. We do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change," the corporation's ability to use its net operating losses (NOLs) and other pre-change tax attributes such as research tax credits to offset its post-change taxable income or taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. We completed a Section 382 study and believe we have experienced at least two changes in ownership. Consequently, we may be limited in our ability to use our NOL carryforwards and other tax assets in a future year if taxable income in that given year exceeds our cumulative 382 NOL utilization limits through that specific year. As a result, even if we attain profitability, it is possible 382 limitations on the ability to use our NOL carryforwards and other tax assets could adversely affect our future cash flows. In addition, our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. The Tax Cuts and Jobs Act of 2017 (Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act, imposes certain limitations on the deduction of NOLs, including a limitation on use of NOLs generated in tax years that began on or after January 1, 2018 to offset 80% of taxable income in tax years beginning on or after January 1, 2021. In addition, California has recently proposed a temporary suspension on the use of state net operating loss carryforwards for certain businesses, which may adversely affect our company if it earns taxable income in the impacted tax years. Other state tax limitations may apply.

Changes in the U.S. taxation of international business activities or the adoption of other tax reform policies could materially impact our business, results of operations and financial condition.

Changes to U.S. tax laws that may be enacted in the future could impact the tax treatment of our foreign earnings. If we expand our international business activities, any changes in the U.S. or foreign taxation of such activities may increase our worldwide effective tax rate and adversely affect our business, results of operations and financial condition. For example, the Organization for Economic Cooperation and Development has proposed implementing a global minimum tax of 15%, referred to as Pillar 2, which has been agreed to by over 136 countries. Pillar 2 has been implemented by the member states of the European Union into national legislation as of the end of 2023 and may be adopted by other jurisdictions. In addition, on January 1, 2022, a provision of the Tax Act went into effect that eliminates the option to deduct domestic research and development costs in the year incurred and instead requires taxpayers to amortize such costs over five years. In 2022, the United States also enacted the Inflation Reduction Act of 2022 (IRA), which imposes, among others, a 1% excise tax on certain repurchases of stock and a 15% alternative minimum income tax on "adjusted financial statement income" of certain corporations. Such changes, among others, may adversely affect our effective tax rates, cash flows and general business condition.

Acquisitions or joint ventures could increase our capital requirements, disrupt our business, cause dilution to our stockholders, cause us to incur debt or assume contingent liabilities and otherwise harm our business.

We evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with any strategic partners or suppliers as a result of such a transaction;
- the assumption of additional indebtedness or contingent or otherwise unanticipated liabilities related to acquired companies;
- the issuance of our equity securities;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals;
- increases in our expenses and reductions in our cash available for operations and other uses;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Future credit arrangements may restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. Moreover, we may not be able to identify suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Adverse events or perceptions affecting the financial services industry could adversely affect our operating results, financial condition and prospects.

Limited liquidity, defaults, non-performance or other adverse developments affecting financial institutions or parties with which we do business, or perceptions regarding these or similar risks, have in the past and may in the future lead to market-wide liquidity problems. Such developments, and their effects on the broader financial system, could result in a variety of material and adverse impacts on our business operations and financial conditions, including, but not limited to:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of obligations, including U.S. federal and state wage laws and contracts that may require us to maintain letters or credit or other credit support arrangements; and
- termination of cash management arrangements or delays in accessing or actual loss of funds subject to cash management arrangements.

In such an event, parties with which we have commercial agreements, including collaboration partners and suppliers, may be unable to satisfy their obligations to, or enter into new commercial arrangements with, us.

Concerns regarding the U.S. or international financial systems could impact the availability and cost of financing, thereby making it more difficult for us to acquire financing on acceptable terms or at all. In addition, instability in the financial services industry could spur a deterioration in the macroeconomic environment.

Any of these risks could materially impact our operating results, liquidity, financial condition and prospects.

Risks Related to Our Dependence on Third Parties

We currently rely on third parties to manufacture and deliver our product candidates and provide other services. Any failure by one of these third parties to manufacture and deliver acceptable product candidates and provide other services for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

We currently have limited in-house manufacturing experience and personnel. While we operate a cGMP manufacturing facility for the manufacture of clinical trial drug materials, we expect to continue to rely for some time on third parties to manufacture our product candidates and for the commercial manufacture of some or all of our product candidates, if approved. Bulk drug substance (BDS) for our clinical-stage product candidates is provided from both internal and third-party contract manufacturers. Any reduction or halt in supply of BDS could severely constrain our ability to develop our product candidates until a replacement contract manufacturer is found and qualified. As a result of supply chain constraints and staffing issues at one of our contract manufacturers, we have previously adjusted the anticipated filing date of our IND application for one of our clinical candidates. In addition, we currently rely on a third-party contract research organization for the conduct of our clinical assays and we have experienced, and may continue to experience, delays and interruptions, as well as quality and design errors, in this supply of information to us. If we are unable to arrange for and maintain such third-party manufacturing and analytical sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or clinical sample analysis data, or we may be delayed in doing so. If we are unable to arrange for and maintain such third-party manufacturing sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. A loss of supply of our product candidates or combination agents, for any reason, including as a result of manufacturing, supply or storage issues, damaged shipments, or otherwise, could result in us experiencing further delays, or disruptions, suspensions or terminations of, or being required to restart or repeat, any pending or ongoing clinical trials. Such failure or substantial delay or loss of supply could materially harm our business.

Reliance on third-party manufacturers entails risks to which we may not be subject if we manufactured product candidates ourselves, including:

- the possible failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- reliance on the third party for regulatory compliance and quality control and assurance and failure of the third party to comply with regulatory requirements;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications);
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possibility of termination or nonrenewal of the agreement by the third-party at a time that is costly or damaging to us.

In addition, the FDA, EMA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in sanctions being imposed on us, including fines, injunctions, civil penalties, restrictions on the product or on the manufacturing or laboratory facility, including license revocation, marketed product recall, suspension of manufacturing, product seizure, voluntary withdrawal of the product from the market, operating restrictions or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient

quantities of product candidates in a timely manner, would lead to a delay in, or failure to seek or obtain, regulatory approval of any of our product candidates. Furthermore, any change in manufacturer of our product candidates or approved products, if any, would require new regulatory approvals, which could delay completion of clinical trials or disrupt commercial supply of approved products.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Union and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable cGCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop, and license future product candidates may be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us.

Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

We rely on third parties for various operational and administrative aspects of our business, including for certain cloud-based software platforms, which impact our financial, operational and research activities. If any of these third parties fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected.

We currently rely upon third party consultants and contractors to provide certain operational and administrative services. These services include tax advice and clinical and research consultation. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third-party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high-quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance.

Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on “cloud-based” platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, and computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud-based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business.

Strategic partnerships may be important to us. We will face significant competition in seeking new strategic partners.

We have limited capabilities for drug development and manufacturing and do not yet have any capability for sales, marketing or distribution. For some of our product candidates, we may determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. For example, we have entered into a collaboration with Sanofi for the development and potential commercialization of certain therapeutic products. The competition for strategic partners is intense. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the strategic partner’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product candidate.

Strategic partnerships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Even if we are successful in entering into collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements with other potential collaborators.

If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and adversely affected. Any collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the partner terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, and increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. Accordingly, although there can be no assurance that we will undertake or successfully complete any

transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches the market.

If we are unable to maintain strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.

Any strategic partnerships we enter into may pose a number of risks, including the following:

- we may not be able to enter into critical strategic partnerships or enter them on favorable terms;
- strategic partners have significant discretion in determining the effort and resources that they will apply to such a partnership, and they may not perform their obligations as agreed or expected;
- strategic partners may decide not to pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus (as occurred in April 2024 with respect to the Sanofi Agreement) or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;
- strategic partners may restrict us from researching, developing or commercializing certain products or technologies without their involvement;
- product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates;
- a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates;
- disagreements with strategic partners, including disagreements over proprietary rights, ownership of intellectual property, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic partners may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights relating to our product candidates or discovery programs or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation or other intellectual property related proceedings;
- strategic partners may own or co-own intellectual property covering our product candidates or discovery programs that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or discovery programs;
- we may need the cooperation of our strategic partners to enforce or defend any intellectual property we contribute to or that arises out of our strategic partnerships, which may not be provided to us;
- strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- strategic partners may control certain interactions with regulatory authorities, which may impact our ability to obtain and maintain regulatory approval of our product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;

- strategic partners may grant sublicenses to our technology or product candidates or undergo a change of control and the sublicensees or new owners may decide to take the collaboration in a direction which is not in our best interest;
- strategic partners may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the strategic partner relating to our product candidates or discovery programs;
- strategic partnerships may require us to incur short and long-term expenditures, issue securities that dilute our stockholders or disrupt our management and business;
- if our strategic partners do not satisfy their obligations under our agreements with them, or if they terminate our strategic partnerships with them, we may not be able to develop or commercialize product candidates as planned;
- strategic partners may require us to share in development and commercialization costs pursuant to budgets that we do not fully control and our failure to share in such costs could have a detrimental impact on the strategic partnership or our ability to share in revenue generated under the strategic partnership;
- strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and
- strategic partnership or collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future strategic partner ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated.

In March 2022, we entered into the Sanofi Agreement, pursuant to which we agreed to collaborate with Sanofi to generate, develop, manufacture and commercialize IgM antibodies directed to six primary targets, three of which were intended as oncology targets and three of which are intended as immunology targets. In April 2024, we announced that the Sanofi Agreement will focus exclusively on immunology targets, with the oncology targets terminated from the agreement.

Risks Related to Our Intellectual Property

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or may obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position.

Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. We are aware of third-party patents and patent applications containing claims directed to most of our areas of product development, which patents and applications could potentially be construed to cover our product candidates and the use thereof to treat patients. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that third-party patents or patent applications of which we are aware may not ultimately be found to limit our ability to make, use, sell, offer for sale, or import our future approved products or impair our competitive position, even though we do not believe they are relevant to our business. Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. These patents may not expire before we receive marketing authorization for our product candidates, and they could delay the commercial launch of one or more future products. If our products were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms, or at all, our business, financial condition, and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations, and we would be exposed to a threat of litigation.

In the biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace both within and outside the United States including patent infringement lawsuits, oppositions, *inter partes* review (IPR) and post-grant review (PGR) proceedings before the United States Patent and Trademark Office (USPTO), or the applicable foreign patent counterpart. The types of situations in which we may become a party to such litigation or proceedings relating to third party intellectual property include:

- we or our licensors may initiate litigation or other proceedings, including post-grant proceedings such as oppositions, IPRs or PGRs, against third parties seeking to invalidate the patents held by those third parties, to obtain a judgment that

our products or processes do not infringe those third parties' patents or to obtain a judgment that those parties' patents are invalid and/or unenforceable;

- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or on our business, results of operations, financial condition, and prospects. Any of these outcomes could have a material adverse effect on our business.

If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed.

Our strategy depends on our ability to identify, seek, obtain, and maintain patent protection for our discoveries. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies that have patent portfolios consisting of hundreds, and in some case even thousands, of granted patents. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our owned, co-owned, or in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own, or co-own, or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries or that effectively prevent third parties from commercializing competitive product candidates.

Moreover, the patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. We may be subject to a third-party preissuance submission of prior art to the USPTO or a foreign jurisdiction, and such prior art may affect the scope of any claims we ultimately get allowed or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented, or deemed unenforceable, or such third parties may gain rights to such patents. We could also become involved in reexamination, inter-parties review, post-grant review, opposition or derivation proceedings, challenging our patent rights or the patent rights of others. In addition, recent changes in law, such as the U.S. Supreme Court's decision in *Amgen Inc. v. Sanofi*, have introduced changes in the law relevant to biotechnology patents, and future changes in law may further introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. If our patents are narrowed, invalidated, or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is

also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims, or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope, and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own, co-own, or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Moreover, some of our owned or in-licensed patents and patent applications are or may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third-parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for United States-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-United States manufacturers.

In the future, we may obtain funding, in part, from U.S. federal or state governments for research we conduct, and such funding may be used in the advancement of our existing technologies or creation of additional in-licensed patent rights and technology. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. As a result, the U.S. government may have certain rights, including so-called march-in rights, to any future patent rights funded in part by the U.S. federal government and any products or technology developed from such patent rights. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or to allow third parties to use our licensed technology, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or product candidates or we could lose certain rights to grant sublicenses.

We in-license certain patent rights and proprietary technology from third parties that are important to our discovery platform and development of product candidates. In January 2021, we entered into an exclusive license agreement with Medivir AB through which we received global, exclusive development and commercialization rights for birinapant, a clinical-stage SMAC mimetic.

We also in-license, and may in the future in-license, certain antibody binding domains for our discovery and clinical development programs from third parties. Under these license agreements, we are able to research and initially develop discovery programs and are required to make certain annual payments. We also have the option to negotiate or enter into commercial license agreements with these third parties if we elect to continue development or commercialization of any product candidates incorporating the in-licensed antibodies. If we exercise our option to negotiate or enter into any commercial licenses with these third parties, we will likely be subject to various additional obligations, which may include obligations with respect to funding, development and commercialization activities, and payment obligations upon achievement of certain milestones and royalties on product sales.

Our current license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If any of our licenses or future commercial licenses are terminated or breached, we may:

- lose our rights or options to research, develop or commercialize product candidates covered by the licensed technology;
- not be able to secure patent or trade secret protection for product candidates covered by the licensed technology;
- experience significant delays in the development or commercialization of product candidates covered by the licensed technology;
- not be able to obtain other licenses that may allow us to continue to progress the applicable programs on acceptable terms, if at all; or
- incur liability for damages.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from or to third parties. If our licensors and future licensors fail to prosecute, maintain, enforce, and defend patents we may license, or lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that is the subject of such licensed rights could be materially adversely affected.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating, or otherwise violating the licensor's intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In addition, the agreements under which we currently license intellectual property or technology from or to third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse impact on our business and ability to achieve profitability. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected product candidates, which could have a material adverse effect on our business and financial conditions.

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, 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, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be 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 a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms

or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own, co-own, or have licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own, co-own, or have licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful.

Third parties may seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement, which may lead to challenges to the validity or enforceability of our patents. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated, or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by, co-owned by, or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents co-owned by us, or licensed to us;
- third parties may initiate opposition, IPR or PGR proceedings challenging the validity or scope of our patent rights, requiring us and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by, co-owned, or licensed to us; or

- third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by, co-owned by us, or licensed to us, under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed or trade secrets not misappropriated by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using, and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 an adverse effect on the price of our common stock.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or
- we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned, co-owned, and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not receive an extension if we fail to

apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

If we are unable to protect the confidentiality of our trade secrets and proprietary information, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. Trade secrets and know-how can be difficult to protect. Trade secrets and know-how can also in some instances be independently derived or reverse-engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information, in part by entering into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, parties with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition, and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients.

We employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and 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 or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices 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 rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing, the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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. 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.

Patent protection and patent prosecution for some of our product candidates may be dependent on, and the ability to assert patents and defend them against claims of invalidity may be maintained by, third parties.

The prosecution of certain patent applications and the maintenance and enforcement of certain patents that relate to our product candidates are and may be in the future controlled by our licensors or licensees. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. For example, under our collaboration agreement with Sanofi, in specified circumstances, Sanofi controls the prosecution and enforcement of certain of the patents and patent applications licensed to it.

If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Changes in patent laws, patent regulations, or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws, patent office regulations, or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third-party patents. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Additional legislation limiting the value of pharmaceutical and biotechnological patents is pending in Congress. Moreover, the USPTO is seeking to implement regulations that would limit the enforceability of continuation or follow-on patents. Further, recent U.S. Supreme Court and Court of Appeals for the Federal Circuit rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope, and value of patents once obtained.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Additionally, as of June 1, 2023, existing European patents, and European patent applications, upon grant of a patent, have the option of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unified Patent Court (UPC). During a sunrise period that began on March 1, 2023, European patent owners have the ability to opt out of being subjected to the jurisdiction of the UPC. The option of a Unitary Patent will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of 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 current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Recent United States Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States.

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.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own, co-own, or license.

We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with such approval may adversely affect our business.

Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we could lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to Ownership of Our Securities

The market price of our common stock may be volatile, which could result in substantial losses for our securityholders.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- results and timing of our preclinical studies and clinical trials and studies and trials of our competitors' products;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- actual or anticipated changes in our growth rate relative to our competitors;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- commencement or termination of collaborations for our programs; for instance, without limitation, our collaboration with Sanofi;
- announcements by us, our strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- litigation;
- future sales of our common stock by us, our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our product candidates, if approved, to achieve commercial success;
- economic and other external factors or other disasters, crises or public health emergencies, such as the COVID-19 pandemic;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- announcements or expectations of additional financing efforts;
- general market conditions and market conditions for biotechnology stocks;
- overall fluctuations in U.S. equity markets; and
- other factors that may be unanticipated or out of our control.

The stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the issuer of the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

An active trading market for our common stock may not continue to be developed or sustained, and as a result it may be difficult for you to sell your shares of our common stock.

Although our common stock is listed on the Nasdaq Global Select Market (Nasdaq), the market for our shares has demonstrated varying levels of trading activity and an active trading market for our common stock may not be sustained. The lack of an active trading market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares, may impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

We are controlled by a concentrated group of stockholders, whose interests in our business may conflict with yours.

As of June 30, 2024, stockholders with ownership equal to 5% or more of our outstanding capital stock and their respective affiliates, beneficially owned a majority of the shares of our outstanding capital stock. Accordingly, our principal stockholders will be able to control most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, including mergers and sales of all or substantially all of our assets. The interests of these principal stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders. For example, our concentration of ownership could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could cause the market price of our common stock to decline or prevent our stockholders from realizing a premium over the market price for their shares of our common stock.

In addition, pursuant to nominating agreements entered into between us and each of (i) Topsøe Holding A/S, (ii) Baker Brothers Life Sciences L.P. and 667, L.P. (together, Baker Brothers) and (iii) Redmile Biopharma Investments II, L.P., RAF, L.P. and Redmile Strategic Master Fund, LP (together, Redmile), for up to 12 years following the completion of our IPO, so long as Topsøe Holding A/S, Baker Brothers and Redmile, together with their respective affiliates, each beneficially own certain specified amounts of our capital stock, we will have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, (i) two individuals designated by Topsøe Holding A/S, (ii) one individual designated by Baker Brothers and (iii) one individual designated by Redmile, subject to certain customary conditions and exceptions. Each of Topsøe Holding A/S, Baker Brothers and Redmile, and their respective affiliates, may therefore have influence over management and control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation as currently in effect. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales could occur, could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amount of our common stock in the public market, the market price of our common stock could decline significantly. We currently have on file with the SEC an effective shelf registration statement on Form S-3, which allows us to offer debt securities, preferred stock, common stock, non-voting common stock and certain other securities from time to time.

If in the future we issue shares of common stock or securities convertible into common stock, our stockholders would experience dilution and, as a result, the market price of our common stock may decline. We cannot predict the effect that future sales of our securities would have on the market price of our common stock. Additionally, our security holders may be further diluted by the exercise of the pre-funded warrants issued in December 2020 or by any issuance of our voting common stock issuable upon the conversion of issued and outstanding shares of our non-voting common stock.

Certain holders of our common stock (including common stock issuable upon conversion of our non-voting common stock) have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. In addition, we filed a registration statement on Form S-8 to register shares of our common stock reserved for future issuance under our equity compensation plans; shares registered under this Form S-8 will be available for sale in the public market subject to the satisfaction of applicable vesting arrangements and the exercise of such options and, in the case of our affiliates, the restrictions of Rule 144. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

We may from time to time raise additional capital through the sale of equity or convertible securities, including pursuant to an effective shelf registration statement. If we issue additional shares of common stock at a discount from the current trading price of our common stock, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock, common stock, or non-voting common stock.

If in the future we issue shares of common stock or securities convertible into common stock, our stockholders would experience dilution and, as a result, the market price of our common stock may decline. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock. Additionally, our stockholders may be further diluted by the exercise of the pre-funded warrants issued in December 2020 in connection with a financing (see Note 6– Stockholders' Equity to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information) and any issuance of our voting common stock issuable upon the conversion of shares of non-voting common stock currently outstanding.

Further, if we raise additional capital through the sale of equity or convertible securities, the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available at all, may involve fixed payment obligations or agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through partnerships, collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Environmental, social and governance matters may impact our business and reputation.

Companies are increasingly being judged by their performance on a variety of environmental, social and governance (ESG) matters, which are considered to contribute to the long-term sustainability of companies' performance.

A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. Topics considered in such assessments include, among others, the role of the company's board of directors in supervising various ESG issues and board diversity.

In addition, we anticipate higher levels of regulation, disclosure-related and otherwise, with respect to ESG matters in the future. For example, the SEC has adopted final rules regarding climate-related disclosures in public companies' periodic reporting, and compliance with these rules—including the implementation of necessary internal controls and reporting procedures—may lead to increased expenses and additional demands on our management and board of directors.

In light of this increased focus on ESG matters, there can be no certainty that we will manage such these matters successfully, or that we will successfully meet expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our condensed consolidated financial statements or identify other areas for further attention or improvement. We have identified deficiencies in the past which we have taken steps to address. However, our efforts to remediate previous deficiencies may not be effective or prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

In connection with our ongoing evaluations of internal controls over financial reporting, we have made, and may continue to make upgrades to our finance and accounting systems. If we are unable to accomplish these upgrades in a timely and effective manner, our ability to comply with the financial reporting requirements and other rules that apply to reporting companies could be adversely impacted. Any failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock.

As a public company, we are required to disclose material changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Additionally, we are required to include a formal management assessment of the effectiveness of our internal control over financial reporting in our periodic reports, and once we cease to be an emerging growth company, unless another exemption is available, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404.

To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and maintain a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and continue to implement a continuous reporting and improvement process for internal control over financial reporting.

An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. In addition, our independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2023, 2022 or 2021 in accordance with the provisions of the Sarbanes-Oxley Act. Had our independent registered public accounting firm performed such an evaluation, control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses. Undetected material weaknesses in our internal controls could lead to condensed consolidated financial statement restatements and require us to incur the expense of remediation.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to corporate governance standards.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” Our management and other personnel have devoted and will continue to devote a substantial amount of time and incur substantial expense in connection with compliance initiatives. For example, in anticipation of becoming a public company, we adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and adopted an insider trading policy. As a public company,

we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the related rules and regulations implemented by the SEC and Nasdaq, have and will continue to increase legal and financial compliance costs and make some compliance activities more time consuming. We cannot predict or estimate the amount of additional costs we may incur to respond to these requirements or the timing of such costs. We have invested and will continue to invest in resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of Nasdaq, a majority of our board of directors and each member of our audit committee must be an independent director. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common stock from Nasdaq.

We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our common stock less attractive if we choose to rely on these exemptions. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to use this extended transition period until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates. We will cease to be an emerging growth company on December 31, 2024.

We are also currently a "smaller reporting company" as defined in the Exchange Act. Smaller reporting companies may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including, among others, not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Additionally, as a smaller reporting company, we are only required to provide two years of audited financial statements in our SEC reports. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock held by non-affiliates equals or exceeds $250 million as of the prior June 30, or (2) our annual revenues equal or exceed $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates equals or exceeds $700 million as of the prior June 30.

If we take advantage of some or all of the reduced disclosure requirements available to emerging growth companies or smaller reporting companies, investors may find our common stock less attractive, which may result in a less active trading market for our common stock and greater stock price volatility.

We have never paid and do not anticipate paying cash dividends on our common stock, and accordingly, stockholders must rely on share appreciation for any return on their investment.

We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, capital appreciation, if any, will be the sole source of gain on any investment in our common stock for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- 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;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (the DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for certain claims as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty owed by any of our directors, stockholders, officers or other employees to us or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive forum provision will not apply to any causes of action arising under the Exchange Act or any successor thereto. Our amended and restated bylaws further provide that the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act against any person in connection with any offering of our securities. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that

it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in any action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

During the quarter ended June 30, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended				
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-39045	3.1	March 21, 2023
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1†	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2†	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibit 101)				

+ Indicates management contract or compensatory plan.

† The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

IGM Biosciences, Inc.

Date: August 14, 2024	By:	/s/ Fred Schwarzer Fred Schwarzer *Chief Executive Officer, President and Director* *(Principal Executive Officer)*
Date: August 14, 2024	By:	/s/ Misbah Tahir Misbah Tahir *Chief Financial Officer* *(Principal Financial Officer)*
Date: August 14, 2024	By:	/s/ Steven Weber Steven Weber *Senior Vice President, Corporate Controller* *(Principal Accounting Officer)*

Exhibit 3.1

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION OF
IGM BIOSCIENCES, INC.

IGM Biosciences, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify as follows:

A. The name of the Corporation is IGM Biosciences, Inc. The Corporation was originally incorporated pursuant to the General Corporation Law of the State of Delaware ("DGCL") on August 25, 1993 under the name Palingen, Inc. The name of the Corporation was changed on October 13, 2010 to IGM Biosciences, Inc.

B. This Amended and Restated Certificate of Incorporation (this "Amended and Restated Certificate of Incorporation") was duly adopted by the Board of Directors of the Corporation (the "Board of Directors") in accordance with Sections 242 and 245 of the DGCL, and has been duly approved by the written consent of the stockholders of the Corporation in accordance with Section 228 of the DGCL.

C. The text of the Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety to read as follows:

Article I

The name of the Corporation is IGM Biosciences, Inc.

Article II

The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

Article III

The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

Article IV

Section 1. This Corporation is authorized to issue two classes of stock, to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares of stock that the Corporation shall have authority to issue is One Billion Two Hundred Six Million Four Hundred Thirty-One Thousand Two Hundred Eight (1,206,431,208) shares, of which One Billion Six Million Four Hundred Thirty-One Thousand Two Hundred Eight (1,006,431,208) shares are Common Stock, $0.01 par value, and Two Hundred Million (200,000,000) shares are Preferred Stock, $0.01 par value. One Billion (1,000,000,000) shares of the Common Stock are hereby designated "Voting Common Stock" and Six Million Four Hundred Thirty-One Thousand Two Hundred Eight (6,431,208) shares of the Common Stock are hereby designated as "Non-Voting Common Stock," each with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Any reference to "Common Stock" issued by the Corporation in any contract, agreement or otherwise to which the Corporation is a party, whether before or after the date of filing of this Amended and Restated Certificate of Incorporation, shall refer to Voting Common Stock, unless specific reference is made to the Non-Voting Common Stock.

Section 2. Each share of Voting Common Stock shall entitle the holder thereof to one (1) vote on any matter submitted to a vote at a meeting of stockholders. Non-Voting Common Stock (i) shall be non-voting

except as may be required by law and (ii) shall not entitle the holder thereof to vote on the election of directors at any time.

Section 3. The Preferred Stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any wholly unissued series of Preferred Stock, including, without limitation, authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Amended and Restated Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the Corporation shall take all such steps as are necessary to cause the shares constituting such decrease to resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

Section 4. Except as otherwise required by law, holders of Voting Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

Section 5. Each holder of shares of Non-Voting Common Stock shall have the right to convert each share of Non-Voting Common Stock held by such holder into one (1) share of Voting Common Stock at such holder's election by providing written notice to the Corporation; provided, however, that such shares of Non-Voting Common Stock may only be converted into shares of Voting Common Stock during such time or times as immediately prior to or as a result of such conversion would not result in the holder(s) thereof beneficially owning (for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder (collectively, the "Exchange Act")), when aggregated with affiliates with whom such holder is required to aggregate beneficial ownership for purposes of Section 13(d) of the Exchange Act, in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" means initially 4.99% of the Voting Common Stock. Any holder of Non-Voting Common Stock may increase the Beneficial Ownership Limitation with respect to such holder upon 61 days' prior written notice to the Corporation and may decrease the Beneficial Ownership Limitation at any time upon providing written notice of such election to the Corporation; provided, however, that no holder may make such an election to change the percentage with respect to such holder unless all holders managed by the same investment advisor as such electing holder make the same election. The effectiveness of any conversion of any shares of Non-Voting Common Stock into shares of Voting Common Stock is subject to the expiration or early termination of any applicable premerger notification and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

Article V

Section 1. The number of directors that constitutes the entire Board of Directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation. At each annual meeting of stockholders, directors of the Corporation shall be elected to hold office until the expiration of the term for which they are elected and until their successors have been duly elected and qualified or until their earlier resignation or removal; except that if any such meeting shall not be so held, such election shall take place at a stockholders' meeting called and held in accordance with the DGCL.

Section 2. From and after the effectiveness of this Amended and Restated Certificate of Incorporation, the directors of the Corporation (other than any who may be elected by holders of Preferred Stock under specified circumstances) shall be divided into three classes as nearly equal in size as is practicable, hereby designated Class I, Class II and Class III. Directors already in office shall be assigned to each class at the time such classification becomes effective in accordance with a resolution or resolutions adopted by the Board of Directors. At the first annual meeting of stockholders following the date hereof, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following the date hereof, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following the date hereof, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting. If the number of directors is changed, any newly created directorships or decrease in directorships shall be so apportioned hereafter among the classes as to make all classes as nearly equal in number as is practicable, provided that no decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Article VI

Section 1. Any director or the entire Board of Directors may be removed from office at any time, but only for cause, and only by the affirmative vote of the holders of at least a majority of the voting power of the issued and outstanding capital stock of the Corporation entitled to vote in the election of directors.

Section 2. Except as otherwise provided for or fixed by or pursuant to the provisions herein in relation to the rights of the holders of Preferred Stock to elect directors under specified circumstances, newly created directorships resulting from any increase in the number of directors, created in accordance with the Bylaws of the Corporation, and any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other cause shall be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders. A person so elected by the Board of Directors to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen until his or her successor shall have been duly elected and qualified, or until such director's earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Article VII

Section 1. The Corporation is to have perpetual existence.

Section 2. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authority expressly conferred upon them by statute or by this Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

Section 3. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, alter, amend or repeal the Bylaws of the Corporation. The affirmative vote of at least a majority of the Board of Directors then in office shall be required in order for the Board of Directors to adopt, amend, alter or repeal the Corporation's Bylaws. The Corporation's Bylaws may also be adopted, amended, altered or repealed by the stockholders of the Corporation. Notwithstanding the above or any other provision of this Amended and Restated Certificate of Incorporation, the Bylaws of the Corporation may not be amended, altered or repealed except in accordance with Article X of the Bylaws. No Bylaw hereafter legally adopted, amended, altered or repealed shall invalidate any prior act of the directors or officers of the Corporation that would have been valid if such Bylaw had not been adopted, amended, altered or repealed.

Section 4. The election of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

Section 5. No stockholder will be permitted to cumulate votes at any election of directors.

Article VIII

Section 1. Any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

Section 2. Special meetings of stockholders of the Corporation may be called only by the Chairperson of the Board of Directors, the Chief Executive Officer, the President or the Board of Directors acting pursuant to a resolution adopted by a majority of the Board of Directors, and any power of stockholders to call a special meeting of stockholders is specifically denied. Only such business shall be considered at a special meeting of stockholders as shall have been stated in the notice for such meeting.

Section 3. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner and to the extent provided in the Bylaws of the Corporation.

Article IX

Section 1. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended from time to time, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Section 2. The Corporation shall indemnify, to the fullest extent permitted by applicable law, any director or officer of the Corporation who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a “Proceeding”) by reason of the fact that he or she is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding. The Corporation shall be required to indemnify a person in connection with a Proceeding initiated by such person only if the Proceeding was authorized by the Board of Directors.

Section 3. The Corporation shall have the power to indemnify, to the extent permitted by applicable law, any employee or agent of the Corporation who was or is a party or is threatened to be made a party to any Proceeding by reason of the fact that he or she is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding.

Section 4. Neither any amendment nor repeal of any Section of this Article IX, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation inconsistent with this Article IX, shall eliminate or reduce the effect of this Article IX in respect of any matter occurring, or any cause of action, suit, claim or proceeding accruing or arising or that, but for this Article IX, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

Article X

Meetings of stockholders may be held within or outside of the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept (subject to any provision contained in the statutes) outside of the

State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

Article XI

The Corporation reserves the right to amend or repeal any provision contained in this Amended and Restated Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; provided, however, that notwithstanding any other provision of this Amended and Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, the Board of Directors acting pursuant to a resolution adopted by a majority of the Board of Directors and the affirmative vote of sixty-six and two-thirds percent (66 2/3%) of the then outstanding voting securities of the Corporation, voting together as a single class (for clarification, the holders of Non-Voting Common Stock are not entitled to vote in the election of directors and should not be included in the calculation of such percentage of the voting power), shall be required for the amendment, repeal or modification of the provisions of Section 3 of Article IV, Section 2 of Article V, Article VI, Section 5 of Article VII, Article VIII or Article XI of this Amended and Restated Certificate of Incorporation.

IN WITNESS WHEREOF, IGM Biosciences, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by Fred Schwarzer, a duly authorized officer of the Corporation, on this 20th day of September, 2019.

By: /s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer and President

CERTIFICATE OF AMENDMENT TO
AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION OF
IGM BIOSCIENCES, INC.

IGM Biosciences, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

A. The name of the Corporation is IGM Biosciences, Inc. The Corporation was originally incorporated pursuant to the General Corporation Law of the State of Delaware ("DGCL") on August 25, 1993 under the name Palingen, Inc.

B. This Certificate of Amendment to the Amended and Restated Certificate of Incorporation (this "Certificate of Amendment") was duly adopted by the Board of Directors of the Corporation (the "Board of Directors") in accordance with Section 242 of the DGCL, and has been duly approved by the stockholders of the Corporation.

C. Section 1 of Article IV of the Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety to read as follows:

> "This Corporation is authorized to issue two classes of stock, to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares of stock that the Corporation shall have authority to issue is One Billion Four Hundred Million (1,400,000,000) shares, of which One Billion Two Hundred Million (1,200,000,000) shares are Common Stock, $0.01 par value, and Two Hundred Million (200,000,000) shares are Preferred Stock, $0.01 par value. One Billion (1,000,000,000) shares of the Common Stock are hereby designated "Voting Common Stock" and Two Hundred Million (200,000,000) shares of the Common Stock are hereby designated as "Non-Voting Common Stock," each with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Any reference to "Common Stock" issued by the Corporation in any contract, agreement or otherwise to which the Corporation is a party, whether before or after the date of filing of this Amended and Restated Certificate of Incorporation, shall refer to Voting Common Stock, unless specific reference is made to the Non-Voting Common Stock."

* * *

IN WITNESS WHEREOF, IGM Biosciences, Inc. has caused this Certificate of Amendment to be signed by Fred Schwarzer, a duly authorized officer of the Corporation, on this 25th day of June, 2021.

By: /s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer and President

CERTIFICATE OF AMENDMENT
TO THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
IGM BIOSCIENCES, INC.

IGM Biosciences, Inc., a corporation organized and existing under the laws of the State of Delaware (the "**Corporation**"), hereby certifies as follows:

1.The name of the Corporation is IGM Biosciences, Inc. The Corporation was originally incorporated pursuant to the General Corporation Law of the State of Delaware ("**DGCL**") on August 25, 1993 under the name Palingen, Inc. The name of the Corporation was changed on October 13, 2010 to IGM Biosciences, Inc.

2.This Certificate of Amendment to the Amended and Restated Certificate of Incorporation of IGM Biosciences, Inc. was duly adopted in accordance with Section 242 of the DGCL by the Board of Directors and the stockholders of the Corporation.

3.Section 1, Article IX of the Corporation's Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety to read as follows:

"Section 1. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended from time to time, a director or officer of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director or officer. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors or officers, then the liability of a director or officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended."

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by a duly authorized officer of the Corporation, on June 11, 2024.

By: /s/ Fred Schwarzer
Name: Fred Schwarzer
Title: Chief Executive Officer and President

Exhibit 31.1

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

I, Fred Schwarzer, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of IGM Biosciences, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

By: /s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Misbah Tahir, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of IGM Biosciences, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of IGM Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fred Schwarzer, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2024

By: /s/ Fred Schwarzer
Fred Schwarzer
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of IGM Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Misbah Tahir, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2024

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer
(Principal Financial Officer)