REFINITIV

DELTA REPORT

10-Q

GANX - GAIN THERAPEUTICS, INC.

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	2576
CHANGES	95
DELETIONS	553
ADDITIONS	1928

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-O

(Mark

(Mark one)

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

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

For the quarterly period ended June 30, 2023

September 30, 2023

or

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

☐ **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 prece

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 ((

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 gro

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

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 fina

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 October 31, 2023, the registrant had 12,699,422 12,910,342 shares of common stock outstanding.

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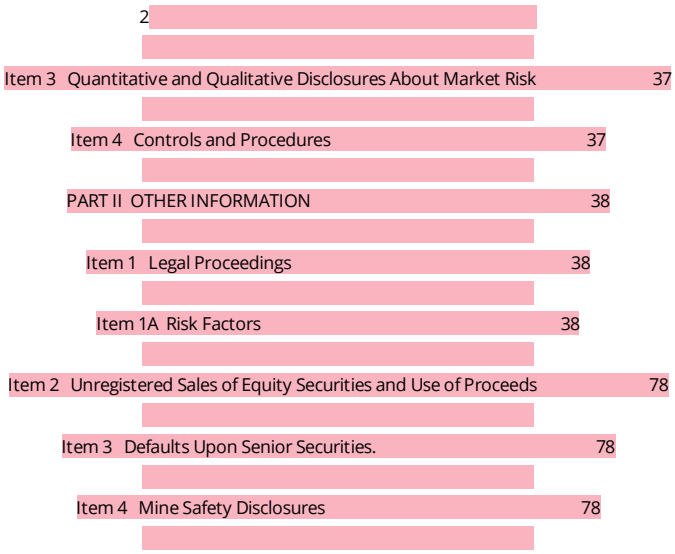

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report" "Quarterly Report") contains forward-looking statements which are made pursuant to the safe
"should," "may," "may "believe," "can," "could," "potential," "plan," "predict," "goals," "seek," "should," "may," "may have," "would," "estimate," "continue," "anticipate
"intend," "expect" " "would," "estimate," "continue," "anticipate," "intend," "expect" or the negative of these terms, other comparable terminology or by discussions

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(R), 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(R) 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

- our ability to continue as a going concern;
- our needs for additional financing;
- the success of our efforts, and those of our advisors, in exploring, and possibly executing on, our strategic alternatives, while preserving our cash bala
- 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-Dire
- 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 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 ability to accurately estimate anticipated operating losses, expenses, future revenues, capital requirements, including our anticipated cash runway
- 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;

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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.

- 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, liquidit
- the impacts of pandemics or endemics including on our operations, access to capital, research and development and clinical trials and potential disrup
- the impact of other global events, including political instability, natural disaster, events of terrorism and wars, including the war between Ukraine 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, unc

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

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Item 1. Financial Statements.

PART I-FINANCIAL 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, $	1,263	1,189
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.		
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

Assets

Current assets:

- Cash and cash equivalents
- Marketable securities - current
- Tax credits
- Prepaid expenses and other current assets

Total current assets

Non-current assets:

- Marketable securities - non current
- Property and equipment, net
- Internal-use software
- Operating lease - right of use assets
- Restricted cash
- Long-term deposits and other non-current assets

Total non-current assets

Total assets

Liabilities and stockholders' equity

Current liabilities:

- Accounts payable
- Operating lease liability - current
- Other current liabilities
- Deferred income - current
- Loans - current

Total current liabilities

Non-current liabilities:

- Defined benefit pension plan
- Operating lease liability - non-current
- Deferred income - non-current
- Loans - non-current

Total non-current liabilities

Total liabilities

Stockholders' equity

- Preferred stock, $0.0001 par value; 10,000,000 shares authorized; nil shares issued and outstanding as of September 30, 2023 and December 31, 2022.

Common stock, $0.0001 par value: 50,000,000 shares authorized; 12,782,861 issued and outstanding as of September 30, 2023; 11,883,368 issued and outstanding	
Additional paid-in capital	
Accumulated other comprehensive income	
Accumulated deficit	
Loss for the period	
Total stockholders' equity	
Total liabilities and stockholders' equity	

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

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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	129,929	59,899	281,964	58,248

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration revenues	$ —	$ —	$ 55,180	$ 132,640
Other income	—	—	—	7,468
Total revenues	$ —	$ —	$ 55,180	$ 140,108
Operating expenses:				
Research and development	(2,367,482)	(1,964,784)	(9,146,630)	(6,103,448)
General and administrative	(2,517,523)	(2,786,200)	(8,754,453)	(7,252,506)
Total operating expenses	(4,885,005)	(4,750,984)	(17,901,083)	(13,355,954)
Loss from operations	$ (4,885,005)	$ (4,750,984)	$ (17,845,903)	$ (13,215,846)
Other income/(expense):				
Interest income, net	106,000	153,332	387,964	211,580
Foreign exchange gain/(loss), net	82,198	43,491	(20,839)	102,865
Loss before income tax	$ (4,696,807)	$ (4,554,161)	$ (17,478,778)	$ (12,901,401)
Income tax	(21,456)	(4,048)	(64,773)	(14,871)
Net loss	$ (4,718,263)	$ (4,558,209)	$ (17,543,551)	$ (12,916,272)
Net loss per shares:				
Net loss per share attributable to common stockholders - basic and diluted	$ (0.37)	$ (0.38)	$ (1.42)	$ (1.09)
Weighted average common shares - basic and diluted	12,701,401	11,883,368	12,342,031	11,883,368

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

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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	(5,104)	42,015	5,104	(1,247)
Defined benefit pension plan	(3,765)	(7,914)	(700)	(1,370)
Foreign currency translation	39,960	(58,051)	(40,135)	(67,941)
Other comprehensive income/(loss)	38,013	(98,696)	(31,266)	(54,923)
Comprehensive loss	$ (7,649,956)	$ (5,116,686)	$ (12,726,592)	$ (8,412,986)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (4,718,263)	$ (4,558,209)	$ (17,543,551)	$ (12,916,272)
Unrealized gain/(loss) on available-for-sale securities	30,025	(103,142)	72,040	(98,038)
Defined benefit pension plan	(642)	3,569	(2,012)	11,483
Foreign currency translation	(73,046)	(51,759)	(14,995)	(119,700)
Other comprehensive income/(loss)	(43,663)	(151,332)	55,033	(206,255)
Comprehensive loss	$ (4,761,926)	$ (4,709,541)	$ (17,488,518)	$ (13,122,527)

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

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GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' STOCKHOLDERS' EQUITY

(unaudited)

Six Months Ended	Common Stock Shares	Amounts	APIC	AOCI	Accumulated Deficit	Total
June 30, 2023						
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)

Three Months Ended	Common Stock Shares	Amounts	APIC	AOCI	Accumulated Deficit	Total
June 30, 2023						
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	12,632,327	1,263	62,298,733	134,323	(	11,092,834

June 30, 2023	51,341,485
	)

Nine Months Ended September 30, 2023	Common Stock Shares	Common Stock Amounts	APIC	AOCI	Accumulated Deficit	Total
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)	159,362	15	2,792,523	—	—	2,792,538
Issuance of shares in at-the-market (ATM) offering (Note 13)	740,131	74	3,147,159	—	—	3,147,233
Defined benefit pension plan (Note 10)		—	—	(2,012)	—	(2,012)
Foreign currency translation		—	—	(14,995)	—	(14,995)
Net unrealized gain on available for sale securities (Note 4)		—	—	72,040	—	72,040
Net loss		—	—	—	(17,543,551)	(17,543,551)
Balance as of September 30, 2023	**12,782,861**	**1,278**	**63,298,577**	**90,660**	**(56,059,748)**	**7,330,767**

Three Months Ended September 30, 2023	Common Stock Shares	Common Stock Amounts	APIC	AOCI	Accumulated Deficit	Total
Balance as of June 30, 2023	**12,632,327**	**$ 1,263**	**$ 62,298,733**	**$ 134,323**	**$ (51,341,485)**	**$ 11,092,834**
Stock-based compensation (Note 14)	91,962	9	842,815	—	—	842,824
Issuance of shares in at-the-market (ATM) offering (Note 13)	58,572	6	157,029	—	—	157,035
Defined benefit pension plan (Note 10)		—	—	(642)	—	(642)
Foreign currency translation		—	—	(73,046)	—	(73,046)
Net unrealized gain on available for sale securities (Note 4)		—	—	30,025	—	30,025
Net loss		—	—	—	(4,718,263)	(4,718,263)
Balance as of September 30, 2023	**12,782,861**	**1,278**	**63,298,577**	**90,660**	**(56,059,748)**	**7,330,767**

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

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GAIN THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' STOCKHOLDERS' EQUITY

(unaudited)

Six Months Ended June 30, 2022	Common Stock Shares	Common Stock Amounts	APIC	AOCI	Accumulated Deficit	Total
Balance as of December 31, 2021	**11,883,368**	**$ 1,189**	**$ 55,832,461**	**$ (**	**$ (**	**$ 34,817,546**
			90,645	**20,925,459**		
				)	**)**	
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	(	(	27,016,655
			145,568	29,283,522		
			)	)		

	Common Stock		APIC	AOCI	Accumulated	Total
Three Months Ended June 30, 2022	Shares	Amounts			Deficit	
Balance as of March 31, 2022	11,883,368	$ 1,189	$ 56,139,006	$ (	$ (	$ 31,827,791
			114,302	24,198,102		
			)	)		
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	(	(	27,016,655
			145,568	29,283,522		
			)	)		

	Common Stock		APIC	AOCI	Accumulated	Total
Nine Months Ended September 30, 2022	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		—	967,742	—	—	967,742
Defined benefit pension plan		—	—	11,483	—	11,483
Foreign currency translation		—	—	(119,700)	—	(119,700)
Net unrealized loss on available for sale securities		—	—	(98,038)	—	(98,038)
Net loss		—	—	—	(12,916,272)	(12,916,272)
Balance as of September 30, 2022	**11,883,368**	**1,189**	**56,800,203**	**(296,900)**	**(33,841,731)**	**22,662,761**

	Common Stock		APIC	AOCI	Accumulated	Total
Three Months Ended September 30, 2022	Shares	Amounts			Deficit	
Balance as of June 30, 2022	**11,883,368**	**$ 1,189**	**$ 56,444,556**	**$ (145,568)**	**$ (29,283,522)**	**$ 27,016,655**
Stock-based compensation		—	355,647	—	—	355,647
Defined benefit pension plan		—	—	3,569	—	3,569
Foreign currency translation		—	—	(51,759)	—	(51,759)
Net unrealized loss on available for sale securities		—	—	(103,142)	—	(103,142)
Net loss		—	—	—	(4,558,209)	(4,558,209)
Balance as of September 30, 2022	**11,883,368**	**1,189**	**56,800,203**	**(296,900)**	**(33,841,731)**	**22,662,761**

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

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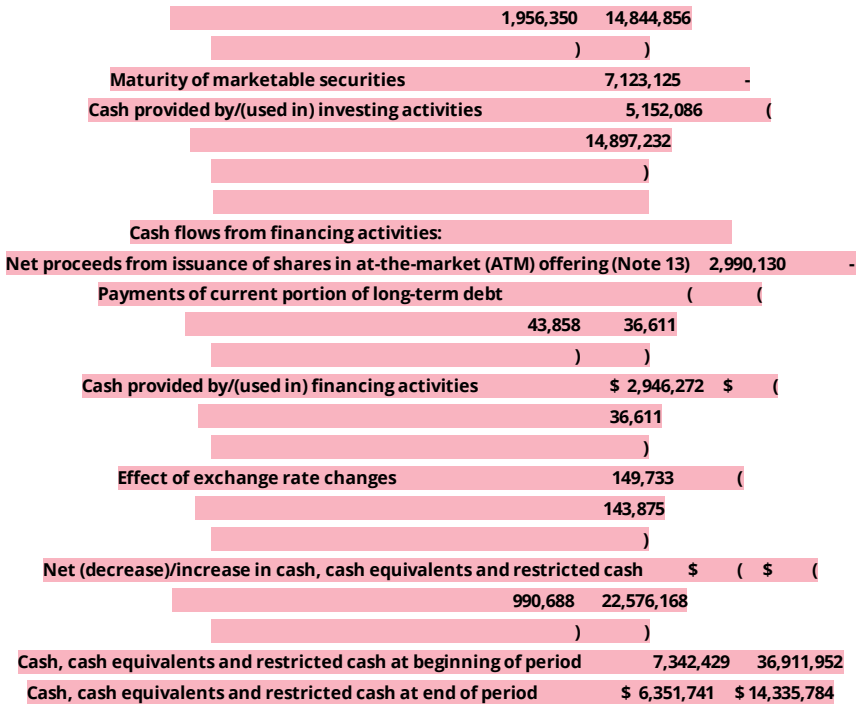
GAIN THERAPEUTICS, INC.

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	(	(



	Nine Months Ended September 30,	
	2023	2022
Operating activities:		
Net loss	$ (17,543,551)	$ (12,916,272)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	59,990	46,058
Stock-based compensation expense	2,703,967	967,742
Other non-cash items	(247,491)	(65,894)
Changes in operating assets and liabilities:		
Prepaid expenses and other currents assets	32,069	(385,568)
Other non-current assets	(7,051)	152,351
Accounts payable and other liabilities	333,622	1,533,555
Defined benefit pension plan	(762)	88,237
Deferred income	1,463,713	(207,735)
Total changes in operating assets and liabilities	1,821,591	1,180,840
Cash used in operating activities	(13,205,494)	(10,787,526)
Cash flows from investing activities:		
Purchase of property and equipment and internal use of software	(15,339)	(109,555)
Purchases of marketable securities	(1,956,350)	(15,804,035)
Maturity of marketable securities	9,052,500	1,004,947
Cash provided by/(used in) investing activities	7,080,811	(14,908,643)
Cash flows from financing activities:		
Net proceeds from issuance of shares in at-the-market (ATM) offering (Note 13)	3,147,233	—
Payments of current portion of long-term debt	(66,488)	(57,192)

Cash provided by/(used in) financing activities	$ 3,080,745	$ (57,192)
Effect of exchange rate changes	5,155	(249,848)
Net (decrease)/increase in cash, cash equivalents and restricted cash	$ (3,038,783)	$ (26,003,209)
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	$ 4,303,646	$ 10,908,743

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

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GAIN THERAPEUTICS, INC.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

1. Nature of the Business and Basis of Presentation

Operations and Business

Gain Therapeutics, Inc. (together with its subsidiary, the "Company" "Company"), was incorporated under the laws of the state of Delaware (U.S.) on June 26 :1 10:1 stock split. The corporate reorganization was accounted for as a recapitalization for accounting purposes, resulting in GT Gain Therapeutics SA becoming the

On March 17, 2021, the Company's Company's registration statement on Form S-1 related to its Initial Public Offering ("IPO" initial public offering ("IPO") wa -for-1. 1-for-1.

The Company is a biotechnology company developing novel small molecule therapeutics to treat diseases across several therapeutic areas, including centr

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 assc

Basis of Presentation

The accompanying unaudited interim condensed financial statements (the "interim "interim financial statements" statements") reflect the accounts of Gair

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The interim financial statements have been prepared on the same basis as applied for the audited annual consolidated financial statements as of and for t

The results for the periods ended June 30, 2023 September 30, 2023 and 2022 are not necessarily indicative of the results to be expected for the year ending

The accompanying interim financial statements reflect the application of significant accounting policies as described below and elsewhere in these notes to 30, 2023 September 30, 2023, the Company's 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 Company's ab

The Company has incurred recurring losses and negative cash flows from operations since its inception and has primarily funded these losses through the

The Company's Company's activities have consisted primarily of organizing and staffing the Company, expanding its operations, securing financing, acquiri
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 commercializatio n 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.

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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 "Disclosure of Uncertainties about an Entity's Entity's Ability to Continue as a Going Concern" Concern", the Accordingly, statements are issued. Because of the consolidated current liquidity situation and lack of expected revenues in the foreseeable future substantial doub

The Company will need to raise additional capital to fund continued operations beyond the third quarter of 2024.

Management plans to raise additional capital primarily through private and/or public equity financings and/or convertible debt financings. As an additiona

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the Company's overall cash burn rate and reducing the research and development expenses and general and administrative expenses. Furthermore, management

The Company may not be successful in its efforts to raise additional funds or achieve profitable operations. The Company continues to explore potential o

If the Company is unable to obtain additional funding to support its current or proposed activities and operations, it may not be able to continue its opera

The future success of the Company is dependent on its ability to raise additional capital and ultimately, upon its ability to develop future profitable operati

The accompanying financial statements have been prepared assuming on a going concern basis which contemplates the realization of assets and the settl

Segment information

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating d

2. Summary of Significant Accounting Policies

Foreign Currency Transactions

The Company is incorporated in the United States of America and has operations in Switzerland, Spain and Spain. Australia. The Company's Company's fun
216,628 a gain of $143,582 and $
158,576
.
$158,576, respectively.

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Use of Estimates

The preparation of the Company's Company's consolidated financial statements in conformity with US GAAP requires management to make estimates, juc

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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

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 requirem

Marketable securities are classified as available-for-sale since the Company does not have the positive intent and the capacity to hold the marketable secu

Marketable securities are classified in the Company's Company's balance sheet based on their maturities and the Company's Company's reasonable expec

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. Finar

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 d

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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

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

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- 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 mai

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 develop 205 $189 thousand and $ 214 $214 thousand, respectively, and refer to the external and internal costs incurred in the development of the Company's Company's enterprise resource planni

The Company amortizes the capitalized software development costs on a straight-line basis over the estimated useful life of the software, which is generall , beginning when the asset is substantially ready for use. The amortization of capitalized software development costs is reflected in general and administrative exp 2023 September 30, 2023 and 2022 was $ 21 $34 thousand and $ 15 $27 thousand, respectively.

Impairment of Long-lived Assets

In accordance with ASC Topic 360-10-20, "Property, "Property, Plant and Equipment," " the Company performs an impairment test whenever events or circ

Patents

Patent-related costs, refer to legal fees incurred in connection with filing and prosecuting patent applications and are expensed as incurred due to uncerta

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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 cont

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; c

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Payables for Social Security Charges

Social security charges are reported in compliance with rules and laws applicable in the countries where Company the Company's employees work. Charge

Accrued Expenses

As part of the process of preparing the Company's Company's consolidated financial statements, the Company is required to estimate its accrued expense

Pension Obligations

The Company operates defined benefit pension plan and defined contribution pension plans in accordance with local regulations and practices in the cour

For defined contribution pension plans, the Company pays contributions to publicly or privately administered pension insurance plans on a mandatory, c

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Stock-based Compensation and Warrants

The Company issues stock-based compensation with service-based, performance-base
d performance-based and market-based vesting conditions. The Company applies the fair value method of measuring equity-based compensation and warrants, w

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 volatil

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The Company recognizes expenses related to Restricted Stock Units (or RSUs) based on their fair market value, determined as the closing price on Nasdaq

The Black-Scholes option pricing model is also used for the warrants issued, using consistent inputs and methodology to quantify such inputs, as describe

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

Revenue Recognition

The Company derives limited revenue from its collaboration and licensing agreements. The Company recognizes revenue related to these agreements in a
"Revenues from Contracts with Customers" Customers" and ASC 808, "
"Collaborative Arrangements"
Arrangements". The terms of these arrangements typically include payment from third-party customers of one or more of the following: non-refundable initiation f

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) ide

Costs and revenues associated with collaborative arrangements are reported in the consolidated statements of operations on a gross basis when the cour

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Research grants

Grants

Under the terms of the research and development grants awarded, the Company is entitled to receive reimbursement of its allowable direct expenses and

Research and Development Expenses

The Company expenses all costs incurred in performing research and development activities. Research and development expenses include salaries and oth

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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 Compa

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

As of each reporting date, the Company considers existing evidence, both positive and negative, that could impact its view with regard to future realizatior

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 ma

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 -

- 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
- Level 3 – Inputs that are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in p

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Table 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.

Contents

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inp

Comprehensive income/(loss)

Comprehensive income/(loss) is composed of net income/(loss) and certain changes in stockholder's stockholder's equity that are excluded from the net ir

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

Table of Contents losses since inception, these potential impacts would be anti-dilutive, and therefore, common stock equivalents have been excluded from the co

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"("FASB") or other standard setting bodies that the Company adopts as of the specified effective date. There were no newaccounting pronouncements effec

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

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 equivalen

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

	September 30, 2023	December 31, 2022
Cash	3,771,956	2,910,446
Money market	500,545	4,401,165
Total cash and cash equivalents	$ 4,272,501	$ 7,311,611
Restricted cash	$ 31,145	$ 30,818

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

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4. Marketable Securities

As of June 30, 2023 September 30, 2023, the Company reports $ 9.9 million $7.9 million of marketable securities within current assets, related to United States Treasury Securities ("USTS" ("USTS"). The USTS purchased have maturity d 1.0 million $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 valu

The following table summarizes the Company's Company's investment in available-for-sale marketable securities with the detail of the unrealized gains /los

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

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	September 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	7,982,552	—	—	(22,241)	7,960,311
Totals	**$ 7,982,552**	**$ —**	**$ —**	**$ (22,241)**	**$ 7,960,311**

As of June 30, 2023 September 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 n risks associated with specific securities. rates. Accordingly, as of June 30, 2023 September 30, 2023, the Company has not recorded an allowance for credit losses rela

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

	September 30, 2023	**December 31, 2022**

Tax credits	101,911	103,877
Prepaid and deferred expenses	616,333	552,882
Other receivables	—	87,430
Prepaid D&O insurance costs	290,501	208,542
Total prepaid expenses and other current assets	$ 906,834	$ 848,854

Tax credits consist of a value added tax credit ("VAT" ("VAT"), which is an indirect tax receivable from Swiss and Spanish tax authorities on purchases of goo

Prepaid expenses refers to pre-payments made to the Company's Company's vendors for future services. Deferred expenses mainly refer to research agre

Prepaid D&O insurance costs relate to an annual insurance premium which will be recognized in the statement of operations on a monthly basis througho

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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

	September 30, 2023	December 31, 2022
Computer	$ 80,110	$ 71,774
Furniture and fixtures	58,152	57,603
Leasehold improvements	31,583	31,437
Laboratory instruments	36,432	36,894
Total property and equipment	$ 206,277	$ 197,708
Less: accumulated depreciation	(78,884)	(53,329)
Property and equipment, net	$ 127,393	$ 144,379

Property and equipment consist of computers, furniture and fixtures, lab instruments. No disposals, nor impairments occurred during the periods. Deprec

17,139 $26,050 and $

11,504
, $18,860, respectively.

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

The Company's Company's leased assets include offices in Bethesda, Maryland, Lugano, Switzerland and Barcelona, Spain and a lab in Barcelona, Spain. The
, years. Renewal options are excluded from the calculation of lease liabilities since the Company is not reasonably 20
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certain that will exercise the renewal option. The Company's Company's lease agreements do not contain residual value guarantees or material restrictive covenant

The breakdown of the significant components of ROU assets, lease liabilities and operating lease expense is reported in the table below, together with the

	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

	September 30, 2023	December 31, 2022
Operating Lease		
Operating lease- right of use assets	$ 490,759	$ 659,933
Operating lease liability - current	$ 231,164	$ 229,080
Operating lease liability - non-current	$ 263,460	$ 441,784
Weighted average remaining lease term - years	2.45	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

	September 30, 2023	September 30, 2022
Operating lease costs	$ 183,976	$ 170,241

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

Fiscal Year	Operating Leases
September 30, 2024	242,287
September 30, 2025	170,404
September 30, 2026	85,785
September 30, 2027	4,955
Total future minimum lease payments	503,431
Less amount representing interest or imputed interest	8,807
Present value of lease liabilities	$ 494,624

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 September 30, 2 0.9 million $1.4 million and $ 1.6 million, $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 September 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

	September 30, 2023	December 31, 2022
Payable for social security and withholding taxes	$ 342,442	$ 256,798
Accrued payroll	944,838	660,556
Accrued expenses	1,336,050	1,082,091
Tax provision	69,257	107,311
Total other current liabilities	$ 2,692,587	$ 2,106,756
Deferred income	1,353,541	55,180
Total other current liabilities and deferred income	$ 4,046,128	$ 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 Res

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

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10. Pension Obligations

Net pension obligation related to the Company's Company's defined pension plan refers only to Swiss employees and as of June 30, 2023 September 30, 20

	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	(1,478)	5,726
Change in accumulated other comprehensive income	(227,131)	1,370
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

	September 30, 2023	December 31, 2022
Reconciliation of funded status:		
Funded status beginning of period	$ (157,580)	$ (329,458)
Expense	(111,457)	(179,924)
Employer contribution	111,320	123,193
Translation differences	(783)	1,478
Change in accumulated other comprehensive income	(2,012)	227,131
Funded status at end of period	$ (160,512)	$ (157,580)
Component of net periodic pension costs:		
Service cost	$ 107,917	$ 169,709
Interest cost	14,381	3,376
Expected return on plan assets	(8,800)	(9,000)
Amortization of (gain)/losses	—	16,753
Amortization of prior service cost	(2,041)	(914)
Total	$ 111,457	$ 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 consol

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 du , 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 an

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

		September, 30					
	Total	2024	2025	2026	2027	2028	Thereafter
Loan	$ 544,219	109,281	87,425	87,425	87,425	87,425	85,238

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 advantageo

The carrying amounts of the Company's Company's cash and cash equivalents, including money market funds, restricted cash and financial liabilities are con

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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 hie

	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	12,826,954	-	-

treasury securities, current			
Debt securities - U.S. government	1,941,488	-	-
treasury securities, non-current			
Total marketable securities	$ 14,768,442	-	-
available for sale			
Cash			
equivalents:			
Money market	4,401,165	-	-
funds			
Total cash	$ 4,401,165	-	-
equivalents			
Total financial	$ 19,169,607	-	-
assets			

	Fair value measurement at reporting date		
	Quoted prices in active market for identical assets (level 1)	Significant other observable inputs (level 2)	Sign
September 30, 2023:			
Assets			
Marketable securities available for sale			
Debt securities - U.S. government treasury securities, current	7,960,311	—	
Debt securities - U.S. government treasury securities, non-current	—	—	
Total marketable securities available for sale	$ 7,960,311	—	
Cash equivalents:			
Money market funds	500,545	—	
Total cash equivalents	$ 500,545	—	
Total financial assets	$ 8,460,856	—	
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

13. Common and Preferred Stock

As of June 30, 2023 September 30, 2023 and December 31, 2022, the authorized capital stock of the Company included 50,000,000 shares of common stock, 0.0001 $0.0001 par value and 10,000,000 shares of preferred stock, $ 0.0001 $0.0001 par value. As of June 30, 2023 September 30, 2023 and December 31, 2022, there were 12,632,327 12,782,861 and 11,883,368 shares of common stock 0.0001 $0.0001 par value, issued and outstanding.

In May 2022, the Company entered into a Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald, Inc. ("Cantor" (“Cantor”), pursuant to which the Cor 16.0 million $16.0 million (the "ATM Program" “ATM Program”). Sales under the ATM Program are made by any method permitted by law that is deemed to be an "at “at

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stock under the ATM Program at an average selling price of $ 4.86 $4.80 per share for aggregate gross proceeds of $ 3.3 million $3.5 million (of which $ 0.3 million $0.4 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 “2020 Omnibus Plan" Plan”). The 2020 Omnibus Plan provided for t . 1,153,827.

On December 23, 2021, the Board adopted the Inducement Equity Incentive Plan (the "2021 “2021 Inducement Equity Incentive Plan" Plan”) intended to inc . 1,000,000.

The Company's Company’s 2022 Equity Incentive Plan (the "2022 Plan" “2022 Plan”) was approved by the Board on May 12, 2022. On June 16, 2022, at the C . 1,800,000.

On January 1, 2023, the number of shares of common stock issued under the 2022 Plan, increased automatically by 6 % 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 sto . 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. Th

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Stock Option Grants

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

		Weighted Average Grant Date	Weighted Average
	Shares	Fair Value	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

	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 September 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 Septembe

	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	-	-

	Nine Months Ended September 30,	
	2023	2022
Grant date fair value	$ 3.40	$ 2.49
Volatility	77 %	80 %
Expected term (years)	6.60	5.24
Risk-free interest rate	3.49	3.38
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 Company's RSUs and PRSUs activity for the six nine months ended June 30, 2023 September 30, 2023:

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

	Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2022	303,050	$ 1.18
Granted	362,500	4.41
Vested	(159,362)	4.07
Cancelled/forfeited	—	—
Outstanding as of September 30, 2023	506,188	$ 2.59

In December 2021, the Compensation Committee of the Board approved 200,000 awards of performance-based restricted stock units ("PRSUs" ("PRSUs") to
1.1
million, $1.1 million, using the closing price of the Company's 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" ("PRSUs") to an e
25

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services, financing and business development performance and market criteria. The grant date fair value for the PRSUs with financing and business development p

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 Cor

	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

	Three Months Ended September 30		Nine Months Ended September 30	
	2023	2022	2023	2022
Research and development	250,462	167,929	660,220	431,222
General and administrative	565,539	187,718	2,043,747	536,520
Total stock-based compensation	$ 816,001	$ 355,647	$ 2,703,967	$ 967,742

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 spl
5.07 $5.07 per share, valued in the aggregate at $
413,887
. $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 inves
13.75 $13.75 per share, valued in the aggregate at $
1.0
million. $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

16. Collaboration Agreement

On April 20, 2021, the Company entered into a multi-target collaboration agreement (the "Zentalis "Zentalis Collaboration Agreement" Agreement") with Ze

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 cor

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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 following table sets forth the outstanding weighted-average potentially dilutive securities that have been excluded from the calculation of diluted net l

	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

	Three Months Ended September 30		Nine Months Ended September 30	
	2023	2022	2023	2022
Options to purchase common stock	2,599,751	1,505,562	2,349,432	1,221,021
RSUs, PRSUs	565,024	238,839	498,463	213,088
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 Company's Board, shareholder and founder of the Company, is currently the Chairman of the Board of Dir

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).

- 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 mole
- 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

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

19. Commitments

As of June 30, 2023 September 30, 2023, the Company had research commitments for $
2.1
million $4.6 million for activities that will be performed before the end of Q2 2024.

27
within one year.

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Item 2. Management's 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

Overview

We are a biotechnology company developing novel small molecule therapeutics to treat diseases across several therapeutic areas, including central nervou

We have generated an extensive preclinical data package providing evidence of the mechanism of action and effect of our lead product candidate GT-0228 , 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, September 2023, we submitted received approval from the application Bellberry Human Research Ethics Committee (HREC) to conduct half of 2023. Australia. The Phase 1 clinical trial will is intended to evaluate the administration of both single and multiple ascending dose levels of GT-02287 in healt additional programs targeting allosteric binding sites identified with the SEE-Tx(R) platform second dose level. No drug-related adverse effects have been observed academic partnerships, co-development and licensing arrangements, we intend to develop a broad pipeline the first half of therapeutics, using our novel approach of identifying and targeting previously unknown allosteric sites. 2024.

In response to the current financing environment, we continue to streamline our operational plans to become more capital efficient and remain opportun computational SEE-Tx(R) drug discovery platform to protein targets of interest to collaboration partners. programs. In addition, we expect to continue to develop our alpha-1 antitrypsin deficiency program and our oncology programs while se

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We continue to monitor the impacts on our operations and access to financing of global and worsening macroeconomic conditions, such as the war in Ukr

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inflation and rising interest rates, exchange rate fluctuations, supply chain disruptions, liquidity concerns at and failures of banks and other financial institutions ar

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 mo

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, includi 2023 September 30, 2023, we have raised an aggregate of $63 million of gross proceeds through equity financings, including the issuance of convertible preferred st

As of June 30, 2023 September 30, 2023, we had cash, cash equivalents and marketable securities of $16.2 million $12.3 million. We have incurred recurring lo

Going Concern

As of September 30, 2023 and December 31, 2022, we had an accumulated deficit of $56 million and $38.5 million, respectively, and as of September 30, 202

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future capital and potential cost-reduction measures. Investors should read the section below titled “Liquidity and Capital Resources” for additional information re

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 ne

The war in Ukraine, the conflict between Hamas and Israel, global geopolitical tension, and the post COVID-19 environment continue to have unpredictable Requirements" “—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-

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 a

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

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

- expenses incurred under collaborations with third parties, including contract research organizations (“CROs”) and Universities, that conduct research,

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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.

manufacturing and control materials, process characterization, scale-up and transfer, clinical trial expenses, on our behalf;

- employee salaries, benefits and other related costs, including share-based compensation expenses, for employees engaged in research and developm
- 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 mar

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 $

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Preclinical activities, clinical activities and outside services	1,316,741 $	1,183,325 $	5,664,401 $	3,699,574 $
Personnel expenses	1,051,710	750,243	3,154,579	2,293,455
Other	148,966	64,529	535,323	211,868
Research grants	(149,935)	(33,313)	(207,673)	(101,449)
Total research and development expenses	2,367,482 $	1,964,784 $	9,146,630 $	6,103,448 $

We recognize research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completio

Our primary research and development focus since inception has been the application of our in-licensed SEE-Tx(R) SEE-Tx® platform to various indications

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally incur higher de

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries, bonus and other related costs, including share-based compensation, for personnel in ou

We anticipate that will continue to focus on preserving 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 liquidity resources while we increase our headcount seek to support the expected gro additional personnel and the potential commercialization of our product candidates. We also maximize shareholder's value, we 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.
continue the efforts started during the current quarter to limit administrative expenses.

Other Financial Income (Expense)

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

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Consolidated Results of Operations

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Increase (Decrease)	2023	2022	Increase (Decrease)
Revenues:						
Collaboration agreements	—	—	—	55,180	132,640	(77,460)
Other income	—	—	—	—	7,468	(7,468)
Total revenues	$ —	$ —	$ —	$ 55,180	$ 140,108	$ (84,928)
Operating expenses:						
Research and development	(2,367,482)	(1,964,784)	402,698	(9,146,630)	(6,103,448)	3,043,182
General and administrative	(2,517,523)	(2,786,200)	(268,677)	(8,754,453)	(7,252,506)	1,501,947
Total operating expenses	(4,885,005)	(4,750,984)	134,021	(17,901,083)	(13,355,954)	4,545,129
Loss from operations	$ (4,885,005)	$ (4,750,984)	$ 134,021	$ (17,845,903)	$ (13,215,846)	$ 4,630,057
Interest income, net	106,000	153,332	(47,332)	387,964	211,580	176,384
Foreign exchange gain/(loss), net	82,198	43,491	38,707	(20,839)	102,865	(123,704)
Loss before income tax	$ (4,696,807)	$ (4,554,161)	$ 142,646	$ (17,478,778)	$ (12,901,401)	$ 4,577,377
Income tax	(21,456)	(4,048)	17,408	(64,773)	(14,871)	49,902
Net loss	$ (4,718,263)	$ (4,558,209)	$ 160,054	$ (17,543,551)	$ (12,916,272)	$ 4,627,279
Net loss per ordinary share:						
Basic and diluted loss per share	(0.37)	(0.38)	(0.01)	(1.42)	(1.09)	0.33
Weighted-average ordinary shares used in per share calculations – basic and diluted	12,701,401	11,883,368		12,342,031	11,883,368	

Comparison of the Three Months ended June 30, 2023 Ended September 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 $0.4 million to $4.0 million $2.4 million for the three months ended June 30, 2023 September

General and Administrative Expenses

General and administrative expenses decreased by $0.3 million to $2.5 million for the three months ended September 30, 2023 as compared to $2.8 million

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Comparison of the Nine Months Ended September 30, 2023 and 2022

Revenues

For the nine months ended September 30, 2023 and 2022, total revenues were $55 thousand and $140 thousand, respectively, and consisted mainly of inc

Research and Development Expenses

Research and development expenses increased by $3 million to $9 million for the nine months ended September 30, 2023 as compared to $6 million for the

General and Administrative Expenses

General and administrative expenses increased by $1.0 million $1.5 million to $3.7 million $8.7 million for the three nine months ended June 30, 2023 Septem

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 $0.4 million for the six nine months ended June 30, 2023 September 30, 2023 as compared to $0

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 o

As of June 30, 2023 September 30, 2023, and December 31, 2022, we had $16.2 million $12.3 million and $22.1 million $22.1 million in cash and cash equivalents and marketable securities, respectively, and an accumulated deficit of $51.3 million $56 million and $38.5 million, r
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had indebtedness of $0.58 million $0.54 million and $0.60 million as of June 30, 2023 September 30, 2023 and December 31, 2022, respectively. We believe that our ex
expenses and capital expenditure requirements. requirements through the third quarter of 2024. There is substantial doubt about our ability to continue as a goir

Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or to achieve profit

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

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currently subject to General Instruction I.B.6 to Form S-3 (the "Baby "Baby Shelf Rule" Rule"), and the amount of funds we can raise through primary public offerings

In May 2022, we entered into a Controlled Equity Offerings℠ Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to whi
2023 September 30, 2023, we sold an aggregate of 681,559 740,131 shares of common stock at an average price of $4.86 $4.80 per share, raising gross proceeds of $3

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 ne

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operatio

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
product candidates even if we would otherwise prefer to develop and market
such product candidates ourselves.
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seek relief under applicable bankruptcy laws.

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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)

	Nine Months Ended September 30,	
	2023	2022
Cash used in operating activities	$ (13,205,494)	$ (10,787,526)
Cash (used in)/provided by investing activities	7,080,811	(14,908,643)
Cash (used in)/provided by financing activities	3,080,745	(57,192)
Effect of exchange rate changes	5,155	(249,848)
Net (decrease)/increase in cash, cash equivalents and restricted cash	$ (3,038,783)	$ (26,003,209)

Cash Flows from Operating Activities

During the six nine months ended June 30, 2023 September 30, 2023 and 2022, we used $9.2 million $13.2 million and $7.5 million $10.8 million of cash, respe

Cash Flows from Investing Activities

During the six nine months ended June 30, 2023 September 30, 2023, net cash provided by investing activities was $5.0 million $7.1 million primarily due to r

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

Cash Flows from Financing Activities

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

During the six nine months ended June 30, 2022 September 30, 2022, cash used in financing activities was approximately $40 $57 thousand, related to the p

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

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable

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;

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- 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 candidate

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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.

- the extent to which we encounter increased costs as a result of global and macroeconomic conditions, including heightened inflation and rising interes
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual
- 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 ou
- 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 dev

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, de

Critical Accounting Policies and Use of Estimates

Our management's management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial stat

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JOBS Act

We qualify as an "emerging "emerging growth company" company", as defined in the JOBS Act. For so long as we remain an emerging growth company, we

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure "disclosure controls and procedures," " as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to er

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

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

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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 oc

PART II-OTHER 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 materia

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 th

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 dis

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

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- there is substantial doubt about our ability to continue as a going concern. We have a history of operating losses and expect to incur losses for the foreseeab
- 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 ma
- 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 m
- 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 fo
- our product candidates are novel and still in development. If we are unable to successfully develop, receive regulatory approval for and commercialize our cu
- we have just started testing one of our product candidates in clinical trials . Success in early preclinical studies or clinical trials may not be indicative of results
- 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 technol

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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.

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 commercializ

- 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 right
- we are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privac
- global and macroeconomic conditions, including worldwide economic, political and social instability could adversely affect our revenue, financial condition, o

Risks Related to Our Business

There is substantial doubt about our ability to continue as a going concern. We have a history of operating losses and expect to incur losses for the foreseeabl

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 operati

We plan to raise additional capital primarily through private equity financings and/or convertible debt financings. However, financing may not be available

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 rapidl

The process of developing our product candidates requires significant time, effort and expenses in preclinical, clinical and regulatory development. In addit

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research and development expenses will continue to increase in the foreseeable future as we (i) increase personnel costs, including stock-based compensation, (ii)

The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenu

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successfully commercializing our products; establishing a favorable competitive position; and raising sufficient funds to finance our activities. Many of these factors

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

We are a preclinical an early clinical stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited t 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 suc

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 obtain additional funding to develop our product candidates, the extent to which we are able to obtain such funding on favorable terms,
- 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 d

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.

- 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 and the conflict between Hama
- the impact of other global and macroeconomic conditions, including heightened inflation and rising interest rates, liquidity concerns at and failures of
- 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

We expect to complete the preclinical development and submit the regulatory dossier to the Human Research Ethics Committee in Australia to initiate are currently conducting a first-in-human Phase 1 clinical trial in our Parkinson's Parkinson'

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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.

- 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 sufficient

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 n

We rely and expect to continue to rely on third parties, including contract research organizations ("CROs" ("CROs") and outside consultants, to conduct, sup

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.

- 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 nu

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

- 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;

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

- 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 cl
- 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 c

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

Genetically defined disorders generally, and especially those for which our current product candidates are targeted, have low incidence and prevalence. We

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.

- 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 t

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 fr

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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

Our product candidates are novel and still in development. If we are unable to successfully develop, receive regulatory approval for and commercialize our cu

Because the SEE-Tx(R) SEE-Tx® platform remains untested and our product candidates are in early stages of development, they will require extensive precl

Table of Contents viable drugs for any of several reasons. For example, we may fail to identify appropriate targets or compounds, our product candidates may fail t

Further, we and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing

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

Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage de

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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 diseas

Table of Contents successfully complete IND-enabling and GLP-compliant preclinical studies, and the effectiveness of our platform. The scientific discoveries that fc

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that n

Because we have limited financial and human resources, we are currently focusing primarily on development of our Parkinson's Parkinson's and Gaucher d

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 ef

Our clinical trials may be conducted in patients with neurodegenerative diseases, and in some cases, our product candidates are expected to be used in co

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The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and

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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 c

We are not yet a clinical stage company and our

Our success is dependent upon our ability to initiate and successfully complete clinical trials and obtain regulatory approval for and commercialization of o

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.

- 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,

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 addi

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 GL

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

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storage, approval, advertising, promotion, sale, distribution, import and export of biopharmaceutical products. If products employing our technologies are market

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whether or not they have obtained the FDA's FDA's or comparable foreign regulatory authorities' authorities' approval for a given product and its uses. Such foreig

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling our products. The regulatory review

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

If we, our collaborators, or our manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such nonc

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

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

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 associat

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. Regulato

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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. Opportuniti

Table of Contents 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

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 thes

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 orpha

Orphan medicinal product designation, entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the central

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

Orphan Drug Designation in the United States, or orphan medicinal product designation the EU, neither shortens the development time or regulatory revie

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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 FDA's

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

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory a

Our product candidates may cause serious adverse events ("SAEs" ("SAEs") or undesirable side effects which may delay or prevent marketing approval, or, if ap

SAEs or undesirable side effects from our product candidates could arise either during development or, if approved, after the approved product has been

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 impose a clinical hold or REMS, or comparable foreign regulatory strategies, which could result in substantial delays, signific
- regulatory authorities may require the addition of statements, specific warnings, or contraindications to the product label, or restrict the product's ind
- we may be required to change the way the product is administered or conduct additional clinical trials;
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- 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;

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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.

- 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 commercial

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 c

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of

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 o

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;

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects (including drowsiness and dry mouth), as compared to alte
- 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;

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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.

- reimbursement policies of government and third-party payors, and the willingness of patients to pay out of pocket in the absence of adequate third-p
- 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, th

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 technolo

To develop and bring our product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical studies

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.

- 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
- 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 profit

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vary materially from those now planned because of changes in direction of our research and development programs, competitive and technical advances, patent c

We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical studies and clinical

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 remain

We face intense competition in the markets targeted by our product candidates. Many of our competitors have substantially greater resources than we do, an

We expect that all of our product candidates under development, if approved, will face intense competition from existing and future drugs marketed by lar

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 ca

In the EU, following grant of a related marketing authorization, innovative medicinal products generally benefit from eight years of data exclusivity and ten

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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

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would

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 pharma

Other companies may succeed in developing products earlier than us, obtaining FDA or comparable foreign regulatory authority approval for products mo

We may not be able to obtain marketplace acceptance for any of our product candidates as readily as these or other competing treatments. Furthermore,

The pharmaceutical research industry is diverse, complex, and rapidly changing, and inherently involves significant and numerous business risks. The effec

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, c

The COVID-19 pandemic and the resulting post-pandemic environment has impacted clinical site activation and patient enrollment. Clinical trial sites have c

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enrollment and delayed site initiations across the industry. Our inability to successfully recruit and retain patients and principal investigators and site staff could ac

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 right

We are significantly dependent upon our license with Minoryx Therapeutics S.L. (the "Minoryx License" "Minoryx License"), as described in the section "Bus

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 is

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 ac

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 c

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treatments that prove successful as a matter of public policy regarding worldwide health concerns; and countries other than the United States may have less robus

Moreover, any patents issued to us may not provide us with meaningful protection, or others may challenge, circumvent or narrow our patents. Third part

In addition, the PTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology

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

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to

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

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 e

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Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. Third parties may assert that our

Third parties may also assert that our patents are invalid in patent office administrative proceedings. These proceedings include oppositions in the Europe

Interference or derivation proceedings brought before the PTO may be necessary to determine priority of inventions disclosed in our patents or patent ap

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference or derivation proc

Also, a third party may assert that our patents are invalid or unenforceable. There are not currently any unresolved communications, allegations, complain

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 ha

In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, ther

We have licensed all of the rights, assets and technology related to the SEE-Tx(R) SEE-Tx® platform from Minoryx and we believe that they owned all of suc

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seeking to enjoin commercial activities relating to our SEE-Tx(R) SEE-Tx® platform or our processes could subject us to potential liability for damages and require us

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 l

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 thei

We and our CROs are required to comply with the FDA's FDA's Good Clinical Practices ("GCPs" ("GCPs") and foreign equivalents for conducting, recording an

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

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 d

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 pro

We have no manufacturing facilities and we intend to rely on third-party contract manufacturing organizations ("CMOs" ("CMOs") to manufacture some or

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candidates are approved, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to mar

We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate

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 ot

Failure by our third-party manufacturers to comply with the regulatory guidelines set forth by the FDA or comparable foreign regulatory authorities with resp

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

We may be in competition with other companies for access to these manufacturers' manufacturers' facilities and may be subject to delays in manufacture i

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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 a

Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the Drug Enforcement Administration ("DEA" ("DEA") and corres

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

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 a

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 marke

Our strategy for our product candidates is to control, directly or through contracted third parties, all or most aspects of the product development process,

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

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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' patients' medical expenses by government health care programs and p

Our business strategy might involve out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharma

We, as a company, have no experience in marketing or selling pharmaceutical products and currently have no sales, marketing, or distribution infrastructu

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

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 cand

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

We face a number of risks in connection with our current and future collaborations. Our collaboration agreements are subject to termination under variou

General Risk Factors

We previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future o

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the E

For example, in our IPO, we previously disclosed material weaknesses relating to the following: (1) lack of sufficient accounting and supervisory personnel v

While we believe the remediation efforts both addressed the identified material weaknesses and also enhanced our overall financial control environment,

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

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit avai

Our general business strategy, as well as our suppliers' suppliers' ability to provide us with raw materials and components, may be adversely affected by ar

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 proc

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.

- 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 dire
- 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.

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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 ser

Because of the specialized nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personne

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

To incentivize valuable employees to join and remain at our company, in addition to salary and other employee benefits, we have provided stock option a

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 b

Our employment arrangements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from

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 re

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse law

Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any pro

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future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and st

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.

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among oth
- HIPAA, which created new federal criminal statutes that prohibit a person from, among other things, knowingly and willfully executing a scheme or ma
- HIPAA, as amended by HITECH and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the Patient Protection and Affordable Care Act ("ACA

- state and foreign law equivalents of each of the above federal laws, state laws and foreign law equivalents that require manufacturers to report inform
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in signi

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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 ac

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case la

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

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 profi

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for

Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceiling

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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

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

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stat

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions to Medicare payments to providers

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescrip

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pharmaceutical industry. In addition, in response to the Biden administration's administration's October 2022 executive order, on February 14, 2023, HHS released

In addition, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to cor

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 additi

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 an

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could

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

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;

- 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 busir

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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.

- 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
- business interruptions resulting from geopolitical actions, including war (such as Russia's invasion of Ukraine and the conflict between Hamas and Isra
- 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-comp

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. (s) § 201, the

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, vari

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

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

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

decreased demand for any product candidates that we may develop;

injury to our reputation and significant negative media attention;

initiation of investigations by regulators;

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

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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.

- 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 cl

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies, contractual and other obligations related

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, enacted These new comprehensive data privacy laws including Virginia, Colorado, Connecticut (including the CCPA) and Utah, all individuals' exercise of which became or will become effective in 2023. their rights under these laws may impact our business and ability to provide our products

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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 Europea

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Kingdom GDPR (UK GDPR) (collectively, GDPR) impose strict requirements for processing personal information, and violators of these laws face significant penalties 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. Euro

Our employees and personnel may use generative artificial intelligence ("AI" ("AI") technologies to perform their work, and the disclosure and use of persor

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to s

Furthermore, we publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory princ

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Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creati

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Table of Contents and practices and to those of any third parties that process personal information on our behalf. Although we endeavor to comply with all applica

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 f

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequer

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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 i

Cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities are prevalent and continue to increase. These thre

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 th

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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 exam

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Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize netwo

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and otl

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could resul

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certa

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 ident

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the di

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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 suf

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 pharmaceutic

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;

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- results from, and any delays in our preclinical studies and any other future clinical development programs, including any delays related to the health e
- actual or anticipated changes in estimates as to financial results, development timelines and other company milestones or recommendations by secu
- 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
- 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;

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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.

- 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 fluct
- the impact of political instability, natural disasters, events of terrorism and/or war, such as the war in Ukraine and the conflict between Hamas and Isra
- 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 i

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 requirement

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.

- 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, p
- 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 t

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, ac

While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued b

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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 finan

We are an "emerging "emerging growth company," " and the reduced reporting requirements applicable to emerging growth companies may make our commo

We qualify as an "emerging "emerging growth company," " as defined in the JOBS Act. For so long as we remain an emerging growth company, we are perm

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

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. M

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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

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

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

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

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

We also expect that significant additional capital may be needed in the future to continue our research and development activities and costs associated wi

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 dir

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If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely

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 busine

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

Our amended and restated certificate of incorporation (the "Amended Charter" "Amended Charter") and amended and restated bylaws (the "Amended By

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.

- allow us to authorize the issuance of undesignated preferred stock in connection with a stockholder rights plan or otherwise, the terms of which may b
- 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 l

- establish advance notice requirements for nominations for elections to our board of directors or for proposing matters that can be acted upon by sto

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

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

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 a

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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 direc

Provisions in our organizational documents regarding exculpation and indemnification of our directors and officers may result in substantial expenditures by

Our Amended Charter and Amended Bylaws provide for the elimination, to the maximum extent permissible under Delaware law, of the personal liability o

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 cor

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 pers

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 pursua

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

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Item 6. Exhibits.

		Incorporated by Reference			
Exhibit No.	Exhibit Description	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)**

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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

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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 undersigne

GAIN THERAPEUTICS, INC.
(Registrant)

August 10, 2023 /s/

	GAIN THERAPEUTICS, INC. (Registrant)
November 14, 2023 Date	/s/ Matthias Alder Matthias Alder Chief Executive Officer *(Principal Executive Officer)*
November 14, 2023 Date	/s/ C. Evan Ballantyne C. Evan Ballantyne Chief Financial Officer *(Principal Financial Officer)*
November 14, 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 Therapeutic**

WITNESSETH THAT:

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors and/or officers or in other capacities u

WHEREAS, the Board of Directors of the Company (the "**Board**") has determined that, in order to attract and retain qualified individuals, the

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

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses o

WHEREAS, this Agreement is a supplement to and in furtherance of the Bylaws and Certificate of Incorporation of the Company and any res

WHEREAS, Indemnitee does not regard the protection available under the Company's Bylaws and Certificate of Incorporation and insurance

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

1. Indemnity of Indemnitee. The Company hereby agrees to hold harmless and indemnify Indemnitee to the fullest extent permitted by

   (a) Proceedings Other Than Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnifi

   (b) Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnification provided in this Se

   (c) Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provision of this Agreer

   (d) Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for

2. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1 of this Ag

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Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or activ

3. Contribution.

   (a) Whether or not the indemnification provided in Sections 1 and 2 hereof is available, in respect of any threatened, pending or c

   (b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, I

   (c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be b

   (d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to I

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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, b

5. Advancement of Expenses. Notwithstanding any other provision of this Agreement, the Company shall advance all Expenses incurred

6. Procedures and Presumptions for Determination of Entitlement to Indemnification. It is the intent of this Agreement to secure for Ind

   (a) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein

   (b) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 6(a) hereof, a determination

   (c) If the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 6(b) hereof, t

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Independent Counsel so selected does not meet the requirements of "**Independent Counsel**" as defined in Section 13 of this Agreement, and the c

   (d) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making s

   (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 t

   (f) If the person, persons or entity empowered or selected under Section 6 to determine whether Indemnitee is entitled to indemn

requires such additional time to obtain or evaluate documentation and/or information relating thereto; and provided further, that the foregoing pro

(g) Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitler

(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

(i) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or up

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 indemni

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following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 7(a). The Company shall not oppo

(b) In the event that a determination shall have been made pursuant to Section 6(b) of this Agreement that Indemnitee is not entit

(c) If a determination shall have been made pursuant to Section 6(b) of this Agreement that Indemnitee is entitled to indemnificati

(d) In the event that Indemnitee, pursuant to this Section 7, seeks a judicial adjudication of Indemnitee's rights under, or to recove

(e) The Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 7 that the proc

(f) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this

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 Indem

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indemnification than would be afforded currently under the Certificate of Incorporation, Bylaws and this Agreement, it is the intent of the parties he

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, er

(c) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or i

(d) [Except as provided in paragraph (c) above, i][I]n the event of any payment under this Agreement, the Company shall be subro

(e) [Except as provided in paragraph (c) above, t][T]he Company shall not be liable under this Agreement to make any payment of

(f) [Except as provided in paragraph (c) above, t][T]he Company's obligation to indemnify or advance Expenses hereunder to Inde

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employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of

9. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company shall not be obligated under th

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provi

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Comp

(c) except as provided in Section of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by

10. Duration of Agreement. All agreements and obligations of the Company contained herein shall continue for five years following the d

11. Security. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time pr

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12. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and sup

(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 I

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 Com

(b) "**Disinterested Director**" means a director of the Company who is not and was not a party to the Proceeding in respect of wh

(c) "**Enterprise**" shall mean the Company and any other corporation, partnership, joint venture, trust, employee benefit plan or o

(d) "**Expenses**" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, tra

(e) "**Independent Counsel**" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and r

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indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable

(f) "**Proceeding**" includes any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediat

14. Severability. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other

15. Modification and Waiver. No supplement, modification, termination or amendment of this Agreement shall be binding unless execute

16. Notice By Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving a

17. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effe

(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

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

20. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and const

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 O

Email: malder@gaintherapeut

Address: 4800 Montgomery Lan
Bethesda, Maryland 20

[

INDEMNITEE:

[_____]

_____

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, Date 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 m

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial conditi

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to pr

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of th

(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 quarte

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 au

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adve
(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 finan

November 14, 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, ir

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, res

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that m

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to prov

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the

(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 (

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 a

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to advers
(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 financia

November 14, 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 September 30, 2023 as filed with the Secu

August 10, 2023 /s/ C. of the Company, and Charles Evan Ballantyne, Date C. Evan Ballantyne as Chief Financial Officer (Principal Financial Officer)

August 10, 2023 /s/ Gianluca Fuggetta
Date Gianluca Fuggetta
Senior Director, Corporate Reporting
(Principal Accounting Officer)

{graphic omitted}
{graphic omitted}

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: November 14, 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)

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