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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, 2023

or

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

For the transition period from to

Commission File Number: 001-40237

GAIN THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-1726310**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4800 Montgomery Lane, Suite 220 **Bethesda, Maryland**	**20814**
(Address of principal executive offices)	(Zip Code)

(301) 500-1556
(Registrant's telephone number, including area code)

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 $0.0001 per share	GANX	Nasdaq Stock Market LLC

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

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

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

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

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

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

As of July 31, 2023, the registrant had12,699,422 shares of common stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts and are often characterized by the use of words such as "aim", "believe," "can," "could," "potential," "plan," "predict," "goals," "seek," "should," "may," "may have," "would," "estimate," "continue," "anticipate," "intend," "expect" or the negative of these terms, other comparable terminology or by discussions of strategy, plans or intentions. These include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- the success of our efforts to expand our pipeline of product candidates and develop marketable products through the use of our in-licensed Site-Directed Enzyme Enhancement Therapy, or SEE-Tx®, platform;
- our ability to develop, obtain regulatory approval for and commercialize our current and future product candidates;
- our expectations regarding collaborations and other agreements with third parties and their potential benefits;
- the timing of investigational new drug, or IND, submissions, initiation of preclinical studies and clinical trials, and timing of expected clinical results for our product candidates;
- our success in early preclinical studies, which may not be indicative of results obtained in later studies or clinical trials;
- the potential benefits of our product candidates;
- our ability to identify patients with the diseases treated by our product candidates, and to enroll healthy volunteers and patients in clinical trials;
- our ability to obtain, maintain and protect our intellectual property;
- our reliance upon intellectual property licensed from third parties, including the license to use the SEE-Tx® platform;
- our ability to identify, recruit and retain key personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, including our anticipated cash runway;
- our financial performance;
- developments or projections relating to our competitors or our industry;
- the impact of laws and regulations;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- the impact of worsening macroeconomic conditions, including heightened global inflation, actions taken by central banks to counter inflation, liquidity concerns at and failures of banks and other financial

institutions, capital market instability, exchange rate fluctuations, supply chain disruptions and increases in commodity, energy and fuel prices;

- the impacts of pandemics or endemics including on our operations, access to capital, research and development and clinical trials and potential disruption in the operations and business of third-party manufacturers, contract research organizations, other service providers, and collaborators with whom we conduct business;
- the impact of other global events, including political instability, natural disaster, events of terrorism and wars, including the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China; and
- other factors and assumptions described in this Quarterly Report.

You should read this Quarterly Report with the understanding that such forward-looking statements involve known and unknown risks, expectations, uncertainties, assumptions, estimates and projections about our company and other important factors that could cause our actual results, performance or achievements, actual industry results, or other actual results or events to differ materially from historical results, from any plans, intentions, or expectations disclosed in such forward-looking statements or from any future results, performance, achievements or other events expressed, suggested or implied by such forward-looking statements. Therefore, you should not rely on any forward-looking information or statements as predictors of future results or events. Factors that could cause or contribute to such differences in results and events include, without limitation, those specifically addressed under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Conditions and Results of Operations” in this Quarterly Report and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (“Annual Report”) filed with the Securities and Exchange Commission (“SEC”) on March 23, 2023. The effect of these factors is difficult to predict. In addition, factors other than these could also adversely affect our results, and the reader should not consider these factors to be a complete set of all potential risks or uncertainties. New factors emerge from time to time, and management cannot assess the impact of any such factor on our business or the extent to which any factor, or combination of factors, may cause results or events to differ materially from those contained in any forward-looking statement.

Any forward-looking statements included herein speak only as of the date of this Quarterly Report, and we undertake no obligation to update any forward-looking information or statements for any reason after the date of this Quarterly Report to conform these statements to actual results or changes in expectations, except as required by law. All forward-looking statements attributable to us are expressly qualified by the foregoing cautionary statements.

Item 1. Financial Statements.

PART I—FINANCIAL INFORMATION

GAIN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,319,925	$ 7,311,611
Marketable securities - current	9,873,209	12,826,954
Tax credits	160,730	103,877
Prepaid expenses and other current assets	954,584	848,854
Total current assets	$ 17,308,448	$ 21,091,296
Non-current assets:		
Marketable securities - non current	$ —	$ 1,941,488
Property and equipment, net	138,556	144,379
Internal-use software	204,549	213,967
Operating lease - right of use assets	559,771	659,933
Restricted cash	31,816	30,818
Long-term deposits and other non-current assets	17,734	17,506
Total non-current assets	952,426	3,008,091
Total assets	$ 18,260,874	$ 24,099,387
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 924,390	$ 1,626,100
Operating lease liability - current	235,798	229,080
Other current liabilities	3,247,233	2,106,756
Deferred income - current	1,069,107	55,180
Loans - current	111,636	108,135
Total current liabilities	$ 5,588,164	$ 4,125,251
Non-current liabilities:		
Defined benefit pension plan	$ 174,185	$ 157,580
Operating lease liability - non-current	330,071	441,784
Deferred income - non-current	608,982	—
Loans - non-current	466,638	495,258
Total non-current liabilities	1,579,876	1,094,622
Total liabilities	$ 7,168,040	$ 5,219,873
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; nil shares issued and outstanding as of June 30, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value: 50,000,000 shares authorized; 12,632,327 issued and outstanding as of June 30, 2023; 11,883,368 issued and outstanding as of December 31, 2022.	1,263	1,189
Additional paid-in capital	62,298,733	57,358,895
Accumulated other comprehensive income	134,323	35,627
Accumulated deficit	(38,516,197)	(20,925,459)
Loss for the period	(12,825,288)	(17,590,738)
Total stockholders' equity	11,092,834	18,879,514
Total liabilities and stockholders' equity	$ 18,260,874	$ 24,099,387

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

GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration revenues	$ —	$ 95,102	$ 55,180	$ 132,640
Other income	—	—	—	7,468
Total revenues	$ —	$ 95,102	$ 55,180	$ 140,108
Operating expenses:				
Research and development	(3,987,943)	(2,582,224)	(6,779,148)	(4,138,664)
General and administrative	(3,743,171)	(2,689,263)	(6,236,930)	(4,466,306)
Total operating expenses	(7,731,114)	(5,271,487)	(13,016,078)	(8,604,970)
Loss from operations	$ (7,731,114)	$ (5,176,385)	$ (12,960,898)	$ (8,464,862)
Other income/(expense):				
Interest income, net	129,929	59,899	281,964	58,248
Foreign exchange gain/(loss), net	(60,195)	40,212	(103,037)	59,374
Loss before income tax	$ (7,661,380)	$ (5,076,274)	$ (12,781,971)	$ (8,347,240)
Income tax	(26,589)	(9,146)	(43,317)	(10,823)
Net loss	$ (7,687,969)	$ (5,085,420)	$ (12,825,288)	$ (8,358,063)
Net loss per shares:				
Net loss per share attributable to common stockholders - basic and diluted	$ (0.62)	$ (0.43)	$ (1.05)	$ (0.70)
Weighted average common shares - basic and diluted	12,387,089	11,883,368	12,157,969	11,883,368

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

GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (7,687,969)	$ (5,085,420)	$ (12,825,288)	$ (8,358,063)
Unrealized gain/(loss) on available-for-sale securities	(1,247)	5,104	42,015	5,104
Defined benefit pension plan	(700)	3,765	(1,370)	7,914
Foreign currency translation	39,960	(40,135)	58,051	(67,941)
Other comprehensive income/(loss)	38,013	(31,266)	98,696	(54,923)
Comprehensive loss	$ (7,649,956)	$ (5,116,686)	$ (12,726,592)	$ (8,412,986)

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

GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(unaudited)

	Common Stock		APIC	AOCI	Accumulated	Total
Six Months Ended June 30, 2023	**Shares**	**Amounts**			**Deficit**	
Balance as of December 31, 2022	**11,883,368**	**$ 1,189**	**$ 57,358,895**	**$ 35,627**	**$ (38,516,197)**	**$ 18,879,514**
Stock-based compensation (Note 14)	67,400	6	1,949,708	—	—	1,949,714
Issuance of shares in at-the-market (ATM) offering (Note 13)	681,559	68	2,990,130	—	—	2,990,198
Defined benefit pension plan (Note 10)		—	—	(1,370)	—	(1,370)
Foreign currency translation		—	—	58,051	—	58,051
Net unrealized gain on available for sale securities (Note 4)		—	—	42,015	—	42,015
Net loss		—	—	—	(12,825,288)	(12,825,288)
Balance as of June 30, 2023	**12,632,327**	**1,263**	**62,298,733**	**134,323**	**(51,341,485)**	**11,092,834**

	Common Stock		APIC	AOCI	Accumulated	Total
Three Months Ended June 30, 2023	**Shares**	**Amounts**			**Deficit**	
Balance as of March 31, 2023	**12,087,142**	**$ 1,209**	**$ 58,694,827**	**$ 96,310**	**$ (43,653,516)**	**$ 15,138,830**
Stock-based compensation (Note 14)	67,400	6	1,384,276	—	—	1,384,282
Issuance of shares in at-the-market (ATM) offering (Note 13)	477,785	48	2,219,630	—	—	2,219,678
Defined benefit pension plan (Note 10)		—	—	(700)	—	(700)
Foreign currency translation		—	—	39,960	—	39,960
Net unrealized loss on available for sale securities (Note 4)		—	—	(1,247)	—	(1,247)
Net loss		—	—	—	(7,687,969)	(7,687,969)
Balance as of June 30, 2023	**12,632,327**	**1,263**	**62,298,733**	**134,323**	**(51,341,485)**	**11,092,834**

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

GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(unaudited)

Six Months Ended June 30, 2022	Common Stock		APIC	AOCI	Accumulated	Total
	Shares	Amounts			Deficit	
Balance as of December 31, 2021	**11,883,368**	**$ 1,189**	**$ 55,832,461**	**$ (90,645)**	**$ (20,925,459)**	**$ 34,817,546**
Stock-based compensation		—	612,095	—	—	612,095
Defined benefit pension plan		—	—	7,914	—	7,914
Foreign currency translation		—	—	(67,941)	—	(67,941)
Net unrealized gain on available for sale securities		—	—	5,104	—	5,104
Net loss		—	—	—	(8,358,063)	(8,358,063)
Balance as of June 30, 2022	**11,883,368**	**1,189**	**56,444,556**	**(145,568)**	**(29,283,522)**	**27,016,655**

Three Months Ended June 30, 2022	Common Stock		APIC	AOCI	Accumulated	Total
	Shares	Amounts			Deficit	
Balance as of March 31, 2022	**11,883,368**	**$ 1,189**	**$ 56,139,006**	**$ (114,302)**	**$ (24,198,102)**	**$ 31,827,791**
Stock-based compensation		—	305,550	—	—	305,550
Defined benefit pension plan		—	—	3,765	—	3,765
Foreign currency translation		—	—	(40,135)	—	(40,135)
Net unrealized gain on available for sale securities		—	—	5,104	—	5,104
Net loss		—	—	—	(5,085,420)	(5,085,420)
Balance as of June 30, 2022	**11,883,368**	**1,189**	**56,444,556**	**(145,568)**	**(29,283,522)**	**27,016,655**

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

GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Operating activities:		
Net loss	$ (12,825,288)	$ (8,358,063)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	39,481	28,230
Stock-based compensation expense	1,796,640	612,095
Other non-cash items	(76,383)	(30,049)
Changes in operating assets and liabilities:		
Prepaid expenses and other currents assets	(151,210)	(868,292)
Other non-current assets	(4,688)	—
Accounts payable and other liabilities	379,722	1,232,968
Defined benefit pension plan	9,951	70,967
Deferred income	1,592,996	(186,306)
Total changes in operating assets and liabilities	1,826,771	249,337
Cash used in operating activities	(9,238,779)	(7,498,450)
Cash flows from investing activities:		
Purchase of property and equipment and internal use of software	(14,689)	(52,376)
Purchases of marketable securities	(1,956,350)	(14,844,856)
Maturity of marketable securities	7,123,125	—
Cash provided by/(used in) investing activities	5,152,086	(14,897,232)
Cash flows from financing activities:		
Net proceeds from issuance of shares in at-the-market (ATM) offering (Note 13)	2,990,130	—
Payments of current portion of long-term debt	(43,858)	(36,611)
Cash provided by/(used in) financing activities	$ 2,946,272	$ (36,611)
Effect of exchange rate changes	149,733	(143,875)
Net (decrease)/increase in cash, cash equivalents and restricted cash	$ (990,688)	$ (22,576,168)
Cash, cash equivalents and restricted cash at beginning of period	7,342,429	36,911,952
Cash, cash equivalents and restricted cash at end of period	$ 6,351,741	$ 14,335,784

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

GAIN THERAPEUTICS, INC.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Operations and Business

Gain Therapeutics, Inc. (together with its subsidiary, the "Company"), was incorporated under the laws of the state of Delaware (U.S.) on June 26, 2020. On July 20, 2020, the Company consummated a corporate reorganization, pursuant to which all of the issued and outstanding common and preferred stock of GT Gain Therapeutics SA, a Swiss company formed in 2017, were exchanged for common stock or preferred stock, as applicable, of Gain Therapeutics, Inc., reflecting a 10:1 stock split. The corporate reorganization was accounted for as a recapitalization for accounting purposes, resulting in GT Gain Therapeutics SA becoming the predecessor entity of the Company. As a result of the corporate reorganization, GT Gain Therapeutics SA became a wholly-owned subsidiary of Gain Therapeutics, Inc.

On March 17, 2021, the Company's registration statement on Form S-1 related to its Initial Public Offering ("IPO") was declared effective by the Securities and Exchange Commission ("SEC"). In conjunction with the IPO the Company completed a reverse stock split of the Company's outstanding equity instruments. The reverse stock split was approved by the stockholders on March 4, 2021 and became effective on March 17, 2021. Upon closing of the IPO, the Series A and the Series B Preferred Stock, as resulting from the reverse stock split, were converted to common stock at a ratio of 1-for-1.

The Company is a biotechnology company developing novel small molecule therapeutics to treat diseases across several therapeutic areas, including central nervous system ("CNS") disorders, lysosomal storage disorders ("LSDs"), metabolic disorders, and other diseases that can be targeted through protein degradation, such as oncology. The Company uses its exclusively in-licensed computational target and drug discovery platform, Site-Directed Enzyme Enhancement Therapy ("SEE-Tx®"), to discover novel allosteric binding sites on proteins implicated in a disease and to identify proprietary small molecules that bind these sites to modulate protein function and treat the underlying cause of the disease.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, risks associated with completion and success of preclinical studies and clinical testing, dependence on key personnel, protection of proprietary technology, compliance with applicable governmental regulations, development by competitors of new technological innovations, protection of proprietary technology and the ability to secure additional capital to fund operations. Drug candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Basis of Presentation

The accompanying unaudited interim condensed financial statements (the "interim financial statements") reflect the accounts of Gain Therapeutics, Inc., GT Gain Therapeutics SA and its wholly owned branch, Gain Therapeutics Sucursal en España. All intercompany transactions and balances have been eliminated in the preparation of the interim financial statements. The interim financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The interim financial statements have been prepared on the same basis as applied for the audited annual consolidated financial statements as of and for the year ended December 31, 2022, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2023, the results of its operations and its statements of stockholders' equity and its statements of cash flows for the periods ended June 30, 2023 and 2022.

The results for the periods ended June 30, 2023 and 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2022, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the "Annual Report").

The accompanying interim financial statements reflect the application of significant accounting policies as described below and elsewhere in these notes to the unaudited condensed consolidated financial statements. As of June 30, 2023, the Company's significant accounting policies and estimates, which are detailed in the Annual Report, have not changed.

Going Concern

At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company is required to make certain additional disclosures if it concludes substantial doubt exists about the Company's ability to continue as a going concern.

The Company has incurred recurring losses and negative cash flows from operations since its inception and has primarily funded these losses through the completion of its initial public offering ("IPO") in March 2021, other equity financings and research grants. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. Substantial additional capital will be needed by the Company to fund its operations and to develop its product candidates.

The Company's activities have consisted primarily of organizing and staffing the Company, expanding its operations, securing financing, acquiring, developing and securing its in-licensed technology, performing research and conducting preclinical studies. The Company faces risks associated with early-stage biotechnology companies whose product candidates are in development. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing, establishing manufacturing capacity and obtaining regulatory approval prior to commercialization. These efforts require significant amounts of additional capital for the Company to complete its research and development activities, achieve its research and development objectives, defend its intellectual property rights, and recruit and retain skilled personnel, and key members of management. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

The Company plans to seek additional funding through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding when and if needed, the Company could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects.

The Company's ability to continue operations after our current cash resources are exhausted depends on its ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. If adequate additional funds are not available when required, or if the Company is unsuccessful in entering into partnership agreements for further development of its pipeline, management may need to curtail the Company's development efforts and planned operations to conserve cash.

Management believes that the Company will be able to fund its operating expenses and capital expenditure requirements into the third quarter of 2024. The Company based this estimate on assumptions that may prove to be wrong, and the Company could exhaust the available capital resources sooner than expected.

In accordance with ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. As of the issuance date of these financial statements, the Company expects that its cash and cash equivalents will be sufficient to fund its forecasted operating expenses and capital expenditure requirements for at least the next twelve months from the issuance date of these financial statements.

Accordingly, the consolidated financial statements have been prepared assuming that the Company will continue as a going concern.

Segment information

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company's chief operating decision-maker, the Chief Executive Officer, oversees the Company's operations and manages the business as a single operating segment, which is research and development in the pharmaceutical sector with a focus on developing novel therapeutics to treat diseases caused by protein misfolding, such as rare genetic diseases and neurological disorders. Geographically, the research and development activities are mainly performed in Switzerland and Spain. The Company does not consider these geographies to be separate segments.

2. Summary of Significant Accounting Policies

Foreign Currency Transactions

The Company is incorporated in the United States of America and has operations in Switzerland and Spain. The Company's functional currency is U.S dollars (USD). The functional currencies of the Company's foreign operations are the local currencies (Swiss Franc in Switzerland and Euro in Spain). Assets and liabilities reported in the consolidated balance sheets are translated into USD (the currency in which these financial statements are presented) at the exchange rates applicable at the balance sheet dates and for the consolidated statement of operations at the average exchange rates for the periods presented. Items representing the share capital and additional paid-in capital are presented at the historical exchange rates. Adjustments resulting from the translation of the financial statements of the Company's foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income/(loss), a separate component of shareholders' equity. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure. As of June 30, 2023 and December 31, 2022, accumulated currency translation adjustment recorded in accumulated other comprehensive loss amounted to $216,628 and $158,576.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with US GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. On an ongoing basis, the Company evaluates its estimates, judgments and assumptions including those related to going concern assessment, recognition of accrued expenses, defined benefit pension liability, share-based compensation, and recognition of research grants. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable by management under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. Changes in estimates are recorded in the period in which they become known. To the extent that material differences arise between the estimates and actual results, the Company's future results of operations will be affected.

Cash and Cash Equivalents

The Company classifies cash on hand and held at banks, and all highly liquid investments in money market, certificates of deposit, time deposit, and other short-term liquid securities with original maturities of less than 90 days, as cash and cash equivalents.

Marketable Securities

The Company classifies marketable securities as held-to-maturity or available-for-sale at the time these instruments are purchased, based on the requirements of ASC 320.

Marketable securities are classified as available-for-sale since the Company does not have the positive intent and the capacity to hold the marketable securities until the maturity date. Available-for-sale marketable securities are carried out at fair value with the "unrealized gains/loss" excluded from the computation of the earnings of the period and accounted for in other comprehensive loss. The accretion of discounts (or amortization of premiums) are accounted for in the Company's statements of operations as financial income (or expense).

Marketable securities are classified in the Company's balance sheet based on their maturities and the Company's reasonable expectations with regard to those securities. Marketable securities with a maturity date within 12 months from reporting date are classified as "current assets". Marketable securities with a maturity date over 12 months from reporting date are classified as "non-current assets".

Concentrations of Credit Risk

The Company has no significant off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that may expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents which are deposited in accredited financial institutions in excess of federally insured limits. The Company deposits its cash and cash equivalents in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Deferred Issuance Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred issuance costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction of the proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred issuance costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations.

Property and Equipment

Property and equipment are stated at cost, including any accessory and direct costs that are necessary to make the assets fit for use, and adjusted by the corresponding accumulated depreciation. The depreciation expenses are recorded using the straight-line method in the consolidated financial statements of operations and have been calculated by taking into consideration the use, purpose and financial-technical duration of the assets, on the basis of their estimated useful economic lives. The Company believes the above criteria to be represented by the following depreciation rates:

- Equipment & Furniture	12.5%
- Electronic office equipment:	20%
- Leasehold Improvements:	based on the terms of the lease
- Laboratory equipment:	15%

Ordinary maintenance costs are entirely attributed to the consolidated statements of operations in the year in which they are incurred. Extraordinary maintenance costs, the purpose of which is to extend the useful economic life of the asset, to technologically upgrade it and/or to increase its productivity or safety for the purposes of the economic productivity of the Company, are attributed to the asset to which they refer and depreciated on the basis of its estimated useful economic lives. Amortization of leasehold improvements is computed using the straight-line method based upon the terms of the applicable lease or estimated useful life of the improvements, whichever is lower.

Capitalized Software Development Costs

The Company capitalizes the costs of software obtained for internal use in accordance with ASC 350-40, Internal-Use Software. Capitalized software development costs consist of costs incurred during the development stage and include purchased software licenses, implementation costs, consulting costs, and payroll-related costs for projects that qualify for capitalization. All other costs, primarily related to maintenance and minor software fixes, are expensed as incurred. As of June 30, 2023 and December 31, 2022, internal-use software amount to $205 thousand and $214 thousand, respectively, and refer to the external and internal costs incurred in the development of the Company's enterprise resource planning system.

The Company amortizes the capitalized software development costs on a straight-line basis over the estimated useful life of the software, which is generally six years, beginning when the asset is substantially ready for use. The amortization of capitalized software development costs is reflected in general and administrative expenses. Amortization expense for the periods ended June 30, 2023 and 2022 was $21 thousand and $15 thousand, respectively.

Impairment of Long-lived Assets

In accordance with ASC Topic 360-10-20, "Property, Plant and Equipment," the Company performs an impairment test whenever events or circumstances indicate that the carrying value of long-lived assets with finite lives may be impaired. Impairment is measured by comparing the carrying value of the long-lived assets to the estimated undiscounted pre-tax cash flows expected to result from the use of such assets and their ultimate disposition. In circumstances where impairment is determined to exist, the Company will write down the asset to its fair value based on the present value of estimated cash flows. No impairments have been identified by management as of and for any periods presented.

Patents

Patent-related costs, refer to legal fees incurred in connection with filing and prosecuting patent applications and are expensed as incurred due to uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Leases

The Company determines if an arrangement contains a lease at inception based on whether or not the Company has the right to control the asset during the contract period and other facts and circumstances as per ASC 842. Operating lease right of use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease, both of which are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. Leases with a term of 12 months or less at inception are expensed on a straight-line basis over the lease term in the consolidated statement of operations. The Company determines the lease term by assuming the exercise of renewal options that are reasonably certain.

Accounts Payable

Accounts payable are reported at their nominal amounts due to their short-term maturities. Trade accounts payable are recorded net of trade discounts; cash discounts are recorded at the time of payment.

Payables for Social Security Charges

Social security charges are reported in compliance with rules and laws applicable in the countries where Company employees work. Charges are accrued in accordance with the policies stipulated and in connection with salaries due for the period.

Accrued Expenses

As part of the process of preparing the Company's consolidated financial statements, the Company is required to estimate its accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with the Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The Company makes estimates of its accrued expenses as of each balance sheet date based on facts and circumstances known at the time of the preparation of its consolidated financial statements. There may be instances in which payments made to the Company's vendors exceed the level of services provided, and result in a prepayment reported under other current assets, which is subsequently expensed in the consolidated statement of operations when the related activity has been performed. To date, there have been no material differences between the Company's estimates of accrued expenses reported at each balance sheet date and the amounts actually incurred.

Pension Obligations

The Company operates defined benefit pension plan and defined contribution pension plans in accordance with local regulations and practices in the countries in which the Company operates. These plans are funded by regular contributions made by the Company and its employees. For the defined benefit pension plan, the liability recognized in the consolidated balance sheets is the present value of the defined benefit obligation at the balance sheet date less the fair value of plan assets. The overfunded or underfunded status of the defined benefit plan is calculated as the difference between plan assets and the projected benefit obligations. Estimates are used in determining the assumptions incorporated in the calculation of the pension obligations, which is supported by input from independent actuaries. Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized in the consolidated statements of equity under accumulated other comprehensive income (loss), and are charged or credited to income over the employees' expected average remaining working lives. The measurement date used for the Company's employees defined benefit plan is December 31.

For defined contribution pension plans, the Company pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Company has no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expense when they are due.

Stock-based Compensation and Warrants

The Company issues stock-based compensation with service-based, performance-based and market-based vesting conditions. The Company applies the fair value method of measuring equity-based compensation and warrants, which requires an entity to measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. The Company recognizes the corresponding expense in the statement of operations over the period the participants are required to render service. Forfeitures are recognized as they occur.

The fair value of each stock option award is estimated on the grant date using the Black-Scholes option pricing model. The Company determines the volatility and the expected term for awards granted based on an analysis of reported data for a peer group of similar biopharmaceutical companies. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be nil.

The Company recognizes expenses related to Restricted Stock Units (or RSUs) based on their fair market value, determined as the closing price on Nasdaq of the Company's common stock as of the grant date, on a straight-line basis over the requisite service period. For Restricted Stock Units with market or performance -based vesting conditions (or PRSUs), the fair value at grant date is calculated using an option-pricing model (Monte Carlo Simulation) or based on management's assessment of the likelihood of concurrence of the underlying performance, respectively.

The Black-Scholes option pricing model is also used for the warrants issued, using consistent inputs and methodology to quantify such inputs, as described above in relation to equity-based compensation.

The assumptions used in calculating the fair value of share-based awards and warrants represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Revenue Recognition

The Company derives limited revenue from its collaboration and licensing agreements. The Company recognizes revenue related to these agreements in accordance with ASC 606, "*Revenues from Contracts with Customers"* and ASC 808, " *Collaborative Arrangements"*. The terms of these arrangements typically include payment from third-party customers of one or more of the following: non-refundable initiation fee, reimbursement of development costs, future development and regulatory milestone payments and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations, the Company applies the five-step model of ASC606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. If a contract is determined to be within the scope of ASC 606 at inception, the Company assesses the goods or services promised within such contract, determines which of those goods and services are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Costs and revenues associated with collaborative arrangements are reported in the consolidated statements of operations on a gross basis when the counterpart is identified as being a customer, when the performance obligations incurred and rendered to fulfil the agreements are deemed to be in the ordinary course of the Company's business, or when there is an expectation that the collaborative arrangement will result in a future constant flow of revenues in the form of sales of products, royalties or licenses.

Research grants

Under the terms of the research and development grants awarded, the Company is entitled to receive reimbursement of its allowable direct expenses and payroll costs. Contributions from research and development activities under the grants are recorded based on management's best estimate of the periods in which the related expenditures are incurred and activities performed and are classified in the consolidated statement of operations as a reduction to research and development expenses.

Research and Development Expenses

The Company expenses all costs incurred in performing research and development activities. Research and development expenses include salaries and other related costs, materials and supplies, preclinical expenses, manufacturing expenses, contract services and other third-party expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, for personnel and consultants in the Company's executive, administrative and finance functions. General and administrative expenses also include professional fees for legal, finance, accounting, intellectual property, auditing, tax and consulting services, travel expenses and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs not otherwise included in research and development expenses.

Income taxes

The Company accounts for income taxes under the liability method. Under this method deferred income tax liabilities and assets are determined based on the difference between the financial statements carrying amounts of assets and liabilities and the related tax basis using enacted tax rates in effect in the years in which the associated deferred taxes are expected to reverse. A valuation allowance is recorded if it is "more likely than not" that a portion or all of a deferred tax asset will not be realized.

As of each reporting date, the Company considers existing evidence, both positive and negative, that could impact its view with regard to future realization of deferred tax assets. In consideration of the start-up status of the Company, a full valuation allowance has been established to offset the deferred tax assets, as the related realization is currently uncertain. In the future, should management conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance will be reduced to the extent of such expected realization, and the corresponding amount will be recognized as income tax benefit in the Company's consolidated statement of operations.

Fair value measurement

The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies the following fair value hierarchy, which prioritizes the inputs used to measure fair value into three levels based on their observability in the market and degree of judgment involved:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, 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 – Inputs that are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability.

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 and consider counterparty credit risk in their assessment of fair value.

Comprehensive income/(loss)

Comprehensive income/(loss) is composed of net income/(loss) and certain changes in stockholder's equity that are excluded from the net income/(loss), primarily foreign currency translation adjustments, defined benefit obligation adjustments and unrealized income/(loss) on available for sale securities.

Net Loss per Share

Basic net loss per share is computed by dividing the reported net loss by the weighted average number of shares of common stock outstanding during the period. The Company gives consideration to all potentially dilutive impacts, except where the effect of including such securities would be antidilutive. As of June 30, 2023 and December 31, 2022 common stock equivalents consisted of stock options, RSUs, PRSUs and warrants. Because the Company has reported net

losses since inception, these potential impacts would be anti-dilutive, and therefore, common stock equivalents have been excluded from the computation, resulting in basic and diluted net loss per share being the same for all periods presented.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. There were no new accounting pronouncements effective in 2023 with a material impact on the Company's consolidated financial statements.

3. Cash, cash equivalents and restricted cash

The Company considers all short-term, highly liquid investments, with an original maturity of three months or less, to be cash equivalents. The Company's cash and cash equivalents include short-term highly liquid investments which are readily convertible into cash and relate to money market securities. The Company's institutional money market accounts permit daily redemption and the fair values of these investments are based upon the quoted prices in active markets provided by the holding financial institutions, which are considered Level 1 inputs in the fair value hierarchy. Given their short-term maturities and the underlying value being mainly represented by cash equivalents, their face value amount approximates the related fair market value.

The Company has not experienced any losses in these accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Cash, cash equivalents and restricted cash are broken down as follows:

	June 30, 2023	December 31, 2022
Cash	3,553,451	2,910,446
Money market	2,766,474	4,401,165
Total cash and cash equivalents	$ 6,319,925	$ 7,311,611
Restricted cash	$ 31,816	$ 30,818

Restricted cash refers to an amount required under the Company's office lease agreement in Lugano and deposited into a restricted bank account as a guarantee.

4. Marketable Securities

As of June 30, 2023, the Company reports $9.9 million of marketable securities within current assets, related to United States Treasury Securities ("USTS"). The USTS purchased have maturity dates ranging from July 2023 to April 2024, on a monthly basis, in tranches of $1.0 million each month. The Company classifies the USTS, which are accounted for as available-for-sale, within the Level 1 fair value hierarchy as the fair value is based on quoted market prices in active markets with a high level of daily trading volume.

The following table summarizes the Company's investment in available-for-sale marketable securities with the detail of the unrealized gains /losses and the estimated fair value as of June 30, 2023:

	June 30, 2023				
	Amortized Cost	Allowance for Credit Losses	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities available for sale					
Debt Securities - U.S. government treasury securities, current	9,925,473	—	—	(52,264)	9,873,209
Totals	**$ 9,925,473**	**$ —**	**$ —**	**$ (52,264)**	**$ 9,873,209**

As of June 30, 2023, the Company did not intend to sell any of the debt securities included in the table above, and it is not more likely than not that the Company will be required to sell any of these securities before recovery of the unrealized losses, which will be at maturity. Unrealized losses on available-for-sale debt securities as of June 30, 2023 were primarily due to changes in interest rates, and not due to increased credit risks associated with specific securities. Accordingly, as of June 30, 2023, the Company has not recorded an allowance for credit losses related to its available-for-sale debt securities.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2023	December 31, 2022
Tax credits	160,730	103,877
Prepaid and deferred expenses	506,583	552,882
Other receivables	—	87,430
Prepaid D&O insurance costs	448,001	208,542
Total prepaid expenses and other current assets	$ 954,584	$ 848,854

Tax credits consist of a value added tax credit ("VAT"), which is an indirect tax receivable from Swiss and Spanish tax authorities on purchases of goods and services executed in those countries.

Prepaid expenses refers to pre-payments made to the Company's vendors for future services. Deferred expenses mainly refer to research agreements entered into with third parties for research projects that will be recognized as expenses throughout the research period.

Prepaid D&O insurance costs relate to an annual insurance premium which will be recognized in the statement of operations on a monthly basis throughout the one-year insurance period.

6. Property and Equipment, net

Property and equipment, net consisted of the following：

	June 30, 2023	December 31, 2022
Computer	$ 81,244	$ 71,774
Furniture and fixtures	59,324	57,603
Leasehold improvements	32,343	31,437
Laboratory instruments	37,578	36,894
Total property and equipment	$ 210,489	$ 197,708
Less: accumulated depreciation	(71,933)	(53,329)
Property and equipment, net	$ 138,556	$ 144,379

Property and equipment consist of computers, furniture and fixtures, lab instruments. No disposals, nor impairments occurred during the periods. Depreciation has been calculated by taking into consideration the use, purpose and financial-technical duration of the assets, based on their estimated economic lives. Depreciation expense for the six months ended June 30, 2023 and 2022 was $17,139 and $11,504, respectively.

7. Operating Lease; Right of Use ("ROU") Assets

The Company's leased assets include offices in Bethesda, Maryland, Lugano, Switzerland and Barcelona, Spain and a lab in Barcelona, Spain. The current lease portfolio consists of leases with remaining terms ranging from three to five years. Renewal options are excluded from the calculation of lease liabilities since the Company is not reasonably

certain that will exercise the renewal option. The Company's lease agreements do not contain residual value guarantees or material restrictive covenants.

The breakdown of the significant components of ROU assets, lease liabilities and operating lease expense is reported in the table below, together with the discount rate used in order to calculate the net present value of the lease liabilities as of those periods.

	June 30, 2023	December 31, 2022
Operating Lease		
Operating lease- right of use assets	$ 559,771	$ 659,933
Operating lease liability - current	$ 235,798	$ 229,080
Operating lease liability - non-current	$ 330,071	$ 441,784
Weighted average remaining lease term - years	2.68	3.05
Weighted average discount rate	1.52	1.53

The operating lease expenses were as follows:

	June 30, 2023	June 30, 2022
Operating lease costs	$ 122,127	$ 112,466

The future minimum lease payments for the Company's operating leases as of June 30, 2023, are as follows:

Fiscal Year	Operating Leases
June 30, 2024	247,945
June 30, 2025	192,032
June 30, 2026	125,134
June 30, 2027	11,779
Total future minimum lease payments	576,890
Less amount representing interest or imputed interest	11,021
Present value of lease liabilities	$ 565,869

8. Accounts Payable

Accounts payable refer to amounts due to third parties on outstanding invoices received for services already provided. As of June 30, 2023 and December 31, 2022, accounts payable amounted to $0.9 million and $1.6 million, respectively. All accounts payable are due in less than 12 months.

9. Other Current Liabilities and Deferred Income

Other current liabilities and deferred income consist of the following as of June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Payable for social security and withholding taxes	$ 592,670	$ 256,798
Accrued payroll	715,990	660,556
Accrued expenses	1,753,880	1,082,091
Tax provision	184,693	107,311
Total other current liabilities	$ 3,247,233	$ 2,106,756
Deferred income	1,678,089	55,180
Total other current liabilities and deferred income	$ 4,925,322	$ 2,161,936

Accrued payroll refers to accruals for year-end bonuses, accrued vacations and overtime to be paid to employees.

Accrued expenses refer to invoices to be received from vendors for services performed and not yet billed.

Deferred income refers to the upfront payment that the Company has received in the second quarter of 2023 after the successful application regarding Research and Development Grants with Innosuisse.

Tax provision refers to a tax payable due to the Spanish Tax Authorities related to taxable income generated in Spain.

10. Pension Obligations

Net pension obligation related to the Company's defined pension plan refers only to Swiss employees and as of June 30, 2023 and December 31, 2022, can be summarized as follows:

	June 30, 2023	December 31, 2022
Reconciliation of funded status:		
Funded status beginning of period	$ (157,580)	$ (329,458)
Expense	(73,523)	(179,924)
Employer contribution	64,014	123,193
Translation differences	(5,726)	1,478
Change in accumulated other comprehensive income	(1,370)	227,131
Funded status at end of period	$ (174,185)	$ (157,580)
Component of net periodic pension costs:		
Service cost	$ 71,187	$ 169,709
Interest cost	9,487	3,376
Expected return on plan assets	(5,805)	(9,000)
Amortization of (gain)/losses	—	16,753
Amortization of prior service cost	(1,346)	(914)
Total	$ 73,523	$ 179,924

Service cost is reported in general and administrative expenses. All other components of net period costs are reported in interest income, net in the consolidated statement of operations.

11. Loans

In August 2020, the Company obtained a CHF 638,000 ($700,221 at the historical foreign exchange rate) nine-year loan. The loan has zero interest and is due in quarterly installments of CHF 20,000, with payments commencing on December 31, 2021 and ending on September 30, 2029. The loan is part of the infrastructure put in place by the Federal Council and Swiss Parliament in view of the economic consequences of the COVID-19 pandemic, and the loan issued under the program does not bear interest and there are no applicable issuance costs. The Company accounts for its loan at face value, which is deemed to approximate the related fair value.

The future payments under the loan are reported in the table below:

		June, 30					
	Total	2024	2025	2026	2027	2028	Thereafter
Loan	$ 578,274	111,636	89,309	89,309	89,309	89,309	109,402

12. Fair Value Measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The carrying amounts of the Company's cash and cash equivalents, including money market funds, restricted cash and financial liabilities are considered to be representative of their respective fair values because of the short-term nature and the contractual terms of those instruments. The fair values of money market funds are based upon the quoted prices in active markets provided by the holding financial institution, which are considered Level 1 inputs in the fair value hierarchy according to ASC 820. There have been no changes to the valuation methods utilized by the Company, nor were there transfers between levels of the fair value hierarchy.

	Fair value measurement at reporting date		
	Quoted prices in active market for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
June 30, 2023:			
Assets			
Marketable securities available for sale			
Debt securities - U.S. government treasury securities, current	9,873,209	—	—
Debt securities - U.S. government treasury securities, non-current	—	—	—
Total marketable securities available for sale	$ 9,873,209	—	—
Cash equivalents:			
Money market funds	2,766,474	—	—
Total cash equivalents	$ 2,766,474	—	—
Total financial assets	$ 12,639,683	—	—
December 31, 2022:			
Assets			
Marketable securities available for sale			
Debt securities - U.S. government treasury securities, current	12,826,954	—	—
Debt securities - U.S. government treasury securities, non-current	1,941,488	—	—
Total marketable securities available for sale	$ 14,768,442	—	—
Cash equivalents:			
Money market funds	4,401,165	—	—
Total cash equivalents	$ 4,401,165	—	—
Total financial assets	$ 19,169,607	—	—

The carrying amounts of prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value due to their short-term maturities.

13. Common and Preferred Stock

As of June 30, 2023 and December 31, 2022, the authorized capital stock of the Company included 50,000,000 shares of common stock, $0.0001 par value and 10,000,000 shares of preferred stock, $0.0001 par value. As of June 30, 2023 and December 31, 2022, there were 12,632,327 and 11,883,368 shares of common stock respectively, $0.0001 par value, issued and outstanding.

In May 2022, the Company entered into a Controlled Equity Offering SM Sales Agreement with Cantor Fitzgerald, Inc. ("Cantor"), pursuant to which the Company was able to sell from time to time, through the Agent, shares of common stock, having an aggregate offering price of up to $16.0 million (the "ATM Program"). Sales under the ATM Program are made by any method permitted by law that is deemed to be an "at the market" offering as defined in Rule 415 issued under the Securities Act, including, without limitation, sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Company's common stock, through a market maker or as otherwise agreed by the Company and Cantor. During the six months ended June 30, 2023, the Company sold an aggregate of 681,559 shares of common stock under the ATM Program at an average selling price of $ 4.86 per share for aggregate gross proceeds of $3.3 million (of which $0.3 million reflect sales commissions and other offering expenses).

14. Equity Incentive Plans

On September 24, 2020, the Board adopted the 2020 Omnibus Incentive Plan (the "2020 Omnibus Plan"). The 2020 Omnibus Plan provided for the granting of equity-based awards to our named executive officers, other employees, consultants and non-employee directors at a price to be determined by the Company's Board. The maximum number of shares to be issued under the 2020 Omnibus Plan was 1,153,827.

On December 23, 2021, the Board adopted the Inducement Equity Incentive Plan (the "2021 Inducement Equity Incentive Plan") intended to induce new employees to join the Company for the benefit of individuals who satisfy the standards for inducement grants under Rule 5635(c)(4) of the Nasdaq Listing Rules. The maximum number of shares reserved for issuance pursuant to awards granted under the 2021 Inducement Equity Incentive Plan is 1,000,000.

The Company's 2022 Equity Incentive Plan (the "2022 Plan") was approved by the Board on May 12, 2022. On June 16, 2022, at the Company's annual meeting of stockholders, the Company's stockholders approved the 2022 Plan. The 2022 Plan is the successor to and continuation of the 2020 Omnibus Plan. The number of newly authorized shares reserved for issuance under the 2022 Equity Incentive Plan was 646,173, and the total number of shares initially reserved for issuance under the 2022 Plan (including shares remaining available under the 2020 Omnibus Plan) is 1,800,000.

On January 1, 2023, the number of shares of common stock issued under the 2022 Plan, increased automatically by 6% or 713,002, based on the number of shares of common stock issued and outstanding as of December 31, 2022. Following such increase, the number of shares of common stock that may be issued under the 2022 Plan totaled 2,513,002.

No incentive stock options may be granted under the 2022 Plan after May 12, 2032 and the Board may suspend or terminate the 2022 Plan at any time. The Board is responsible for administering the 2022 Plan.

Stock Option Grants

The following table summarizes the Company's stock option activity for the six months ended June 30, 2023:

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price
Options outstanding as of December 31, 2022	1,879,662	$ 2.94	$ 4.42
Options granted	721,851	3.40	4.81
Options exercised	—	—	—
Options cancelled/forfeited	(1,762)	2.42	3.38
Options outstanding as of June 30, 2023	2,599,751	$ 3.06	$ 4.53

The assumptions that the Company used to determine the grant-date fair value of stock options granted during the periods ended June 30, 2023 and 2022 were as follows, presented on a weighted-average basis:

	Six Months Ended June 30,	
	2023	2022
Grant date fair value	$ 3.40	$ 2.88
Volatility	77 %	80 %
Expected term (years)	6.60	7.00
Risk-free interest rate	3.49	3.14
Expected dividend yield	—	—

Each of these inputs is subjective and generally requires significant judgment to determine.

Restricted Stock Units and Performance Restricted Stock Units

The following table summarizes the Company's RSUs and PRSUs activity for the six months ended June 30, 2023:

	Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2022	303,050	$ 1.18
Granted	362,500	4.41
Vested	(67,400)	4.37
Cancelled/forfeited	—	—
Outstanding as of June 30, 2023	598,150	$ 2.78

In December 2021, the Compensation Committee of the Board approved 200,000 awards of performance-based restricted stock units ("PRSUs") to an executive officer of the Company, subject to vesting on the achievement of certain services, business development and clinical development performance criteria. The grant date fair value for these PRSUs award was determined to be nil under ASC 718 based upon a determination that as of the grant date, it was not probable that the performance conditions will be achieved. The Company evaluates the performance targets in the context of its business development plan and product candidates' development pipeline and recognized compensation expense based on the probable number of PRSUs that will ultimately vest. The potential fair value for the PRSU award, based on achieving the maximum level of performance under the award as of the grant date, was calculated to be $1.1 million, using the closing price of the Company's common stock at grant date.

In April 2023, the Compensation Committee of the Board approved 100,000 awards of performance-based restricted stock units ("PRSUs") to an executive officer of the Company, subject to vesting on the achievement of certain

services, financing and business development performance and market criteria. The grant date fair value for the PRSUs with financing and business development performance was determined based on the closing price of the Company's common stock at grant date and for the PRSUs with market condition, through an option-pricing model (Monte Carlo Simulation).

Options, RSUs and PRSUs do not have voting rights and the underlying shares are not considered issued and outstanding.

The total stock-based compensation expense for stock options, RSUs and PRSUs, granted to employees and non-employees, has been reported in the Company's consolidated statements of operations as follows:

	Three Months Ended June 30		Six Months Ended June 30	
	2023	2022	2023	2022
Research and development	244,393	149,175	409,758	263,293
General and administrative	1,080,099	156,375	1,478,208	348,802
Total stock-based compensation	$ 1,324,492	$ 305,550	$ 1,887,966	$ 612,095

15. Warrants

In July 2020, in connection with a private placement, the Company issued equity-classified warrants to placement agent designees. After a reverse stock split in March 2021, the aggregate number of outstanding warrants totaled 237,249 shares with an exercise price of $5.07 per share, valued in the aggregate at $413,887. The warrants vested immediately upon issuance, provide for a cashless exercise right and are exercisable for a period of five years until July 20, 2025.

On May 6, 2021, the Company entered into an investment banking services and financial advisory agreement and issued equity-classified warrants to investment bank designees to purchase an aggregate of 200,000 shares of the Company common stock at an exercise price of $ 13.75 per share, valued in the aggregate at $1.0 million. The warrants vested immediately upon issuance, do not provide cashless exercise right and are exercisable for a period of four years from May 6, 2021. The fair value of the warrants was fully recognized on a straight-line basis over the service period as general and administrative expense. As of June 30, 2023, no warrants have been exercised or exchanged.

16. Collaboration Agreement

On April 20, 2021, the Company entered into a multi-target collaboration agreement (the "Zentalis Collaboration Agreement") with Zentalis to discover new product candidates for the treatment of cancer. Under the terms of the Zentalis Collaboration Agreement, the Company will use its in-licensed SEE-Tx® computational platform technology to identify binding sites on target proteins and determine the potential suitability of these sites as drug targets, as well as their prospective therapeutic use in oncology. Pursuant to the terms of the Zentalis Collaboration Agreement, Zentalis agreed to pay the Company, on a program-by-program basis, a non-creditable, non-refundable, program initiation fee and reimbursement of expenses incurred by the Company in accordance with the agreed-upon research budget for each target in a multi-target agreement with a maximum of five mutually agreed to targets at the option of Zentalis. The collaboration between the Company and Zentalis has been concluded.

17. Net loss per common share

Basic net loss per common share is computed by dividing the net loss available to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding during the period. For purposes of the diluted net loss per share calculation, preferred stock, warrants, stock options and RSUs are considered to be potentially dilutive securities,

but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore basic and diluted net loss per share are the same for all periods presented.

The following table sets forth the outstanding weighted-average potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would have resulted in anti-dilutive impacts:

	Three Months Ended June 30		Six Months Ended June 30	
	2023	2022	2023	2022
Options to purchase common stock	2,515,314	1,191,403	2,222,188	1,076,448
RSUs, PRSUs	607,514	200,000	464,631	200,000
Warrants to purchase common stock	425,387	425,387	425,387	425,387

18. Related Parties

Dr. Khalid Islam, the Chairman of the Company's Board, shareholder and founder of the Company, is currently the Chairman of the Board of Directors of Minoryx Therapeutics SL ("Minoryx"), and therefore, Minoryx is considered a related party of the Company. In December 2017, the Company entered into an exclusive worldwide, royalty-bearing, assignable, transferable license agreement with Minoryx to use and exploit Minoryx's intellectual property and into an exclusive worldwide, royalty-bearing, assignable, transferable sublicense agreement with Universitat de Barcelona and Institucio Catalana Recerca Estudis Avancats in order to be able to develop its business, directly or indirectly, through sub-licensing to third parties or any other way of operation. According to the terms and conditions of the Minoryx License Agreement, the Company shall pay to Minoryx as royalties:

- an amount equal to 8% of (i) net revenues with regard to products that would infringe (a) at least one composition of matter claim or (b) Minoryx molecules and (ii) sublicensing revenues; and
- an amount equal to 3% of net revenues with regard to products that would infringe at least (a) one method of claim; or (b) Minoryx know-how (as such term is defined in the agreement).

As of June 30, 2023 and December 31, 2022, there were no receivables and payables, revenues or expenses with Minoryx.

19. Commitments

As of June 30, 2023, the Company had research commitments for $ 2.1 million for activities that will be performed before the end of Q2 2024.

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

You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited interim condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report and the audited financial statements and related notes and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2022 included in our Annual Report. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and belief. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A, below.

Overview

We are a biotechnology company developing novel small molecule therapeutics to treat diseases across several therapeutic areas, including central nervous system ("CNS") disorders, lysosomal storage disorders ("LSDs"), metabolic disorders, and oncology. We use our exclusively in-licensed computational target and drug discovery platform, Site-Directed Enzyme Enhancement Therapy ("SEE-Tx®"), to discover novel allosteric binding sites on proteins implicated in a disease and to identify proprietary small molecules that bind these sites to modulate protein function and treat the underlying cause of the disease. We believe that SEE-Tx® is uniquely suited to identify allosteric binding sites on the protein surface, which are different from the protein's active (or orthosteric) binding site where the natural ligand of the protein binds. Targeting an allosteric binding site instead of the active binding site of a protein provides numerous advantages, including: the ability to restore or disrupt the function of proteins implicated in disease through several different mechanisms of action covering both functional and conformational effects, including stabilization, destabilization, targeted degradation, allosteric inhibition, and allosteric activation of the targeted protein; improved specificity of small molecules because binding to an allosteric binding site is non-competitive with the natural substrate that binds to the active binding site; and the ability to identify small molecules with more favorable drug-like properties. The SEE-Tx® platform has been used to identify novel allosteric sites and small molecules for all of our pipeline programs. Discovering and targeting novel allosteric sites with our platform not only reduces traditional drug discovery timelines but enables rational drug design and offers the potential for superior small molecule drugs that are highly specific and that can penetrate hard to reach tissues and cross the blood-brain barrier where necessary.

We have generated an extensive preclinical data package providing evidence of the mechanism of action and effect of our lead product candidate GT-02287 for the treatment of GBA1 Parkinson's disease, including restoration of GCase function, reduction of toxic lipid substrates and toxic forms of alpha-synuclein, improved survival of dopaminergic neurons, increased dopamine levels and improved locomotor function in animal models. We plan to present results of additional in vivo studies in Parkinson's disease models at scientific conferences in 2023. In July, we submitted the application to conduct a Phase 1 clinical trial in Australia and expect to initiate that study in the second half of 2023. The Phase 1 clinical trial will evaluate the administration of both single and multiple ascending dose levels of GT-02287 in healthy volunteers to assess safety and pharmacokinetics.

In addition, we plan to continue to advance research programs and initiate additional programs targeting allosteric binding sites identified with the SEE-Tx® platform in various therapeutic areas, mainly oncology. Through academic partnerships, co-development and licensing arrangements, we intend to develop a broad pipeline of therapeutics, using our novel approach of identifying and targeting previously unknown allosteric sites.

In response to the current financing environment, we continue to streamline our operational plans to become more capital efficient and remain opportunistic in the pursuit of partnering opportunities for our pipeline programs, including our lead program in Parkinson's disease and our lysosomal storage disease programs, and of drug discovery collaborations applying our computational SEE-Tx® drug discovery platform to protein targets of interest to collaboration partners. In addition, we expect to continue to develop our alpha-1 antitrypsin deficiency program and our oncology programs while seeking non-dilutive funding in order to continue or progress our other research programs.

We continue to monitor the impacts on our operations and access to financing of global and worsening macroeconomic conditions, such as the war in Ukraine, global geopolitical tension, heightened inflation and rising interest rates, exchange rate fluctuations, supply chain disruptions, liquidity concerns at and failures of banks and other financial institutions and increases in commodity, energy and fuel prices.

Financial Condition

Since our inception in 2017, we have devoted substantially all of our resources to identify and develop next-generation brain-penetrant allosteric small molecules for the treatment of devastating diseases with high-unmet medical needs using our in-licensed SEE-Tx® platform. Our operations have consisted primarily of organizing and staffing the Company, expanding its operations, securing financing, performing research, conducting preclinical studies and acquiring, developing and securing our in-licensed technology. To date, we do not have any product candidates approved for sale and have not generated any revenue from product sales, and as a result, we face risks associated with early-stage biotechnology companies whose product candidates are in development. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. We expect our research and development expenses to remain significant and to increase to support progress in our research and development activities. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. These efforts require significant amounts of additional capital for us to complete our research and development, achieve our research and development objectives, defend our intellectual property rights, and recruit and retain skilled personnel, and key members of management. Even if our product development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

In March 2021, we completed our initial public offering (IPO) of approximately 4.1 million shares of our common stock at a price of $11.00 per share, including approximately 0.5 million shares in connection with the full exercise of the underwriters' option to purchase additional shares, resulting in net proceeds of approximately $40.5 million, net of the underwriting discounts and commissions and other expenses. From inception through June 30, 2023, we have raised an aggregate of $63 million of gross proceeds through equity financings, including the issuance of convertible preferred stock, our IPO and sales under our ATM Program.

As of June 30, 2023, we had cash, cash equivalents and marketable securities of $16.2 million. We have incurred recurring losses and negative cash flows from operations since inception and as of June 30, 2023 and December 31, 2022, had an accumulated deficit of $51.3 million and $38.5 million, respectively. We anticipate incurring additional losses until such time, if ever, that we can generate sales of our product candidates currently in development. We have not generated any product revenues and have not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, we will need significant additional financing to fund our operations and to develop our product candidates. Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our pipeline, management may need to curtail our development efforts and planned operations to conserve cash.

Financing Requirements; Current Financing Environment

Until such time, if ever, as we can generate substantial product revenues to support our business and corporate strategy, we expect to finance our cash needs through a combination of public and private equity offerings, including the ATM Program, debt financings, government or private party grants, collaborations, strategic alliances and licensing arrangements. We may not be able to obtain financing on acceptable terms, or at all, and we may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect our holdings or the rights of our stockholders. If we are unable to obtain funding, we could be required to delay, limit, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves, which could adversely affect our business prospects.

The war in Ukraine, global geopolitical tension, and the post COVID-19 environment continue to have unpredictable impacts on global societies, economies, financial markets, and business practices. Recently worsening global macroeconomic conditions, including actions taken by central banks to counter inflation, liquidity concerns at and failures of banks and other financial institutions, volatility in the capital markets, and related market uncertainty, may impact our ability to obtain additional financing when needed on favorable terms or at all. For additional discussion of our financing requirements, see "—Liquidity and Capital Resources" and "—Funding Requirements" below.

Strategic Transactions; Collaboration and Licensing Agreements

In connection with our business development activities, we enter into collaboration and licensing arrangements with third parties, to use our licensed SEE-Tx® computational platform technology to discover novel allosteric sites on misfolded proteins and identify proprietary small molecules that bind these sites, potentially restoring protein folding and treating disease. We expect to continue to identify and evaluate collaboration, co-development and licensing opportunities that may be similar to or different from the collaboration and licenses arrangements that we have entered into.

Components of Our Consolidated Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval and successfully commercialize them, we will not generate revenues in the future. Historically, we have received limited collaboration revenue pursuant to the Zentalis collaboration agreement.

Total Operating Expenses

Our operating expenses since inception have consisted solely of research and development and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, which include:

- expenses incurred under collaborations with third parties, including contract research organizations ("CROs") and Universities, that conduct research and preclinical studies, such as in-vitro and in-vivo absorption, distribution, metabolism and excretion ("ADME"), cell model studies, in-vivo pharmacology and pharmacokinetic studies, toxicology studies and chemical synthesis, stability studies, manufacturing and control materials, process characterization, scale-up and transfer, on our behalf;

- employee salaries, benefits and other related costs, including share-based compensation expenses, for employees engaged in research and development functions and overhead allocations consisting of various

support and facilities-related expenses, which include rent, utilities and maintenance of our facilities, depreciation, travel and conference expenses;

- fees paid to consultants who assist with research and development activities and related travel expenses; and
- the cost of sponsored research, which includes laboratory materials and supplies, manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical studies.

The following table provides a breakdown of our research and development expenses by major category:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Preclinical activities and outside services	2,670,956 $	1,721,954 $	4,347,660 $	2,516,250 $
Personnel expenses	1,122,292	816,258	2,102,868	1,543,212
Other	252,433	77,439	386,358	147,338
Research grants	(57,738)	(33,427)	(57,738)	(68,136)
Total research and development expenses	3,987,943 $	2,582,224 $	6,779,148 $	4,138,664 $

We recognize research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses. We anticipate that our research and development expenses will increase substantially in future periods to support progress in our research and development activities, including the commencement of the clinical trials for product candidates we are developing. These increases will likely also result from increased headcount, expanded infrastructure and increased insurance costs. Such expenses are offset by contributions from research grants, which are recorded as a reduction to research and development expenses based on our best estimate of the periods in which the related expenditures are incurred and activities performed.

Our primary research and development focus since inception has been the application of our in-licensed SEE-Tx® platform to various indications and targets. We are using our platform to generate a broad pipeline of product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will continue to increase in the foreseeable future as we (i) increase personnel costs, including stock-based compensation, (ii) continue preclinical development of our lead compounds, (iii) initiate clinical trials for certain product candidates, (iv) continue to discover and develop additional product candidates, and (v) pursue later stages of clinical development of product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, bonus and other related costs, including share-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel expenses, and facility-related expenses, and other operating costs.

We anticipate that our general and administrative expenses will increase in the future, in the form of additional compensation, including salaries, benefits, incentive arrangements and share-based compensation awards, as we increase our headcount to support the expected growth, attract and retain additional personnel and the potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs.

Other Financial Income (Expense)

Other financial income (expense) consists of interest income, interest expense and foreign exchange gain or loss, net.

Consolidated Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2023 and 2022.

	Three Months Ended June 30,			Six Months Ended June 30,		
	2023	2022	Increase (Decrease)	2023	2022	Increase (Decrease)
Revenues:						
Collaboration agreements	—	95,102	(95,102)	55,180	132,640	(77,460)
Other income	—	—	—	—	7,468	(7,468)
Total revenues	$ —	$ 95,102	$ (95,102)	$ 55,180	$ 140,108	$ (84,928)
Operating expenses:						
Research and development	(3,987,943)	(2,582,224)	1,405,719	(6,779,148)	(4,138,664)	2,640,484
General and administrative	(3,743,171)	(2,689,263)	1,053,908	(6,236,930)	(4,466,306)	1,770,624
Total operating expenses	(7,731,114)	(5,271,487)	2,459,627	(13,016,078)	(8,604,970)	4,411,108
Loss from operations	$ (7,731,114)	$ (5,176,385)	$ 2,554,729	$ (12,960,898)	$ (8,464,862)	$ 4,496,036
Interest income, net	129,929	59,899	70,030	281,964	58,248	223,716
Foreign exchange gain/(loss), net	(60,195)	40,212	(100,407)	(103,037)	59,374	(162,411)
Loss before income tax	$ (7,661,380)	$ (5,076,274)	$ 2,585,106	$ (12,781,971)	$ (8,347,240)	$ 4,434,731
Income tax	(26,589)	(9,146)	17,443	(43,317)	(10,823)	32,494
Net loss	$ (7,687,969)	$ (5,085,420)	$ 2,602,549	$ (12,825,288)	$ (8,358,063)	$ 4,467,225
Net loss per ordinary share:						
Basic and diluted loss per share	(0.62)	(0.43)	0.19	(1.05)	(0.70)	0.35
Weighted-average ordinary shares used in per share calculations – basic and diluted	12,387,089	11,883,368		12,157,969	11,883,368	

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

Revenues

For the three months ended June 30, 2023 and 2022, total revenues were nil and $95 thousand, respectively, and consisted mainly of income from the Zentalis Collaboration Agreement.

Research and Development Expenses

Research and development expenses increased by $1.4 million to $4.0 million for the three months ended June 30, 2023 as compared to $2.6 million for the three months ended June 30, 2022. The increase in research and development expenses for the three months ended June 30, 2023 was primarily attributable to an increase in third party services related to research and development of our Parkinson's disease program.

General and Administrative Expenses

General and administrative expenses increased by $1.0 million to $3.7 million for the three months ended June 30, 2023 as compared to $2.7 million for the three months ended June 30, 2022. The increase in general and administrative expenses for the three months ended June 30, 2023 was primarily attributable to an increase in legal fees relating to intellectual property and general corporate matters, professional fees for accounting services and increases in personnel-related costs.

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

Revenues

For the six months ended June 30, 2023 and 2022, total revenues were $55 thousand and $140 thousand, respectively, and consisted mainly of income from the Zentalis Collaboration Agreement.

Research and Development Expenses

Research and development expenses increased by $2.7 million to $6.8 million for the six months ended June 30, 2023 as compared to $4.1 million for the six months ended June 30, 2022. The increase in research and development expenses for the six months ended June 30, 2023 was primarily attributable to an increase in third party services related to research and development of our Parkinson's disease program.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million to $6.2 million for the six months ended June 30, 2023 as compared to $4.5 million for the six months ended June 30, 2022. The increase in general and administrative expenses for the six months ended June 30, 2023 was primarily attributable to an increase in legal fees relating to intellectual property and general corporate matters, professional fees for accounting services and increases in personnel-related costs.

Interest income, net

Interest income, net increased by $0.2 million to $0.3 million for the six months ended June 30, 2023 as compared to $0.1 million for the six months ended June 30, 2022. The increase in interest income, net is mainly attributable to interest income derived from our investment in available for sale treasury securities.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We have not yet received approval for or commercialized any products or technologies, and we do not expect to generate revenue from sales of any products in the near term, if at all. As described in additional detail under "Financial Condition" above, we have funded our operations to date primarily through a combination of sales of our securities and research grants.

As of June 30, 2023, and December 31, 2022, we had $16.2 million and $22.1 million in cash and cash equivalents and marketable securities, respectively, and an accumulated deficit of $51.3 million and $38.5 million, respectively. We

had indebtedness of $0.58 million and $0.60 million as of June 30, 2023 and December 31, 2022, respectively. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements. Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our pipeline, management may need to curtail our development efforts and planned operations to conserve cash.

In May 2022, we filed a shelf registration statement on Form S-3, which covers the offering, issuance and sale of up to a maximum aggregate offering price of $100.0 million of any combination of our common stock, preferred stock, debt securities and/or warrants from time to time in one or more offerings (the “Shelf Registration Statement”). We are currently subject to General Instruction I.B.6 to Form S-3 (the “Baby Shelf Rule”), and the amount of funds we can raise through primary public offerings of securities in any twelve-month period using our Shelf Registration Statement is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We will be limited by the Baby Shelf Rule until such time as our public float exceeds $75.0 million.

In May 2022, we entered into a Controlled Equity Offering ^{SM} Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $16.0 million from time to time through or to Cantor, acting as our agent or principal, in a series of one or more at-the-market equity offerings, which we refer to as our ATM Program. Cantor is not required to sell any specific amount but acts as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. Shares sold pursuant to the Sales Agreement are sold pursuant to the Shelf Registration Statement and count towards the limit of the Baby Shelf Rule. Our common stock is sold at prevailing market prices at the time of sale, and as a result, prices may vary. During the six months ended June 30, 2023, we sold an aggregate of 681,559 shares of common stock at an average price of $4.86 per share, raising gross proceeds of $3.3 million, which includes $0.3 million in sales and commissions and other offering expenses. We have approximately $12.7 million of remaining capacity under the ATM Program as of June 30, 2023.

Until such time, if ever, as we can generate substantial product revenues to support our business and corporate strategy, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, government or private party grants, collaborations, strategic alliances, licensing arrangements as well as via the ATM Program. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. We may not be able to obtain additional funds through equity or debt financings when needed on favorable terms or at all, including as a result of rising interest rates, liquidity concerns at, and failures of, banks and other financial institutions, volatility in the capital markets and related market uncertainty. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Six Months Ended June 30,	
	2023	2022
Cash used in operating activities	$ (9,238,779)	$ (7,498,450)
Cash (used in)/provided by investing activities	5,152,086	(14,897,232)
Cash (used in)/provided by financing activities	2,946,272	(36,611)
Net (decrease)/increase in cash, cash equivalents and restricted cash	$ (990,688)	$ (22,576,168)

Cash Flows from Operating Activities

During the six months ended June 30, 2023 and 2022, we used $9.2 million and $7.5 million of cash, respectively, in operating activities, primarily to fund our operations related to the development of our pipeline and product candidates as well as related general and administrative support activities.

Cash Flows from Investing Activities

During the six months ended June 30, 2023, net cash provided by investing activities was $5.0 million primarily due to maturity of marketable securities for $7.2 million partially offset by the purchase of marketable securities for $2.0 million.

During the six months ended June 30, 2022, net cash used in investing activities was $15 million, primarily due to purchases of marketable securities.

Cash Flows from Financing Activities

During the six months ended June 30, 2023, cash provided by financing activities was approximately $3.0 million mainly related to the ATM Program.

During the six months ended June 30, 2022, cash used in financing activities was approximately $40 thousand, related to the payments of current portion of long-term debt.

Funding Requirements

Our primary use of cash is to fund our operating expenses, which consist of research and development and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;

- the extent to which we encounter increased costs as a result of global and macroeconomic conditions, including heightened inflation and rising interest rates, supply chain disruptions, fluctuating exchange rates, and increases in commodity, energy and fuel prices ;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- our ability to establish additional collaborations on favorable terms, if at all;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We will need additional funding to meet our operational needs and capital requirements for our preclinical studies and clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with the development of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, government or private party grants, collaborations, strategic alliances and licensing arrangements. We may not be able to obtain additional funds through equity or debt financings when needed on favorable terms or at all. See "Financing Requirements; Current Financing Environment" and "Liquidity and Capital Resources".

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, defined benefit pension liability, share-based compensation and recognition of research grants. Our actual results may differ from these estimates under different assumptions or conditions. During the six months ended June 30, 2023, there were no material changes to our critical accounting policies. For additional information, see Item 8 of Part II, "Financial Statements and Supplementary Data — Note 2 — Summary of Significant Accounting Policies" of our Annual Report and Item 1 of Part I, "Financial Statements — Note 2 — Summary of Significant Accounting Policies," of this Quarterly Report. Although we believe that our estimates, assumptions, and judgments are reasonable, they are based upon information presently available. Actual results may differ significantly from these estimates under different assumptions, judgments, or conditions.

JOBS Act

We qualify as an "emerging growth company", as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to report only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial conditions and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements 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. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. As a result, the information we provide might be different from the information that is available for other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and the market price of our common stock may be more volatile.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.07 billion or more, (ii) December 31, 2026, (iii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years or (iv) the date on which we are deemed a "large accelerated filer" under the rules of the SEC with at least $700 million of outstanding equity securities held by non-affiliates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Under SEC rules and regulations, because we are a "smaller reporting company", we are not required to provide the information required by this item in this Quarterly Report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute

assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

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, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the following risks and other information included or incorporated by reference in this Quarterly Report in evaluating us and our Common Stock. Any of the following risks could materially and adversely affect our results of operations, our financial condition, and the market price of our Common Stock. Although the risk factors are grouped by general category, many of the risks described in a given category relate to multiple categories. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. See "Cautionary Statement Regarding Forward-Looking Statements" in this Quarterly Report. If any of these risks actually materialize, our business, prospects, financial condition and results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Risk Factor Summary

We are providing the following summary of the risk factors contained in this Quarterly Report to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Quarterly Report in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- we have a history of operating losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability;
- we have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance;
- if preclinical studies or clinical trials for our product candidates cannot be initiated or completed or if they are delayed or unsuccessful, we will be unable to meet our future development and commercialization goals;
- the disorders we seek to treat have low prevalence and it may be difficult to identify patients with these disorders, which may lead to delays in enrollment for our trials or slower commercial revenue if approved, and we may also face enrollment challenges as a result of other factors;
- our product candidates are novel and still in development. If we are unable to successfully develop, receive regulatory approval for and commercialize our current or future product candidates, our business will be harmed;
- we have not tested any of our product candidates in clinical trials. Success in early preclinical studies or clinical trials may not be indicative of results obtained in later preclinical studies and clinical trials;
- clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain;
- we will need to raise additional capital, which may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates, and additional capital may not be available

on favorable terms or at all, which may force us to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations;

- we are subject to extensive and costly government regulation;
- even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market;
- we rely on a license to use the technology that is material to our business and if the agreement underlying the license were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition;
- we are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, (including calss claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse business consequences; and
- global and macroeconomic conditions, including worldwide economic, political and social instability could adversely affect our revenue, financial condition, or results of operations.

Risks Related to Our Business

We have a history of operating losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability.

We are focused on product development, and we have not generated any significant revenues to date. We have incurred losses in each year of our operations, and we expect to continue to incur operating losses for the foreseeable future. These operating losses have adversely affected and are likely to continue to adversely affect our working capital, total assets and shareholders' equity.

We and our prospects should be examined in light of the risks and difficulties frequently encountered by new and early-stage companies in new and rapidly evolving markets. These risks include, among other things, the speed at which we can scale up operations, our complete dependence upon development of our product candidates that currently have no market acceptance, our ability to establish and expand our brand name, our ability to expand our operations to meet the commercial demand of our clients, our development of and reliance on strategic and customer relationships and our ability to minimize fraud and other security risks.

The process of developing our product candidates requires significant time, effort and expenses in preclinical, clinical and regulatory development. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical studies and clinical trial activities increase. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will continue to increase in the foreseeable future as we (i) increase personnel costs, including stock-based compensation, (ii) continue preclinical development of our lead compounds, (iii) initiate clinical trials for certain product candidates, (iv) continue to discover and develop additional product candidates, and (v) pursue later stages of clinical development of product candidates.

The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the foreseeable future, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of preclinical development and testing and clinical trials of our product candidates; obtaining necessary regulatory approvals from the FDA and comparable foreign regulatory authorities; establishing manufacturing, sales and marketing arrangements with third parties;

successfully commercializing our products; establishing a favorable competitive position; and raising sufficient funds to finance our activities. Many of these factors will depend on circumstances beyond our control. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects and results of operations may be materially adversely affected.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a preclinical stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to organizing and staffing our company, expanding its operations, performing research, acquiring, developing and securing our in-licensed technology and preclinical development of our product candidates. We have not yet begun or successfully completed any clinical trials, completed Investigational New Drug ("IND") enabling or Good Laboratory Practice ("GLP") compliant studies for any of our product candidates, manufactured our products candidates at clinical or commercial scale or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include, among other factors described elsewhere in this Quarterly Report:

- our ability to obtain additional funding to develop our product candidates, the extent to which we are able to obtain such funding on favorable terms, and changes to our operations or strategy that may be necessitated due to the need for additional funding;
- our ability to conduct and complete preclinical studies, including GLP-compliant and IND-enabling preclinical studies;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our preclinical studies and clinical trials through all phases of development;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions;
- our ability to successfully commercialize product candidates for which we obtain regulatory approval, within expected timelines or at all;
- potential toxicity and/or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies ("REMS"), or comparable foreign strategies, or cause an approved drug to be taken off the market;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- market acceptance of our product candidates;
- competition from existing products, new products or new therapeutic approaches that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;

- our ability to leverage our in-licensed technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- the impact of political instability, natural disasters, events of terrorism and wars, including Russia's invasion of Ukraine;
- the impact of other global and macroeconomic conditions, including heightened inflation and rising interest rates, liquidity concerns at and failures of banks and other financial institutions, supply chain disruptions, fluctuating exchange rates, and increases in commodity, energy and fuel prices; and
- potential product liability claims.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We may conduct certain of our clinical trials for our product candidates outside of the U.S. which, among other risks, exposes us to the possibility that the FDA and other comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We expect to complete the preclinical development and submit the regulatory dossier to the Human Research Ethics Committee in Australia to initiate a first-in-human Phase 1 clinical trial in our Parkinson's disease program. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. For studies that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates conducted outside of the United States, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and

- diminished protection of intellectual property in some countries.

By extension, clinical trials that are predominantly conducted in the United States or primarily based on feedback from the FDA may not result in sufficiently diverse patient populations to warrant approval in other countries (for example, Japan) or those other comparable foreign regulatory authorities may have differences of opinion on appropriateness of trial design or differences in interpretation of some data. In those situations, approvals in other countries outside the United States may be delayed or never approved, which would materially detract from the commercial success of any impacted product candidates.

If preclinical studies or clinical trials for our product candidates cannot be initiated or completed or if they are delayed or unsuccessful, we will be unable to meet our future development and commercialization goals.

We rely and expect to continue to rely on third parties, including contract research organizations ("CROs") and outside consultants, to conduct, supervise or monitor some or all aspects of preclinical studies and clinical trials involving our product candidates. We have less control over the timing and other aspects of these preclinical studies and clinical trials than if we performed the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our preclinical studies and clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in preclinical studies and clinical trials could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and study sites;
- developing a stable formulation of a product candidate;
- manufacturing sufficient quantities of a product candidate; and
- obtaining institutional review board ("IRB") approval or ethic committee opinions to conduct a clinical trial at a prospective site.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other comparable foreign regulatory authorities due to a number of factors, including:

- ongoing discussions with the FDA or other comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated recruitment or retention rate of patients in clinical trials;
- inspection of the clinical trial operations or study sites by the FDA or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials;
- negative results of clinical trials;
- investigational drug product out-of-specification; or

- nonclinical or clinical safety observations, including adverse events and SAEs.

If clinical trials are unsuccessful, and we are not able to obtain regulatory approvals for our product candidates under development, we will not be able to commercialize these products, and therefore may not be able to generate sufficient revenues to support our business.

The disorders we seek to treat have low prevalence and it may be difficult to identify patients with these disorders, which may lead to delays in enrollment for our trials or slower commercial revenue if approved, and we may also face enrollment challenges as a result of other factors.

Genetically defined disorders generally, and especially those for which our current product candidates are targeted, have low incidence and prevalence. We expect to rely in part on relationships with clinical centers of excellence, key opinion leaders and patient advocacy groups to assist in identifying eligible patients, and any deterioration of those relationships could impede our ability to successfully enroll patients. Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- design of the study protocol;
- the eligibility criteria for the trial;
- the perceived risks, benefits and convenience of administration of the product candidate being studied;
- our efforts to facilitate timely enrollment in clinical trials;
- the availability of other clinical trials being conducted for the same indication;
- the patient referral practices of physicians; and
- the proximity and availability of clinical trial sites to prospective patients.

Our inability to enroll a sufficient number of patients with these diseases for our future clinical trials would result in significant delays and could require us to not initiate or to abandon clinical trials for one or more indications altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Additionally, the reported number of people in the indication we aim to treat, as well as the people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, the final approved product labeling for each of our product candidates, if our product candidates are approved for sale in our target indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients globally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Our product candidates are novel and still in development. If we are unable to successfully develop, receive regulatory approval for and commercialize our current or future product candidates, our business will be harmed.

Because the SEE-Tx® platform remains untested and our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. Our product candidates will require significant additional development, preclinical and IND-enabling studies and clinical trials, regulatory clearances and additional investment by us or our collaborators before they can be commercialized. Our drug development methods may not lead to commercially

viable drugs for any of several reasons. For example, we may fail to identify appropriate targets or compounds, our product candidates may fail to be safe and effective in clinical trials, or we may have inadequate financial or other resources to pursue development efforts for our product candidates. Also, third parties we rely on for preclinical development, such as the providers of supercomputer time needed for our SEE-Tx® platform and collaborators that provide us with materials and resources may fail to fulfill their obligations to us in a timely manner or at all and the development of our product candidates could be significantly delayed as a result. In addition, we are still developing proof of concept for our product candidates in animals and positive data from animal models may not be predictive of positive human results and patients may have side effects that were not observed in animals.

Further, we and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. Obtaining FDA and comparable foreign regulatory authority approval is a lengthy, expensive and uncertain process. If required regulatory registrations or approvals are delayed, denied, withdrawn, suspended or varied or if the regulatory authorities question the efficacy of our new small molecules as a treatment, such events are likely to have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

We have not tested any of our product candidates in clinical trials. Success in early preclinical studies or clinical trials may not be indicative of results obtained in later preclinical studies and clinical trials.

We have not tested any of our product candidates in clinical trials. Success in early preclinical studies or any clinical trials we may conduct not be indicative of results obtained in later preclinical studies and clinical trials.

We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Trial designs and results from early-phase trials are not necessarily predictive of future clinical trial designs or results, and initial positive results we may observe may not be confirmed in later-phase clinical trials. Our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development even if they successfully advance through initial clinical trials. We may not be able to demonstrate the safety and efficacy of our STAR molecules in our clinical trials. Even if our clinical trials demonstrate acceptable safety and efficacy of STAR molecules for a targeted disease, the labeling we obtain through negotiations with the FDA or comparable foreign regulatory authorities may not include data on secondary endpoints and may not provide us with a competitive advantage over other products approved for the same or similar indications.

Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and there is a high failure rate for product candidates proceeding through clinical trials. We may face similar setbacks or failures. Different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways. Accordingly, the FDA or comparable foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval. If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld, varied or withdrawn. Regulatory delays or rejections may also be encountered as a result of many other factors, including changes in regulatory policy during the period of product development.

The approach we are taking to discover and develop our product candidates is novel and may never lead to marketable products.

We have concentrated our efforts and research and development activities on our novel small molecules for potential treatment of rare and genetic diseases caused by protein misfolding and SEE-Tx®, our target identification platform. Our future success depends on the successful development of such product candidates, including our ability to

successfully complete IND-enabling and GLP-compliant preclinical studies, and the effectiveness of our platform. The scientific discoveries that form the basis for our efforts to discover and develop new drugs are relatively new. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. Skepticism as to the feasibility of developing small molecules of this type that can cross the blood-brain barrier generally has been, and may continue to be, expressed in scientific literature. In addition, decisions by other companies with respect to their therapeutic development efforts may increase skepticism in the marketplace regarding the potential for potential therapeutics. There are currently no companies with approved drugs for these indications that have the ability to cross the blood-brain barrier.

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

Because we have limited financial and human resources, we are currently focusing primarily on development of our Parkinson's and Gaucher disease programs. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

To obtain FDA or comparable foreign regulatory authority approval to market a new pharmaceutical product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct “adequate and well controlled” clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per study. Delays in clinical trials for our product candidates may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: inability to manufacture sufficient quantities of stable and qualified materials under current good manufacturing practices (“cGMPs”) for use in clinical trials; slower than expected rates of patient recruitment; failure to recruit a sufficient number of patients, which is a common issue in studies for rare disorders such as the indications we are currently pursuing; modification of clinical trial protocols; changes in regulatory requirements for clinical trials; the lack of effectiveness during clinical trials; the emergence of unforeseen safety issues; delays, suspension, or termination of the clinical trials due to the investigatory authority responsible for overseeing the trial at a particular trial site; and government or regulatory delays or “clinical holds” requiring suspension or termination of the studies.

Our clinical trials may be conducted in patients with neurodegenerative diseases, and in some cases, our product candidates are expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our product candidates. Any safety issues that arise with respect to our product candidates may delay or prevent clinical development.

The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates that use a similar therapeutic approach. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay our ability to obtain regulatory approvals for and commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations.

We have limited experience as a company conducting clinical trials and may be unable to complete pivotal clinical trials for any product candidates we may develop.

We are not yet a clinical stage company and our success is dependent upon our ability to initiate and successfully complete clinical trials and obtain regulatory approval for and commercialization of our product candidates. We have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidate. The successful commercialization of any product candidate may require us to perform a variety of functions, including:

- continuing to undertake preclinical development;
- obtaining approval to commence clinical trials;
- successfully planning and enrolling subjects in clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

We have limited experience designing, conducting and enrolling subjects in clinical trials. While certain members of our management and staff have significant experience in conducting clinical trials, to date, we have not successfully begun or completed any clinical trials as a company. Until recently, our operations have been limited primarily to organizing and staffing our company, expanding its operations, performing research, acquiring, developing and securing our in-licensed technology and preclinical development of our product candidates. These operations provide a limited basis to assess our ability to develop and commercialize our product candidates.

Because of this lack of experience, any future clinical trials we may conduct may not be completed on time, if at all. Large-scale trials require significant additional financial and management resources, monitoring and oversight, and reliance on third-party clinical investigators, consultants or contract research organizations ("CROs"). Relying on third-party clinical investigators, CROs and manufacturers, which are all also subject to governmental oversight and regulations, may also cause us to encounter delays that are outside of our control.

In addition, we are still in the drug discovery and preclinical development stage for our product candidates and have not yet begun discussions with the FDA or comparable foreign regulatory authorities as to the design, structure and number of clinical trials that our product candidates would require for approval. Consequently, we may be unable to successfully and efficiently advance any candidates we select for clinical trials or execute and complete necessary GLP-compliant preclinical and IND-enabling studies in a way that leads to IND submission and approval of any product candidate. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of any product candidates that we develop. Failure to commence or complete, or delays in, future planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments and their respective foreign equivalents. The FDA and comparable foreign regulatory authorities regulate the research, development, preclinical studies and clinical trials, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of biopharmaceutical products. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments,

whether or not they have obtained the FDA's or comparable foreign regulatory authorities' approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling our products. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials. We or our collaborators must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy, and in the case of biologics also potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, suspended or varied, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, or our manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production, distribution, manufacturing or clinical trials; civil penalties; withdrawals, suspension or variation of previously approved marketing applications or licenses; recommendations by the FDA or comparable foreign other regulatory authorities against governmental contracts; and/or criminal prosecutions.

If we decide to pursue a Fast Track Designation, or comparable foreign regulatory procedures, for some of our product candidates, it may not lead to a faster development or regulatory review or approval process.

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

If we decide to seek Orphan Drug Designation for some of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for one or more of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and European countries, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug 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 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as a tax credit. Opportunities for grant funding toward clinical trial costs may also be available for clinical

trials of drugs for rare diseases, regardless of whether the drugs are designated for the orphan use. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. If a competitor with a product that is determined by the FDA to be the same as one of our product candidates obtains marketing approval before us for the same indication we are pursuing and obtains orphan drug exclusivity, our product candidate may not be approved until the period of exclusivity ends unless we are able to demonstrate that our product candidate is clinically superior. Even after obtaining approval, we may be limited in our ability to market our product. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different principal molecular structural features can be approved for the same condition.

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan drug by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan medicinal product designation, entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Orphan Drug Designation in the United States, or orphan medicinal product designation the EU, 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. While we may seek Orphan Drug Designation in the United States, or orphan medicinal product designation the EU, for our product candidates, we may never receive such designation.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates.

Following completion of clinical trials, the results are evaluated and, depending on the outcome, an NDA is submitted to the FDA to obtain the FDA's approval of the product and authorization to commence commercial marketing. In responding to an NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study and other commitments or reporting requirements or other restrictions on product distribution, or may deny the application. The FDA has established performance goals for review of NDAs: six months for priority applications and ten months for standard applications. However, the FDA is not required to complete its review within these time periods. The timing of final review by the FDA and action varies greatly but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Product sales in the United States may commence only when an NDA is approved. Comparable procedures and limitations are applicable in the EU and in other jurisdictions.

To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our products in the United States or in any foreign jurisdiction. None of our product candidates have been determined to be safe and effective, and we have not submitted an IND or an NDA to the FDA or an equivalent application to any comparable foreign regulatory authorities for any of our product candidates.

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, may adversely affect the successful commercialization of any drugs or biologics that we or our partners develop, may impose additional costs on us or our collaborators, may diminish any competitive advantages that we or our partners may attain, and/or may adversely affect our receipt of revenues or royalties.

Our product candidates may cause serious adverse events ("SAEs") or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

SAEs or undesirable side effects from our product candidates could arise either during development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause SAEs or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other comparable foreign regulatory authorities.

If any of our product candidates cause SAEs or undesirable side effects or suffer from quality control issues:

- regulatory authorities may impose a clinical hold or REMS, or comparable foreign regulatory strategies, which could result in substantial delays, significantly increase the cost of development, and/or adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of statements, specific warnings, or contraindications to the product label, or restrict the product's indication to a smaller potential treatment population;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;
- we may be required to limit the participants who can receive the product;
- we may be subject to limitations on how we promote the product;
- we may, voluntarily or involuntarily, initiate field alerts for product recall, which may result in shortages;
- sales of the product may decrease significantly;

- regulatory authorities may require us to take our approved product off the market;
- 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 significant revenues from the sale of our products.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other monitoring and reporting obligations by the FDA, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain the FDA's approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with the FDA's and others' requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Equivalent requirements and penalties are provided in the EU both at EU level and at national level in individual EU Member States.

Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA or a comparable foreign regulatory authority approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid or comparable foreign programs. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payors; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any pharmaceutical product that we develop will depend on a number of factors, including:

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects (including drowsiness and dry mouth), as compared to alternative products or treatment methods;
- the timing of market entry as compared to competitive products;
- the rate of adoption of our products by doctors and nurses;
- product labeling or product insert required by the FDA and comparable foreign regulatory authorities for each of our products;

- reimbursement policies of government and third-party payors, and the willingness of patients to pay out of pocket in the absence of adequate third-party payor coverage and reimbursement;
- effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and
- unfavorable publicity concerning our products or any similar products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and require us to seek additional financing, which may not be available.

Risks Related to Our Financial Condition and Capital Requirements; Competition

We will need to raise additional capital, which may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates, and additional capital may not be available on favorable terms or at all, which may force us to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations.

To develop and bring our product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical studies and clinical trials and marketing activities. Until such time, if ever, as we can generate substantial product revenue, we expect to seek additional funding to meet our operational needs and capital requirements. While we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2024, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect, including if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. Our requirements for additional capital will depend on many factors, including:

- changes in direction of our research and development programs;
- the time and expense for preclinical studies and clinical trials for our product candidates;
- the time and costs involved in obtaining regulatory approval for our product candidates;
- the cost increases and other potential impacts of macroeconomic factors, including heightened inflation and rising interest rates, liquidity concerns at and failures of banks and other financial institutions, exchange rate fluctuations, supply chain disruptions and increases in commodity, energy and fuel prices, costs associated with protecting our intellectual property rights;
- successful commercialization of our product candidates;
- competitive and technical advances;
- patent development or regulatory changes;
- development of marketing and sales capabilities;
- payments received under current and future collaboration agreements, if any; and
- market acceptance of our products.

Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may

vary materially from those now planned because of changes in direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our pipeline, management may need to curtail our development efforts and planned operations to conserve cash. We expect to finance our operations through a combination of equity offerings, debt financings, government or private party grants, collaborations, strategic alliances and licensing arrangements. We do not currently have any other committed external sources of funds. To the extent we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams.

We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization. Such additional sources of financing may not be available on favorable terms, if at all, including as a result of actions taken by central banks to counter inflation, volatility in the capital markets, liquidity concerns at and failures of banks and other financial institutions and related market uncertainty. If we do not succeed in raising additional funds on acceptable terms or if we are unsuccessful in entering into partnership agreements for further development of our pipeline, we may need to curtail our development efforts and planned operations to conserve cash.

Our continued operations may be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets.

We face intense competition in the markets targeted by our product candidates. Many of our competitors have substantially greater resources than we do, and we expect that all of our product candidates under development will face intense competition from existing or future drugs.

We expect that all of our product candidates under development, if approved, will face intense competition from existing and future drugs marketed by large companies. These competitors may successfully market products that compete with our products, successfully identify product candidates or develop products earlier than we do, or develop products that are more effective, have fewer side effects or cost less than our products.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs can extend up to three and one-half years.

In the EU, following grant of a related marketing authorization, innovative medicinal products generally benefit from eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product. After this period, an application for marketing authorization for a generic or biosimilar product may be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of eleven years if, during the first eight years following authorization of the reference product, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is, however, no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for

data exclusivity. In the EU, there is also a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of a related application for marketing authorization. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product.

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies that are pursuing other forms of treatment for the same or similar indications we are pursuing, including established pharmaceutical and biotechnology companies and that have greater financial and other resources. While we are not currently aware of any other companies that are taking the same therapeutic approach to protein folding disorders similar to the ones we are pursuing, we are aware of companies developing products for the same target indications. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors.

Other companies may succeed in developing products earlier than us, obtaining FDA or comparable foreign regulatory authority approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. For example, other companies may succeed in developing a technology that addresses protein misfolding and proves to be more effective or is more readily accepted than STARs. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

We may not be able to obtain marketplace acceptance for any of our product candidates as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA or comparable foreign regulatory authorities, and if they are commercialized before ours they may establish a strong market position before we are able to enter the market. Even if our products are successfully developed and approved for use by all governing regulatory bodies, physicians and patients may not accept our products as a treatment of choice.

The pharmaceutical research industry is diverse, complex, and rapidly changing, and inherently involves significant and numerous business risks. The effects of competition, intellectual property disputes, market acceptance, and FDA and comparable foreign regulatory authority regulations, among other factors described herein, preclude us from forecasting revenues or income with certainty or even confidence.

Our business and operations may be adversely affected by health epidemics or pandemics.

Our business and operations may be adversely affected by pandemics or epidemics, including due to business interruptions caused by travel restrictions, quarantines, “stay-at-home” and "shelter-in-place" orders, shutdowns requested or mandated by governmental authorities, or staffing shortages while employees quarantine as a result of exposure to or transmission of the virus. In addition, health epidemics or pandemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. For example, the COVID-19 pandemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U.S. economy and financial markets.

The COVID-19 pandemic and the resulting post-pandemic environment has impacted clinical site activation and patient enrollment. Clinical trial sites have experienced limited capacity and staffing shortages in a post-COVID-19 environment, partially due to personnel having been reassigned during the pandemic, resulting in a backlog of patient

enrollment and delayed site initiations across the industry. Our inability to successfully recruit and retain patients and principal investigators and site staff could adversely impact our expected future clinical trial operations.

Risks Related to Our Intellectual Property

We rely on a license to use the technology that is material to our business and if the agreements underlying the licenses were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

We are significantly dependent upon our license with Minoryx Therapeutics S.L. (the "Minoryx License"), as described in the section "Business – Strategic Transactions; Collaboration and Licensing Arrangements – Minoryx Therapeutics, S.L." in our Annual Report. The Minoryx License grants us exclusive, worldwide rights to certain patents and related intellectual property. If we breach the terms of the Minoryx License, for example, by failing to comply with any material terms thereof, Minoryx may have the right to terminate the license. If we were to lose our license under this agreement, we would not be able to market certain of our products and technology, which would likely require us to cease our current operations and have an immediate material adverse effect on our business, operating results and financial condition.

Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our products and technologies.

We are currently seeking patent protection for numerous compounds and methods of treating diseases. There is no assurance that these patents will be issued, and no assurance that, if they do issue, they will prevent other companies from competing with us. Our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If, at some point in the future, one or more products resulting from our product candidates is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us to obtain FDA approval.

If we fail to protect our intellectual property rights, our ability to pursue the development of our technologies and products would be negatively affected.

Our success will depend in part on our ability to obtain, maintain and protect intellectual property rights related to our product candidates. If we do not adequately maintain or protect our intellectual property, competitors may be able to use our technologies to produce and market drugs in direct competition with us and erode our competitive advantage. Furthermore, some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the United States. Many companies have had difficulty protecting their proprietary rights in these foreign countries. For example, the legal systems in India, China and certain other developing countries do not favor the enforcement of patents and other intellectual property rights. We may not be able to prevent misappropriation of our proprietary rights and intellectual property rights in these and other countries.

In addition, the patent process is subject to numerous risks and uncertainties, and we may not be successful in protecting our products by obtaining and defending patents related to them. These risks and uncertainties include the following: patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide us any competitive advantage; our competitors, many of which have substantially greater resources than we and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets; there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for

treatments that prove successful as a matter of public policy regarding worldwide health concerns; and countries other than the United States may have less robust patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products using our technologies and patents.

Moreover, any patents issued to us may not provide us with meaningful protection, or others may challenge, circumvent or narrow our patents. Third parties may also independently develop products similar to our products, duplicate our unpatented products or design around any patents or proprietary technologies on products we develop. Additionally, extensive time is required for development, testing and regulatory review of a potential product. While extensions of patent terms due to regulatory delays may be available, it is possible that, before any of our product candidates can be commercialized, any related patent, even with an extension, may expire or remain in force for only a short period following commercialization, thereby reducing any advantages to us of the patent.

In addition, the PTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the innovations specifically exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated, which could deprive us of rights necessary for the successful commercialization of our product candidates.

Our success depends on our patents and patent applications that may be licensed exclusively to us and other patents and patent applications to which we may obtain assignment or licenses. We may not be aware, however, of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our product candidates by us or our licensors, or by covering the same or similar technologies. These patents, patent applications, and published literature may limit the scope of our future patent claims or adversely affect our ability to market our product candidates. We have not conducted any formal search of patents issued to third parties, and third-party patents containing claims covering our product candidates that predate our patents may exist. Because of the number of patents issued and patent applications filed in our technical areas or fields, our competitors or other third parties may assert that our product candidates are covered by United States or foreign patents held by them.

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technology, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access to our trade secrets, which could impair any competitive advantage we may have.

Patent protection and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

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

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of present and future patents and other proceedings of our competitors. The defense and prosecution of intellectual property suits are costly and time-consuming to pursue, divert the attention of our management and scientific personnel, and their outcome is uncertain. Litigation may be necessary to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large, fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. Third parties may assert that our patents are invalid and/or unenforceable in these proceedings. Such litigation can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Third parties may also assert that our patents are invalid in patent office administrative proceedings. These proceedings include oppositions in the European Patent Office and *inter partes* review and post-grant review proceedings in the PTO. The success rate of these administrative challenges to patent validity in the United States is higher than it is for validity challenges in litigation.

Interference or derivation proceedings brought before the PTO may be necessary to determine priority of inventions disclosed in our patents or patent applications. Determining whether a product infringes a patent, as well as priority of inventions and other patent-related disputes, involves complex legal and factual issues and the outcome is often uncertain. During these proceedings, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference or derivation proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference or derivation proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors or securities analysts perceive these results to be negative, the price of our common stock could be adversely affected.

Also, a third party may assert that our patents are invalid or unenforceable. There are not currently any unresolved communications, allegations, complaints or threats of litigation that claim our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation or administrative proceedings could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

If we infringe the rights of third parties, we could be prevented from selling products or forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms or at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents that our future products would infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe.

We have licensed all of the rights, assets and technology related to the SEE-Tx® platform from Minoryx and we believe that they owned all of such rights prior to our license. Although, to our knowledge, no third party has asserted a claim of infringement or other claim against us, others may hold or claim to hold proprietary or other rights that could prevent our SEE-Tx® platform from being developed or marketed. Any legal action against us claiming damages and

seeking to enjoin commercial activities relating to our SEE-Tx® platform or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any future product candidates based upon the SEE-Tx® platform. We may not prevail in any such actions and any license required under any of these patents may not be made available on commercially acceptable terms, if at all. In addition, we may not be able to redesign any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our future product candidates, which could harm our business, financial condition and operating results.

Risks Related to Third Parties and Collaborators

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

We expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that our clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs will not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's Good Clinical Practices ("GCPs") and foreign equivalents for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA and comparable foreign regulatory authorities enforce these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA or comparable foreign regulatory authorities may determine that our clinical trials did not comply with applicable GCPs requirements. In addition, our clinical trials will require enrollment and participation of a sufficiently large number of patients to evaluate the effectiveness and safety of our product candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of participants, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical trials. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We intend to rely on third parties to manufacture the compounds used in our studies, and we intend to rely on them for the manufacture of any approved products for commercial sale. If these third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates could be delayed, prevented or impaired.

We have no manufacturing facilities and we intend to rely on third-party contract manufacturing organizations ("CMOs") to manufacture some or all of our product candidates in future clinical trials and our products that reach commercialization. Initiation and completion of our clinical trials and commercialization of our product candidates requires the manufacture of a sufficient supply of our product candidates. If, for any reason, we become unable to rely on these third parties for the manufacture of our product candidates, either for clinical trials or, in the event any of our product

candidates are approved, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical and commercial purposes, which we may not be able to do on reasonable terms or at all, or we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations.

We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to any specifications previously submitted to the FDA or another comparable foreign regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

We believe that there are a variety of manufacturers that we may be able to retain to produce these products. However, we may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected. In addition, once we retain a manufacturing source, if our manufacturers do not perform in a satisfactory manner, we may not be able to develop or commercialize potential products as planned. Certain specialized manufacturers are expected to provide us with modified and unmodified pharmaceutical compounds, including finished products, for use in our preclinical studies and clinical trials. Some of these materials are available from only one supplier or vendor. Any interruption in or termination of service by such sole source suppliers could result in a delay or interruption in manufacturing until we locate an alternative source of supply. Any delay or interruption in our future supply chain and manufacturing operations (or failure to locate a suitable replacement for such suppliers) as a result of pandemics or epidemics, global geopolitical conflicts or broader global supply chain disruptions, may affect their ability to deliver products to us in a timely manner and, could materially adversely affect our business, prospects, or results of operations. For example, supply chain issues occurred as a result of the COVID-19 pandemic and may continue to occur due to the war between Ukraine and Russia and sanctions resulting therefrom, and global geopolitical tension, including as a result of impacts on energy availability and prices and natural materials availability and prices. We also have a third-party manufacturer in China, which may be impacted by heightened tensions between the United States and China. If we fail to contract for manufacturing on acceptable terms or if third-party manufacturers do not perform as we expect, our development programs could be materially adversely affected. This may result in delays in filing for and receiving FDA or comparable foreign regulatory authority approval for one or more of our products or prevent such approval entirely. Any such delays or failures to obtain regulatory approval could cause our prospects to suffer significantly.

Failure by our third-party manufacturers to comply with the regulatory guidelines set forth by the FDA or comparable foreign regulatory authorities with respect to our product candidates could delay or prevent the completion of clinical trials, the approval of any product candidates or the commercialization of our products.

Third-party manufacturers must be inspected by the FDA and comparable foreign regulatory authorities for cGMP compliance before they can produce commercial products.

We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to

secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected.

Manufacturers are obligated to operate in accordance with requirements mandated by the FDA or comparable foreign regulatory authorities. A failure of any of our third-party manufacturers to establish and follow cGMP requirements and to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials, may delay or prevent filing or approval of marketing applications for our products, and may cause delays or interruptions in the availability of our products for commercial distribution following approval by the FDA or a comparable foreign regulatory authority. This could result in higher costs to us or deprive us of potential product revenues.

Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the Drug Enforcement Administration ("DEA") and corresponding state and foreign regulatory authorities to monitor and ensure strict compliance with cGMP requirements and other requirements under federal drug laws, other government regulations and corresponding foreign laws, regulations and standards. If we or our third-party manufacturers fail to comply with applicable regulations, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure by the government or competent regulatory authorities to grant marketing approval of drugs, delays, suspension, variation or withdrawal of approvals, seizures or recalls of product, shutdown of the manufacturer, invalidation of drug lots or processes, operating restrictions, product recalls and criminal prosecutions.

Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on our entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties and we may not be successful in establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. Any collaborators may not perform their obligations to our satisfaction, or at all, we may not derive any revenue or profits from such collaborations, and any collaborators may ultimately compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, scientists and collaborators to provide us with significant data and other information related to our projects, clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected.

If we fail to establish marketing, sales and distribution capabilities, or fail to enter into arrangements with third parties, we will not be able to create a market for our product candidates.

Our strategy for our product candidates is to control, directly or through contracted third parties, all or most aspects of the product development process, including marketing, sales and distribution. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidates that receive regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts.

To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution

channels, or enter into arrangements with third parties, we will experience delays in product sales and incur increased costs.

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the government or third-party payors, the market for our products will be limited. These third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Recent proposals to change the health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices.

Our business strategy might involve out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. We may not be able to successfully establish marketing, sales, or distribution relationships and such relationships, if established, may not be successful. Further, we may not be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third-parties. If we are unable to establish such third-party sales and marketing relationships, or choose not to do so, we will have to establish and rely on our own in-house capabilities.

We, as a company, have no experience in marketing or selling pharmaceutical products and currently have no sales, marketing, or distribution infrastructure. To market any of our products directly, we would need to develop a marketing, sales, and distribution force that both has technical expertise and the ability to support a distribution capability. The establishment of a marketing, sales, and distribution capability would significantly increase our costs, possibly requiring substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we may not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. We may not be able to establish internal marketing, sales, or distribution capabilities. If we are unable to, or choose not to establish these capabilities, or if the capabilities we establish are not sufficient to meet our needs, we will be required to establish collaborative marketing, sales, or distribution relationships with third parties.

If any of our existing or future collaborative partners do not satisfy their obligations, or if we are unable to enter into collaboration agreements with partners on favorable terms, we will be unable to develop our partnered product candidates.

We may not have day-to-day control over the activities of our existing and future collaborative partners with respect to any of our partnered product candidates. Any collaborative partner may not fulfill its obligations under our collaboration agreements. If a collaborative partner fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the products covered by that agreement or enter into alternative arrangements with a third party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of the agreement. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements will be dependent on the efforts of our collaborative partner. We could also become involved in disputes with a collaborative partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our collaborators' commitment to us and reduce the resources they devote to developing and commercializing our products. Conflicts or disputes with our collaborators, and competition from them, could harm our relationships with our other collaborators, restrict our ability to enter future collaboration agreements and delay the research, development or commercialization of our product candidates. If any collaborative partner terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing or commercializing these product candidates would be materially and adversely affected. We may not be able to enter into collaboration agreements with partners on terms favorable to us, or at all. Our inability to enter into collaborative arrangements with collaborative partners, or our failure to maintain such arrangements, would limit the number of product candidates that we could develop and ultimately decrease our sources of any future revenues.

We face risks in connection with existing and future collaborations with respect to the development, manufacture and commercialization of our product candidates.

We face a number of risks in connection with our current and future collaborations. Our collaboration agreements are subject to termination under various circumstances. Our collaborators may change the focus of their development and commercialization efforts or may have insufficient resources to effectively assist in the development of our products. Any future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties. Further, disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays, might result in litigation or arbitration, or might result in termination of the research, development or commercialization of our products. Any such disagreements would divert management attention and resources and be time-consuming and costly.

General Risk Factors

We previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. In addition, Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) and related SEC rules require management to furnish a report on the effectiveness of our internal control over financial reporting. Effective internal controls are necessary for us to provide reliable financial reports and help us to prevent fraud. The process of implementing our internal controls and complying with Section 404 is expensive and time consuming and requires significant continuous attention of management. We cannot be certain that these measures will ensure that we maintain adequate controls over our financial processes and reporting in the future.

For example, in our IPO, we previously disclosed material weaknesses relating to the following: (1) lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, and (2) lack of adequate procedures and controls to ensure that accurate financial statements can be prepared and reviewed on a timely basis, which we remediated as of December 31, 2021 and December 31, 2022, respectively.

While we believe the remediation efforts both addressed the identified material weaknesses and also enhanced our overall financial control environment, if we fail to maintain the adequacy of our internal controls, including any failure to implement new or improved controls, or if we experience difficulties in their implementation, our business and financial results could be harmed and we would be required to disclose material weaknesses in future filings with the SEC, which could adversely affect our business, investor confidence in our company and the market price of our common stock and could subject us to litigation or regulatory enforcement actions. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the market value of our common stock.

Global and macroeconomic conditions, including economic, political and social instability could adversely affect our revenue, financial condition, or results of operations.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, disruptions in access to bank deposits and lending commitments due to bank failures, declines in economic growth, increases in unemployment rates, supply chain disruptions, heightened interest rates and inflation, stock volatility, as well as uncertainty about economic stability. Such conditions may continue or worsen in the future. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including Russia's invasion of Ukraine, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur.

Our general business strategy, as well as our suppliers' ability to provide us with raw materials and components, may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, which could directly affect our ability to attain our operating goals on schedule and on budget, including requiring us to delay or abandon certain development plans, and could have a material adverse effect on our growth strategy, financial performance and stock price. In addition, there is a risk that one or more of our current suppliers, may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we advance our product candidates through preclinical studies and clinical trials, and develop new product candidates, we will need to increase our product development, scientific, regulatory and compliance and administrative headcount to manage these programs. In addition, to continue to meet our obligations as a public company, and particularly after we will no longer qualify as an emerging growth company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing, distribution and sales infrastructure in addition to a post-marketing surveillance program if we seek to market our products directly; and
- continue to improve our operational, manufacturing, quality assurance, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We depend upon our key personnel and our ability to attract and retain qualified employees.

Our future growth and success will depend in large part on our continued ability to attract, retain, manage and motivate our employees. The loss of the services of a significant portion of our workforce or any member of our senior management or the inability to hire or retain qualified personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we do not have an adequate succession plan or if we cannot recruit suitable replacements in a timely manner. While our senior executive officers are parties to employment agreements with us, these agreements do not guarantee that they will remain employed with us in the future. In addition, these our arrangements with our senior executive officers include only limited, if any, restrictions on our senior executive officers' ability to compete with us after their employment is terminated.

The competition for qualified personnel in the pharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. Due to the intense competition for talent, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. We may also face increased costs in attracting and retaining personnel as a result of heightened global inflation.

To incentivize valuable employees to join and remain at our company, in addition to salary and other employee benefits, we have provided stock option and restricted stock unit awards that vest over time and, in some instances, subject to the achievement of performance milestones. The value to employees of such awards may be significantly affected by movements in our stock price, and current market conditions and extreme stock price volatility may diminish our ability to incentivize employees through the use of such awards.

If we are unsuccessful in our recruitment and retention efforts, our business may be harmed.

Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

Our employment arrangements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work at all or for a sufficient duration of time to prevent members of our management team from competing with us. If we are unable to enforce these covenants not to compete, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our competitiveness may be diminished.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time we will need to hire additional qualified personnel with expertise in drug development, product registration, clinical, preclinical and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel will be critical to our success.

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations including comparable foreign laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

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

future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations, and foreign equivalent laws and regulations. These laws will impact, among other things, our proposed clinical research, sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business, as well as foreign data privacy and security laws and regulations. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- HIPAA, which created new federal criminal statutes that prohibit a person from, among other things, knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

- HIPAA, as amended by HITECH and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and certain health care providers, and their respective business associates and covered subcontractors;

- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the Patient Protection and Affordable Care Act ("ACA"), that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, state laws and foreign law equivalents that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, state laws and foreign law equivalents that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or competent regulatory authority or to adopt compliance programs as prescribed by applicable laws and regulations, or that otherwise restrict payments that may be made to healthcare professionals; and

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

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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 and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign programs, 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.

The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not determine whether or not another payor will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Even if favorable coverage and reimbursement status is attained for any product candidate for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs.

Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Coverage and reimbursement may not be available for any drug that we commercialize and, if reimbursement is available, it is uncertain what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

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/or 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. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA has been subject to judicial and Congressional challenges. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries, Presidential executive orders and proposed and enacted federal and state legislation designed to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain high expenditure single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the

pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Moreover, changes to the political landscape in the United States may impact the market sentiment surrounding the pharmaceutical industry.

In addition, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. The Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 will apply as of January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other comparable foreign programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

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 result in reduced demand for our product candidates or additional pricing pressures.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;
- unexpected changes in tariffs, export controls, sanctions, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- business interruptions resulting from geopolitical actions, including war (such as Russia's invasion of Ukraine) and terrorism, or natural disasters including earthquakes, hurricanes, floods and fires, economic or political instability, sanctions, or public health emergencies, and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; and
- difficulty in importing and exporting clinical trial materials and study samples.

We are subject to U.S. and certain foreign anti-corruption, anti-money laundering, export and import controls, and sanctions laws and regulations. Non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and 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, and contractors, from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, or other partners even if we do not explicitly authorize or have actual knowledge of such activities.

We are also 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. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our product candidates to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo.

We cannot ensure that all of our employees, agents, contractors or those of our affiliates, will comply with all applicable laws and regulations. Violations of anti-corruption, anti-money laundering, import and export control, or sanctions laws and regulations could result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, breach of contract and fraud litigation, reputational harm, and other consequences.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- initiation of investigations by regulators;

- withdrawal of clinical trial participants;
- significant time and expenses to defend the related litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any product candidates that we may develop.

We currently hold limited product liability insurance coverage. We will need to purchase additional product liability insurance coverage as we expand our clinical trials, and if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could cause our stock price to fall.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities may subject us to numerous data privacy and security obligations, 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 information by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of protected health information. As another example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") (collectively, "CCPA"), applies to the personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such California residents to exercise certain rights related to their personal information. The CCPA provides for administrative fines for noncompliance (up to $7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the CPRA expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency, the California Privacy Protection Agency, to implement and enforce the law. Several other states have also enacted data privacy laws, including Virginia, Colorado, Connecticut and Utah, all of which became or will become effective in 2023. In addition, data privacy and security laws have been proposed and others have been passed at the federal, state, and local levels in recent years. While some of these laws exempt data processed in the context of clinical trials, these developments may nonetheless further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United

Kingdom GDPR (UK GDPR) impose strict requirements for processing personal information, and violators of these laws face significant penalties. For example, under GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR (17.5 million British Pounds under the UK GDPR) or 4% of annual global revenue, in either case, whichever is greater, or we may be subject to private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent. In addition, the Swiss Federal Act on Data Protection, or FADP, also applies to the collection and processing of personal information, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The FADP has been revised and adopted by the Swiss Parliament. Companies must comply with the revised version of the FADP and its revised ordinances from September 2023 which may result in an increase of costs of compliance, risks of noncompliance and penalties for noncompliance.

In the ordinary course of business, we may transfer personal information from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the European Economic Area ("EEA"), the UK and Switzerland have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the United States. If there is no lawful manner for us to transfer personal information from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Some European regulators have prevented companies from transferring personal information out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations. For example, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1.2 billion Euro fine against the company and prohibited the company from transferring personal data to the United States.

Our employees and personnel may use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Furthermore, we publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems,

and practices and to those of any third parties that process personal information on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, and proceedings against us by governmental entities or others.

If we or the third parties upon which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we or the third parties upon which we rely process proprietary, confidential, and sensitive data, including personal information (such as health-related data), business plans, financial information, intellectual property, and trade secrets (collectively, sensitive information), and, as a result, we and the third parties upon which we rely face a variety of evolving threats.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized crime threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, including the war in Ukraine, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, and other similar threats. In particular, ransomware attacks, including 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 alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working from home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Additionally, 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 or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities in our information technology systems, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive Company information could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI technologies.

Risks Related to Ownership of Our Common Stock

The market price for our common stock has been and likely will continue to be volatile, and your investment in our securities could decline in value.

Our stock price has been highly volatile since our IPO and is likely to continue to be volatile. The stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. The market price for our common stock may be influenced by many factors, including:

- results from, and any delays in our preclinical studies and any other future clinical development programs, including any delays related to the health epidemics or pandemics or other factors outside of our control;
- actual or anticipated changes in estimates as to financial results, development timelines and other company milestones or recommendations by securities analysts;
- announcements of changes to our operational focus, including changes to the programs we are actively developing;
- announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA or comparable foreign regulatory authority approval or disapproval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical trials;
- developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;
- developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization;
- announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;
- public concerns as to the safety or efficacy of our product candidates or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third-party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;

- changes in financial estimates or recommendations by securities analysts;
- developments involving corporate collaborators, if any;
- changes in accounting principles;
- general economic, industry and market conditions, heightened inflation and measures taken by central banks to combat inflation, exchange rate fluctuations, supply chain disruptions and increasing commodity, energy and fuel prices;
- the impact of political instability, natural disasters, events of terrorism and/or war, such as the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China; and
- the loss of any of our key scientific or management personnel.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities and in particular, biotechnology and pharmaceutical companies. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

Stock market volatility and declines in the price of our common stock also increase the likelihood that we may fail to meet the minimum price requirements for continued listing on the Nasdaq Global Market. If the Nasdaq Global Market delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences, including:

- limited availability of market quotations for our securities;
- a determination that the common stock is a "penny stock" which will require brokers trading in the common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We incur and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we will no longer qualify as an emerging growth company, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, we are required,

pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. The process to document and evaluate our internal control over financial reporting, is both costly and challenging. In this regard, we need to continue to dedicate internal resources, validate through testing that controls are functioning as designed and maintain a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We are an "emerging growth company," and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We qualify as an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to report only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements 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. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. As a result, the information we provide might be different from the information that is available for other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and the market price of our common stock may be more volatile.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the first fiscal year after our annual gross revenue exceeds $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.00 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.

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

We have incurred substantial losses during our history, do not expect to become profitable in the foreseeable future and may never achieve profitability. Net operating losses, or NOLs, of our Swiss subsidiary can be carried forward for seven years and will begin to expire commencing from 2025 for the NOLs generated in 2017 under applicable Swiss tax law. Under applicable U.S. federal income tax law, our federal NOL carryforwards generated in tax years beginning on or before December 31, 2017, are only permitted to be carried forward for 20 years. Our federal NOL carryforwards generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards may be limited. It is uncertain if and to what extent various states will conform to U.S. federal income tax law with respect to the treatment of NOL carryforwards. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset taxable income may be limited, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed by us.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. For instance, the recently enacted IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. In particular, changes in corporate tax rates, the realization of our net deferred tax assets, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act or any future tax reform legislation, could have a material impact on the value of our deferred tax assets, result in significant one-time charges, and increase our future tax expenses.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

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 amounts of our common stock in the public market, the market price of our common stock could decline significantly. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

The rights of the holders of our securities may be impaired by the potential issuance of preferred stock.

Our articles of incorporation give our board of directors the ability to designate and issue preferred stock in one or more series. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the relative voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could have the effect of discouraging, delaying or preventing a change of control of us. The possible impact on takeover attempts could adversely affect the price of our securities. Although we have no present intention to designate any series, or issue any shares, of preferred stock, other than pursuant to the IPO, we may do so in the future.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. 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 in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our organizational documents and Delaware law might discourage or delay attempts to acquire us that you might consider favorable.

Our amended and restated certificate of incorporation (the "Amended Charter") and amended and restated bylaws (the "Amended Bylaws") contain provisions that may make the merger or acquisition of us more difficult without the approval of our board of directors. Among other things, these provisions:

- allow us to authorize the issuance of undesignated preferred stock in connection with a stockholder rights plan or otherwise, the terms of which may be established and the shares of which may be issued without stockholder approval, and which may include super voting, special approval, dividend, or other rights or preferences superior to the rights of the holders of common stock;
- provide that our bylaws may be amended or repealed only by a majority vote of our board of directors or by the affirmative vote of the holders of at least 66 2/3% of the votes which all our stockholders would be entitled to cast in any annual election of directors; and
- establish advance notice requirements for nominations for elections to our board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Further, as a Delaware corporation, we are also subject to provisions of Delaware law, which may impair a takeover attempt that our stockholders may find beneficial. These anti-takeover provisions and other provisions under Delaware law could discourage, delay, or prevent a transaction involving a change in control of us, including actions that our stockholders may deem advantageous, or could negatively affect the market price of our common stock. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing and to cause us to take other corporate actions our stockholders desire.

Our Amended Charter provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders and federal district courts will be the sole and exclusive forum for Securities Act claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our Amended Charter provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or other employees to us or to our stockholders; (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law (the "DGCL"), the Amended Charter or the Amended Bylaws or as to which the DGCL confers exclusive jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine, provided that the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. Our Amended Charter further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts are the sole and exclusive forum for the resolution of any complaint asserting a right under the Securities Act, subject to a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The choice of 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 such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our Amended Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Provisions in our organizational documents regarding exculpation and indemnification of our directors and officers may result in substantial expenditures by us and may discourage lawsuits against our directors and officers.

Our Amended Charter and Amended Bylaws provide for the elimination, to the maximum extent permissible under Delaware law, of the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty. These provisions may discourage us, or our stockholders through derivative litigation, from bringing a lawsuit against any of our current or former directors or officers for any breaches of their fiduciary duties, even if such legal actions, if successful, might benefit us or our stockholders. In addition, our Amended Charter and Amended Bylaws provide that we will, to the fullest extent permitted by Delaware law, indemnify our directors and officers for costs or damages incurred by them in connection with any threatened, pending, or completed action, suit, or proceeding brought against them by reason of their positions as directors and officers. We also intend to enter into indemnification agreements with each of our directors and executive officers. These indemnification obligations could result in us incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers.

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

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds from Initial Public Offering of Common Stock

On March 17, 2021, our Registration Statement on Form S-1, as amended (File No. 333-253303), was declared effective in connection with the IPO of our common stock, pursuant to which we registered an aggregate of 4,181,818 shares of our common stock, which includes the exercise in full of the underwriters' option to purchase up to an additional 545,454 common shares, at a price to the public of $11.00 per share. The offering closed on March 22, 2021, and, as a result, we received net proceeds of $40.5 million (after deducting underwriters' discounts and commissions of approximately $3.2 million and additional offering related costs of approximately $2.0 million). The joint book-running managers of the offering were BTIG, LLC, and Oppenheimer & Co. Inc.

No expenses incurred by us in connection with our IPO were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed by us with the SEC pursuant to Rule 424(b) on March 17, 2021.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Gain Therapeutics, Inc.	8-K	001-40237	3.1	3/17/2021
3.2	Amended and Restated Bylaws of Gain Therapeutics, Inc.	8-K	001-40237	3.2	3/17/2021
10.1	Employment Agreement, by and between the Company and Evan Ballantyne, dated April 10, 2023.	8-K	001-40237	10.1	4/12/2023
10.2	Separation Agreement and Release, by and between GT Gain Therapeutics SA and Salvatore Calabrese, dated April 27, 2023.	8-K	001-40237	10.1	4/28/2023
10.3*	Form of Indemnification Agreement for Officers and Directors.				
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LA*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in exhibit 101)				

* Filed herewith.

† This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing by 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 hereof, regardless of any general incorporation language 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.

GAIN THERAPEUTICS, INC.
(Registrant)

August 10, 2023
Date

/s/ Matthias Alder
Matthias Alder
Chief Executive Officer
(Principal Executive Officer)

August 10, 2023
Date

/s/ C. Evan Ballantyne
C. Evan Ballantyne
Chief Financial Officer
(Principal Financial Officer)

August 10, 2023
Date

/s/ Gianluca Fuggetta
Gianluca Fuggetta
Senior Director, Corporate Reporting
(Principal Accounting Officer)

Exhibit 10.3

INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT (the "**Agreement**") is made and entered into as of _____, 20___ between **Gain Therapeutics, Inc.**, a Delaware corporation (the "**Company**"), and **[_____]** ("**Indemnitee**").

WITNESSETH THAT:

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors and/or officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board of Directors of the Company (the "**Board**") has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company and the Bylaws of the Company require indemnification of the executive officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware ("**DGCL**"). The Bylaws, Certificate of Incorporation, and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the Board, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Bylaws and Certificate of Incorporation of the Company and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Company's Bylaws and Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified.

NOW, THEREFORE, in consideration of Indemnitee's agreement to serve as an officer and/or director from and after the date hereof, the parties hereto agree as follows:

1. Indemnity of Indemnitee. The Company hereby agrees to hold harmless and indemnify Indemnitee to the fullest extent permitted by law, as such may be amended from time to time. In furtherance of the foregoing indemnification, and without limiting the generality thereof:

(a) Proceedings Other Than Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnification provided in this Section I(a) if, by reason of Indemnitee's Corporate Status (as hereinafter defined), the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding (as hereinafter defined) other than a Proceeding by or in the right of the Company. Pursuant to this Section 1(a), Indemnitee shall be indemnified against all Expenses (as hereinafter defined), judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection with such Proceeding or any claim, issue or matter therein, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful.

(b) Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnification provided in this Section 1(b) if, by reason of Indemnitee's Corporate Status, the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company. Pursuant to this Section 1(b), Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee, or on the Indemnitee's behalf, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, if applicable law so provides, no indemnification against such Expenses shall be made in respect of any claim, issue or matter in such Proceeding as to which Indemnitee shall have been adjudged to be liable to the Company unless and to the extent that the Court of Chancery of the State of Delaware shall determine that such indemnification may be made.

(c) Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a party to (or participant in) and is successful, on the merits or otherwise, in any Proceeding, Indemnitee shall be indemnified to the maximum extent permitted by law, as such may be amended from time to time, against all Expenses actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection with each successfully resolved claim, issue or matter. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

(d) Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

2. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1 of this Agreement, the Company shall and hereby does indemnify and hold harmless Indemnitee against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, if, by reason of Indemnitee's Corporate Status, Indemnitee is, or is threatened to be made, a party to or participant in any

Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or active or passive wrongdoing of Indemnitee. The only limitation that shall exist upon the Company's obligations pursuant to this Agreement shall be that the Company shall not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, set forth in Sections 6 and 7 hereof) to be unlawful.

3. Contribution.

(a) Whether or not the indemnification provided in Sections 1 and 2 hereof is available, in respect of any threatened, pending or completed action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such action, suit or proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required to pay all or any portion of any judgment or settlement in any threatened, pending or completed action, suit or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such action, suit or proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary and the degree to which their conduct is active or passive.

(c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors, or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee.

(d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding and/or (ii) the relative fault of the Company (and its

directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

4. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by Indemnitee, or on Indemnitee's behalf, in connection therewith.

5. Advancement of Expenses. Notwithstanding any other provision of this Agreement, the Company shall advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding by reason of Indemnitee's Corporate Status within thirty (30) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by Indemnitee and shall include or be preceded or accompanied by a written undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it shall ultimately be determined that Indemnitee is not entitled to be indemnified against such Expenses. Any advances and undertakings to repay pursuant to this Section 5 shall be unsecured and interest free. This Section shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section .

6. Procedures and Presumptions for Determination of Entitlement to Indemnification. It is the intent of this Agreement to secure for Indemnitee rights of indemnity that are as favorable as may be permitted under the DGCL and public policy of the State of Delaware. Accordingly, the parties agree that the following procedures and presumptions shall apply in the event of any question as to whether Indemnitee is entitled to indemnification under this Agreement:

(a) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification. Notwithstanding the foregoing, any failure of Indemnitee to provide such a request to the Company, or to provide such a request in a timely fashion, shall not relieve the Company of any liability that it may have to Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company. The Company will be entitled to participate in the Proceeding at its own Expense.

(b) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 6(a) hereof, a determination with respect to Indemnitee's entitlement thereto shall be made in the specific case by one of the following four methods, which shall be at the election of the Board: (i) by a majority vote of the disinterested directors, even though less than a quorum, (ii) by a committee of disinterested directors designated by a majority vote of the disinterested directors, even though less than a quorum, (iii) if there are no disinterested directors or if the disinterested directors so direct, by independent legal counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee, or (iv) if so directed by the Board, by the stockholders of the Company. For purposes hereof, disinterested directors are those members of the Board who are not parties to the action, suit or proceeding in respect of which indemnification is sought by Indemnitee.

(c) If the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 6(b) hereof, the Independent Counsel shall be selected as provided in this Section 6(c). The Independent Counsel shall be selected by the Board. Indemnitee may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the

Independent Counsel so selected does not meet the requirements of "**Independent Counsel**" as defined in Section 13 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If a written objection is made and substantiated, the Independent Counsel selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within twenty (20) days after submission by Indemnitee of a written request for indemnification pursuant to Section 6(a) hereof, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Court of Chancery of the State of Delaware or other court of competent jurisdiction for resolution of any objection which shall have been made by the Indemnitee to the Company's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 6(b) hereof. The Company shall pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting pursuant to Section 6(b) hereof, and the Company shall pay all reasonable fees and expenses incurred by the Company and the Indemnitee incident to the procedures of this Section 6(c), regardless of the manner in which such Independent Counsel was selected or appointed.

(d) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence. Neither the failure of the Company (including by its directors or independent legal counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(e) Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise (as hereinafter defined), including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Enterprise. The provisions of this Section shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement. In addition, the knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement. Whether or not the foregoing provisions of this Section are satisfied, it shall in any event be presumed that Indemnitee has at all times acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(f) If the person, persons or entity empowered or selected under Section 6 to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall be deemed to have been made and Indemnitee shall be entitled to such indemnification absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such sixty (60) day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making such determination with respect to entitlement to indemnification in good faith

requires such additional time to obtain or evaluate documentation and/or information relating thereto; and provided further, that the foregoing provisions of this Section 6(f) shall not apply if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 6(b) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination, the Board or the Disinterested Directors, if appropriate, resolve to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat.

(g) Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Independent Counsel, member of the Board or stockholder of the Company shall act reasonably and in good faith in making a determination regarding the Indemnitee's entitlement to indemnification under this Agreement. Any costs or expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(h) In the event that any action, suit or proceeding to which Indemnitee is a party is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such action, suit or proceeding with or without payment of money or other consideration) it shall be presumed that Indemnitee has been successful on the merits or otherwise in such action, suit or proceeding. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(i) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

7. Remedies of Indemnitee.

(a) In the event that (i) a determination is made pursuant to Section 6 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 5 of this Agreement, (iii) no determination of entitlement to indemnification is made pursuant to Section 6(b) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Sections , , or the last sentence of Section of this Agreement within ten (10) days after receipt by the Company of a written request therefor, or (v) payment of indemnification is not made pursuant to Sections , and of this Agreement within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or such determination is deemed to have been made pursuant to Section 6 of this Agreement, Indemnitee shall be entitled to an adjudication in an appropriate court of the State of Delaware, or in any other court of competent jurisdiction, of Indemnitee's entitlement to such indemnification. Indemnitee shall commence such proceeding seeking an adjudication within one hundred eighty (180) days

following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 7(a). The Company shall not oppose Indemnitee's right to seek any such adjudication.

(b) In the event that a determination shall have been made pursuant to Section 6(b) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this Section 7 shall be conducted in all respects as a de novo trial on the merits, and Indemnitee shall not be prejudiced by reason of the adverse determination under Section 6(b).

(c) If a determination shall have been made pursuant to Section 6(b) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this Section 7, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's misstatement not materially misleading in connection with the application for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) In the event that Indemnitee, pursuant to this Section 7, seeks a judicial adjudication of Indemnitee's rights under, or to recover damages for breach of, this Agreement, or to recover under any directors' and officers' liability insurance policies maintained by the Company, the Company shall pay on Indemnitee's behalf, in advance, any and all expenses (of the types described in the definition of Expenses in Section 13 of this Agreement) actually and reasonably incurred by Indemnitee in such judicial adjudication, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of expenses or insurance recovery.

(e) The Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 7 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefore) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(f) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

8. Non-Exclusivity; Survival of Rights; Insurance; Primacy of Indemnification; Subrogation

(a) The rights of indemnification as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders, a resolution of directors of the Company, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL, whether by statute or judicial decision, permits greater

indemnification than would be afforded currently under the Certificate of Incorporation, Bylaws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, employee, agent or fiduciary under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by [] and certain of its affiliates (collectively, the "**Fund Indemnitors**"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Fund Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement and the Certificate of Incorporation or Bylaws of the Company (or any other agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Fund Indemnitors, and (iii) that it irrevocably waives, relinquishes and releases the Fund Indemnitors from any and all claims against the Fund Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Fund Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Fund Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Fund Indemnitors are express third party beneficiaries of the terms of this Section 8(c).]

(d) [Except as provided in paragraph (c) above, i][I]n the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee [(other than against the Fund Indemnitors)], who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(e) [Except as provided in paragraph (c) above, t][T]he Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(f) [Except as provided in paragraph (c) above, t][T]he Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust,

employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.

9. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision[, provided, that the foregoing shall not affect the rights of Indemnitee or the Fund Indemnitors set forth in Section 8(c) above]; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of state statutory law or common law, (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Company by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) except as provided in Section of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (ii) such payment arises in connection with any mandatory counterclaim or cross claim brought or raised by Indemnitee in any Proceeding (or any part of any Proceeding) or (iii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

10. Duration of Agreement. All agreements and obligations of the Company contained herein shall continue for five years following the date that Indemnitee ceases to be an officer or director of the Company (or, if applicable, ceases to serve at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise), and shall continue thereafter so long as Indemnitee shall be subject to any Proceeding (or any proceeding commenced under Section 7 hereof) by reason of Indemnitee's Corporate Status. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors and personal and legal representatives.

11. Security. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time provide security to Indemnitee for the Company's obligations hereunder through an irrevocable bank line of credit, funded trust or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of the Indemnitee.

12. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it hereby in order to induce Indemnitee to serve as an officer or director of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as an officer or director of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.

(c) The Company shall not seek from a court, or agree to, a "bar order" which would have the effect of prohibiting or limiting the Indemnitee's rights to receive advancement of expenses under this Agreement.

13. Definitions. For purposes of this Agreement:

(a) "**Corporate Status**" describes the status of a person who is or was a director, officer, employee, agent or fiduciary of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person is or was serving at the request of the Company.

(b) "**Disinterested Director**" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(c) "**Enterprise**" shall mean the Company and any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that Indemnitee is or was serving at the request of the Company as a director, officer, employee, agent or fiduciary.

(d) "**Expenses**" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in any Proceeding. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including, without limitation, the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent; (ii) Expenses incurred in connection with recovery under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee is ultimately determined to be entitled to such indemnification, advancement or Expenses or insurance recovery, as the case may be, and (iii) for purposes of Section only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, the Certificate of Incorporation, the Bylaws or under any directors' and officers' liability insurance policies maintained by the Company, by litigation or otherwise. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(e) "**Independent Counsel**" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither at present is, nor in the past five years has been, retained to represent (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for

indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(f) "**Proceeding**" includes any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party or otherwise, by reason of Indemnitee's Corporate Status, by reason of any action taken by Indemnitee, or of any inaction on Indemnitee's part, while acting in Indemnitee's Corporate Status; in each case whether or not Indemnitee is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification, reimbursement or advancement of expenses can be provided under this Agreement; including one pending on or before the date of this Agreement, but excluding one initiated by an Indemnitee pursuant to Section 7 of this Agreement to enforce Indemnitee's rights under this Agreement.

14. Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision. Without limiting the generality of the foregoing, this Agreement is intended to confer upon Indemnitee indemnification rights to the fullest extent permitted by applicable laws. In the event any provision hereof conflicts with any applicable law, such provision shall be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.

15. Modification and Waiver. No supplement, modification, termination or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.

16. Notice By Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification covered hereunder. The failure to so notify the Company shall not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise unless and only to the extent that such failure or delay materially prejudices the Company.

17. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent:

(a) To Indemnitee at the address set forth below Indemnitee signature hereto.

(b) To the Company at:

4800 Montgomery Lane, Suite 220
Bethesda, Maryland 20814

Attention: Chief Executive Officer

or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.

18. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

19. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

20. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware (the "**Delaware Court**"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and **(**v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement on and as of the day and year first above written.

COMPANY:

Gain Therapeutics, Inc.

By: _____

Name: Matthias Alder
Title: Chief Executive Officer

Email: malder@gaintherapeutics.com

Address: 4800 Montgomery Lane, Suite 220
Bethesda, Maryland 20814

[

INDEMNITEE:

[_____]

_____
(*Signature*)

Address: [_____]

Email: _____
]

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, Matthias Alder, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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.

August 10, 2023
Date

/s/ Matthias Alder
Matthias Alder
Chief Executive Officer
(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, Charles Evan Ballantyne, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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.

August 10, 2023
Date

/s/ C. Evan Ballantyne
C. Evan Ballantyne
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Gain Therapeutics, Inc. (the "Company") for the quarterly period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Matthias Alder, as Chief Executive Officer of the Company, and Charles Evan Ballantyne, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. §-1350, as adopted pursuant to §-906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Date: August 10, 2023

/s/ Matthias Alder
Matthias Alder
Chief Executive Officer
(Principal Executive Officer)

/s/ C. Evan Ballantyne
C. Evan Ballantyne
Chief Financial Officer
(Principal Financial Officer)