UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39655

GALECTO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**37-1957007**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Ole Maaloes Vej 3 DK-2200 Copenhagen N Denmark	**N/A**
75 State Street, Suite 100 Boston, MA 02109	**02109**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (+45) 70 70 52 10

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 $0.00001 per share	GLTO	The Nasdaq Global Select Market

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

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

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

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

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

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

As of July 31, 2023, the registrant had 27,112,697 shares of common stock, $0.00001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "project," "continue," "potential," "ongoing," or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements regarding:

- the success, cost and timing of our product development activities and planned initiation and completion of clinical trials of our most advanced product candidate, GB0139, and our other current fibrosis and oncology product candidates, including GB2064 and GB1211, and any future product candidates;
- our need to raise additional funding;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our heavy dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates that we may pursue;
- the implementation of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the rate and degree of market acceptance and clinical utility for our current or future product candidates we may develop;
- our estimates about the size of our market opportunity;
- our estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- our financial performance and liquidity;
- our ability to effectively manage our potential growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting;
- the effects of global economic uncertainty and financial market volatility caused by economic effects of rising inflation and interest rates, geopolitical instability, changes in international trade relationships and conflicts, such as the ongoing conflict between Russia and Ukraine, on any of the foregoing or other aspects of our business or operations; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, the reasons described elsewhere in this Quarterly Report on Form 10-Q and those set forth in Part I, Item 1A - "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Any forward-looking statement in this Quarterly Report on Form 10-Q reflects our current view with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by third parties, industry, medical and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, “we,” “us,” “our,” “Galecto,” and the “Company” refer to Galecto, Inc. and, where appropriate, its consolidated subsidiaries.

Trademarks

We have applied for various trademarks that we use in connection with the operation of our business. This Quarterly Report on Form 10-Q includes trademarks, service marks, and trade names owned by us or other companies. All trademarks, service marks, and trade names included in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

GALECTO, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 22,956	$ 32,786
Marketable securities	29,168	27,438
Prepaid expenses and other current assets	3,238	3,686
Total current assets	55,362	63,910
Marketable securities, non-current	—	5,832
Operating lease right-of-use asset	633	810
Equipment, net	328	357
Other assets, non-current	2,480	2,279
Total assets	$ 58,803	$ 73,188
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,557	$ 3,350
Accrued expenses and other current liabilities	9,340	7,757
Total current liabilities	14,897	11,107
Operating lease liabilities, non-current	206	328
Total liabilities	15,103	11,435
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; no shares issued or outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, par value of $0.00001 per share; 300,000,000 shares authorized at June 30, 2023 and December 31, 2022; 27,021,899 and 25,652,392 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	285,311	279,733
Accumulated deficit	(241,474)	(217,736)
Accumulated other comprehensive loss	(137)	(244)
Total stockholders' equity	43,700	61,753
Total liabilities and stockholders' equity	$ 58,803	$ 73,188

See accompanying notes to the unaudited interim condensed consolidated financial statements.

GALECTO, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 8,089	$ 13,707	$ 18,451	$ 26,942
General and administrative	3,070	3,414	6,200	7,118
Total operating expenses	11,159	17,121	24,651	34,060
Loss from operations	(11,159)	(17,121)	(24,651)	(34,060)
Other income (expense), net				
Interest income, net	442	156	876	217
Loss on sale of marketable securities	—	(70)	—	(70)
Foreign exchange transaction gain (loss), net	(27)	148	37	88
Total other income, net	415	234	913	235
Net loss	$ (10,744)	$ (16,887)	(23,738)	(33,825)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.67)	$ (0.91)	$ (1.34)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	26,375,076	25,270,314	26,025,929	25,266,096
Other comprehensive loss, net of tax				
Currency translation loss	(35)	(719)	(10)	(889)
Unrealized gain (loss) on marketable securities	25	(155)	117	(360)
Reclassification adjusment for loss included in net income	—	70	—	70
Other comprehensive gain (loss), net of tax	(10)	(804)	107	(1,179)
Total comprehensive loss	$ (10,754)	$ (17,691)	$ (23,631)	$ (35,004)

See accompanying notes to the unaudited interim condensed consolidated financial statements.

GALECTO, INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

For the Three Months Ended June 30, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at March 31, 2023	25,673,474	$ —	$ 281,190	$ (230,730)	$ (127)	$ 50,333
Stock-based compensation expense	—	—	1,439	—	—	1,439
Issuance of common stock; net of issuance costs of $0.1 million	1,348,425	—	2,682	—	—	2,682
Other comprehensive loss, net	—	—	—	—	(10)	(10)
Net loss	—	—	—	(10,744)	—	(10,744)
Balance at June 30, 2023	27,021,899	$ —	$ 285,311	$ (241,474)	$ (137)	$ 43,700

For the Three Months Ended June 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at March 31, 2022	25,261,832	$ —	$ 275,059	$ (173,050)	$ (695)	$ 101,314
Stock-based compensation expense	—	—	1,419	—	—	1,419
Issuance of common stock; net of issuance costs of $0.1 million	80,306	—	23	—	—	23
Other comprehensive loss, net	—	—	—	—	(804)	(804)
Net loss	—	—	—	(16,887)	—	(16,887)
Balance at June 30, 2022	25,342,138	$ —	$ 276,501	$ (189,937)	$ (1,499)	$ 85,065

See accompanying notes to the unaudited interim condensed consolidated financial statements.

GALECTO, INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

For the Six Months Ended June 30, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2022	25,652,392	$ —	$ 279,733	$ (217,736)	$ (244)	$ 61,753
Stock-based compensation expense	—	—	2,873	—	—	2,873
Issuance of common stock; net of issuance costs of $0.1 million	1,369,507	—	2,705	—	—	2,705
Other comprehensive gain, net	—	—	—	—	107	107
Net loss	—	—	—	(23,738)	—	(23,738)
Balance at June 30, 2023	27,021,899	$ —	$ 285,311	$ (241,474)	$ (137)	$ 43,700

For the Six Months Ended June 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at December 31, 2021	25,261,832	$ —	$ 273,655	$ (156,112)	$ (320)	$ 117,223
Stock-based compensation expense	—	—	2,823	—	—	2,823
Issuance of common stock; net of issuance costs of $0.1 million	80,306	—	23	—	—	23
Other comprehensive loss, net	—	—	—	—	(1,179)	(1,179)
Net loss	—	—	—	(33,825)	—	(33,825)
Balance at June 30, 2022	25,342,138	$ —	$ 276,501	$ (189,937)	$ (1,499)	$ 85,065

GALECTO, INC.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (23,738)	$ (33,825)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation	35	15
Stock-based compensation	2,873	2,823
Amortization of premiums and discounts on marketable securities	(248)	438
Net loss on sale of marketable securities	—	70
Amortization of right of use lease asset	199	207
Accretion of lease liability	30	28
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	450	6,740
Other assets, noncurrent	(203)	(981)
Accounts payable	2,207	1,284
Accrued expenses and other current liabilities	1,639	1,790
Operating lease liabilities	(227)	(226)
Net cash used in operating activities	(16,983)	(21,637)
Cash flows from investing activities:		
Purchases of marketable securities	(21,994)	(40,656)
Proceeds from sale of marketable securities	26,459	30,415
Purchases of property and equipment	—	(17)
Net cash provided by (used in) investing activities	4,465	(10,258)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	2,705	18
Net cash provided by financing activities	2,705	18
Net decrease in cash and cash equivalents	(9,813)	(31,877)
Effect of exchange rate changes on cash and cash equivalents	(17)	(891)
Cash and cash equivalents, beginning of period	32,786	62,563
Cash and cash equivalents, end of period	$ 22,956	$ 29,795
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ —	$ —
Supplemental disclosures of noncash activities:		
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ —

See accompanying notes to the unaudited interim condensed consolidated financial statements.

1. DESCRIPTION OF BUSINESS, ORGANIZATION AND LIQUIDITY

Business and Organization

Galecto, Inc., together with its consolidated subsidiaries (the “Company” or “Galecto”), is a clinical-stage biotechnology company developing novel therapeutics that are designed to target the biological processes that lie at the heart of fibrotic diseases and cancer. The Company’s initial focus is on the development of small molecule inhibitors of galectin-3 and lysyl oxidase-like 2 ("LOXL2”), which play key roles in regulating fibrosis and cancer.

As of June 30, 2023, the Company’s wholly owned subsidiaries were PharmAkea, Inc. or PharmAkea, Galecto Securities Corporation, and Galecto Biotech AB, a Swedish company. Galecto Biotech ApS, a Danish operating company, is a wholly-owned subsidiary of Galecto Biotech AB.

Risks and uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities.

The Company’s product candidates are in development. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Liquidity and management plans

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff and raising capital, and has financed its operations primarily through the issuance of redeemable convertible preferred shares, debt financings, the Company’s initial public offering (“IPO”) and sales of the Company's common stock in "at-the-market" offerings.

As of June 30, 2023, the Company had an accumulated deficit of $241.5 million, from recurring losses since inception in 2011. The Company has incurred recurring losses and has no sales as none of its product candidates have obtained the necessary regulatory approval for commercialization and to be marketed as approved products. The Company expects to continue to incur losses as a result of costs and expenses related to the Company’s clinical development and corporate general and administrative activities. The Company had negative cash flows from operating activities during the six months ended June 30, 2023 and 2022 of $17.0 million and $21.6 million, respectively, and current projections indicate that the Company will have continued negative cash flows for the foreseeable future as it continues to develop its product candidates. Net losses incurred for the three and six months ended June 30, 2023 were $10.7 million and $23.7 million, respectively. Net losses incurred for the three and six months ended June 30, 2022 were $16.9 million and $33.8 million, respectively.

At June 30, 2023, the Company’s cash, cash equivalents and marketable securities amounted to $52.1 million and current assets amounted to $55.4 million and current liabilities amounted to $14.9 million. At December 31, 2022, the Company’s cash, cash equivalents and marketable securities amounted to $66.1 million, current assets amounted to $63.9 million and current liabilities amounted to $11.1 million.

In the future, the Company will consider the following ways to fund its operations including: (1) raising additional capital through equity and/or debt financings; (2) new commercial relationships to help fund future clinical trial costs (i.e. licensing and partnerships); (3) reducing spending on one or more research and development programs by discontinuing development; and/or (4) restructuring operations to change its overhead structure. Volatility in equity capital markets may adversely affect the market price of the Company's shares of common stock, which may materially and adversely affect the Company's ability to fund its business through public or private sales of equity securities. The Company's future liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates, key developments and regulatory events.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying interim condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP").

The accompanying interim condensed consolidated financial statements as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022, and related interim information contained within the notes to the interim condensed consolidated financial statements, are unaudited. In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited consolidated financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company's financial position as of June 30, 2023, results of operations, statement of stockholders' equity for the three and six months ended June 30, 2023 and 2022 and its cash flows for the six months ended June 30, 2023 and 2022. All intercompany balances and transactions have been eliminated. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and accompanying notes contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission ("SEC") on March 9, 2023 ("2022 Consolidated Financial Statements"). The results for the three and six months ended June 30, 2023 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

For the six months ended June 30, 2023, there have been no changes to the significant accounting policies as disclosed in Note 2 to the 2022 Consolidated Financial Statements.

Recently issued accounting standards

The Company periodically reviews new accounting standards that are issued and has not identified any new standards that it believes merit further discussion or would have a significant impact on its financial statements.

3. INVESTMENTS

Cash in excess of the Company's immediate requirements is invested in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

A summary of the Company's available-for-sale investments as of June 30, 2023 and December 31, 2022 consisted of the following (in thousands):

	At June 30, 2023			
Marketable securities:	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Corporate bonds	$ 29,317	$ —	$ (149)	$ 29,168
Total	$ 29,317	$ —	$ (149)	$ 29,168

	At December 31, 2022			
Marketable securities:	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Corporate bonds	$ 27,573	$ —	$ (135)	$ 27,438
Total	$ 27,573	$ —	$ (135)	$ 27,438
Marketable securities, noncurrent:				
Corporate bonds	$ 5,963	$ —	$ (131)	$ 5,832
Total	$ 5,963	$ —	$ (131)	$ 5,832

4. PROPERTY AND EQUIPMENT, NET

Property and equipment as of June 30, 2023 consisted of the following (in thousands):

	June 30, 2023	**December 31, 2022**
Equipment	$ 425	$ 419
Less: accumulated depreciation	(97)	(62)
Equipment, net	$ 328	$ 357

Depreciation expense for the three and six months ended June 30, 2023 was $17,000 and $35,000, respectively. Depreciation expense for the three and six months ended June 30, 2022 was $7,000 and $15,000, respectively.

5. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs.

The Company classified its money market funds within Level 1 because their fair values are based on their quoted market prices. The Company classified its debt securities within Level 2 because their fair values are determined using alternative pricing sources or models that utilized market observable inputs.

A summary of the assets that are measured at fair value as of June 30, 2023 and December 31, 2022 is as follows (in thousands):

	Fair Value Measurement at June 30, 2023			
Assets:	**Carrying Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds[(1)]	$ 10,478	$ 10,478	$ —	$ —
Debt securities	29,168	—	29,168	—
Total	$ 39,646	$ 10,478	$ 29,168	$ —

	Fair Value Measurement at December 31, 2022			
Assets:	**Carrying Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds[(1)]	$ 16,445	16,445	—	—
Debt securities	33,270	—	33,270	—
Total	$ 49,715	$ 16,445	$ 33,270	$ —

(1) Money market funds with maturities of 90 days or less at the date of purchase are included within cash and cash equivalents in the accompanying condensed consolidated balance sheets and are recognized at fair value.

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2023	**December 31, 2022**
Contract research and development costs	$ 1,553	$ 1,450
Research and development tax credit receivable	802	792
Prepaid insurance costs	339	805
Value-added tax refund receivable	390	587
Other	154	52
Total prepaid expenses and other current assets	$ 3,238	$ 3,686

7. LEASES

The Company has the following operating leases:

Location	**Primary Use**	**Lease Expiration Date**	**Renewal Option**
Copenhagen, Denmark	Corporate headquarters	January 2025	None
London, United Kingdom	Office space	February 2024	None
Gothenburg, Sweden	Office space	August 2026	None
Stevenage, United Kingdom	Laboratory space	August 2025	None

The Company has no finance leases and has elected to apply the short-term lease exception to all leases of one year or less. Rent expense for the three and six months ended June 30, 2023 was $0.1 million and $0.3 million, respectively. Rent expense for the three and six months ended June 30, 2022 was $0.1 million and $0.2 million, respectively.

Quantitative information regarding the Company's leases for the three and six months ended June 30, 2023 and 2022 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
Lease Cost	**2023**	**2022**	**2023**	**2022**
Operating lease cost (in thousands)	$ 139	$ 117	$ 276	$ 243
Other Information				
Operating cash flows paid for amounts included in the measurement of lease liabilities (in thousands)	$ 125	$ 120	$ 273	$ 234
Operating lease liabilities arising from obtaining right-of-use assets (in thousands)	$ —	$ —	$ 409	$ —

As of June 30, 2023 and December 31, 2022, the weighted average remaining lease term for operating leases was 1.6 years and 1.8 years, respectively.

As of June 30, 2023 and December 31, 2022, the weighted average discount rate for operating leases was 8% for both periods.

Operating lease liabilities at June 30, 2023 are as follows (in thousands):

Future Lease Payments	**Operating Leases**
2023 (excluding the period ended June 30, 2023)	$ 270
2024	316
2025	68
2026	10
2027	—
Total lease payments	664
Less: imputed interest	(38)
Total lease liabilities	$ 626

8. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 30, 2023	**December 31, 2022**
Contract research and development costs	$ 6,695	$ 6,145
Employee compensation costs	1,770	597
Operating lease liabilities, current	420	476
Other liabilities	455	539
Total accrued expenses and other current liabilities	$ 9,340	$ 7,757

9. COMMITMENTS AND CONTINGENCIES

During the three and six months ended June 30, 2023, there were no material changes to the Company's commitments and contingencies as disclosed in Note 9 of the 2022 Consolidated Financial Statements. Further, the Company's commitments related to lease agreements are disclosed in Note 7 to the Company's unaudited interim condensed consolidated financial statements.

10. STOCK-BASED COMPENSATION

Employee equity plan

In March 2020, the Company's Board of Directors and stockholders approved the 2020 Stock Option and Grant Plan (“2020 Plan”). Holders of stock options under the 2020 Plan shall be entitled to exercise the vested portion of the stock option during the term of the grant. If a qualified exit, as defined in the 2020 Plan, occurs, then all of the holders' unvested options shall vest immediately.

In October 2020, the Company's Board of Directors and stockholders approved the 2020 Equity Incentive Plan (“2020 Equity Plan”). Following the adoption of the 2020 Equity Plan, no further options are available to be issued under the 2020 Plan. Stock options granted under the 2020 Equity Plan generally vest over a four-year period and expire ten years from the grant date. The shares available for grant under the 2020 Equity Plan will cumulatively increase by 5 percent of the number of shares of common stock issued and outstanding on January 1st each year. At June 30, 2023, the Company had 275,362 shares available for future grant under the 2020 Equity Plan.

The following table sets forth the activity for the Company’s stock options during the six months ended June 30, 2023:

	Number of Options	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2022	5,778,885	$ 5.43	7.9	$ —
Granted	1,923,350	1.28	—	433,020
Cancelled	(31,525)	2.58	—	11,445
Outstanding at June 30, 2023	7,670,710	$ 4.40	8.2	$ 3,256,209
Vested and expected to vest at June 30, 2023	7,366,568	$ 4.36	8.2	$ 3,256,209
Vested and exercisable at June 30, 2023	3,670,775	$ 5.39	7.5	$ 744,040

The weighted-average grant date fair value of all stock options granted for the six months ended June 30, 2023 was $0.98. The intrinsic value at June 30, 2023 and December 31, 2022 was based on the closing price of the Company’s common stock on that date of $2.52 and $1.15 per share, respectively.

In November 2022, the Company's Board of Directors approved the 2022 Inducement Plan (the “Inducement Plan”), which allows for the grant of equity awards to be made to a new employee where the equity award is a material inducement to an employee entering into employment with the Company. The Inducement Plan was adopted by the Company's Board of Directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). A total of 250,000 shares of the Company's common stock have been reserved for issuance under the Inducement Plan. As of June 30, 2023, no shares have been issued under the Inducement Plan.

Stock-based compensation

The grant date fair value of stock options vested during the six months ended June 30, 2023 and 2022 was $3.5 million and $4.4 million, respectively. Total unrecognized compensation expense related to unvested options granted under the Company’s stock-based compensation plan was $9.9 million at June 30, 2023, which is expected to be recognized over a weighted average period of 2.0 years. The Company recorded stock-based compensation expense related to the issuance of stock as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 686	$ 670	$ 1,370	$ 1,323
General and administrative	753	749	1,503	1,500
Total stock-based compensation	$ 1,439	$ 1,419	$ 2,873	$ 2,823

The Company uses a Black-Scholes option pricing model to determine fair value of its stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of stock options, the expected volatility based on the historical volatility of a publicly traded set of peer companies and the expected risk-free interest rate based on the implied yield on a U.S. Treasury security.

The fair values of the options granted were estimated using the following assumptions:

	Six Months Ended June 30,	
	2023	2022
Risk-free interest rate	3.8%	1.7%
Expected term (in years)	6.0	6.0
Expected volatility	91.0%	90.0%
Expected dividend yield	—	—

11. NET LOSS PER SHARE

Basic and diluted net loss per share is calculated as follows (in thousands except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (10,744)	$ (16,887)	$ (23,738)	$ (33,825)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	26,375,076	25,270,314	26,025,929	25,266,096
Net loss per common share, basic and diluted	$ (0.41)	$ (0.67)	$ (0.91)	$ (1.34)

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Six Months Ended June 30,	
	2023	2022
Stock options to purchase common stock	7,670,710	5,760,144

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date on which the unaudited interim condensed consolidated financial statements were issued. The Company has concluded that no subsequent events have occurred that require disclosure to the unaudited interim condensed consolidated financial statements.

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

The following information should be read in conjunction with the unaudited interim condensed consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto for the year ended December 31, 2022, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the United States Securities and Exchange Commission, or the SEC, on March 9, 2023. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in other SEC filings.

Overview

We are a clinical-stage biotechnology company developing novel small molecule therapeutics that are designed to target the biological processes that lie at the heart of cancer and fibrotic diseases. Our strategy is to focus on diseases without disease-modifying treatment options and where there is a high unmet medical need. We are concentrating on the development of a new class of medicines: small molecule inhibitors of galectin-3 and lysyl oxidase-like 2, or LOXL2, that target underlying biology for the treatment of multi-factorial diseases like cancer and fibrotic diseases. Galectin proteins, and especially galectin-3, are highly expressed in many cancers, where they promote cancer progression, and fibrotic diseases, where they reduce organ function. The collagen cross-linking enzyme LOXL2 builds the backbone of fibrotic tissue by cross-linking collagen and elastin molecules and has been linked to cancer growth, metastasis and fibrosis. Our product candidates are designed to modulate multiple disease pathways simultaneously by inhibiting the master drivers of the cancer and fibrotic cascades. We believe our galectin and LOXL2 product candidates are distinct from the current generation of anti-cancer and anti-fibrotic agents and have the potential to significantly improve patient outcomes for these complex diseases. In the fourth quarter of 2022 we completed a Phase 1b/2a clinical trial in patients with decompensated liver cirrhosis, and we currently have three other ongoing Phase 2 clinical trials.

GB0139 (Idiopathic Pulmonary Fibrosis, IPF) – GALACTIC-1 Trial

Our most advanced product candidate, GB0139, is an inhaled small molecule inhibitor of galectin-3, one of the key regulators of fibrosis that controls the pro-fibrotic activity of TGF-b. Overexpression of galectin-3 is ubiquitous in fibrotic tissue, including in fibrotic lung tissue, and is linked to both disease severity and disease progression, as well as acute exacerbations of idiopathic pulmonary fibrosis, or IPF. We are initially developing GB0139 for the treatment of IPF, a life-threatening progressive fibrotic disease of the lung. IPF affects approximately 100,000 people in the United States, but limited treatment options have been associated with significant side effects, leading to poor therapeutic adherence or dose reduction. In our clinical trials completed to date, we found orally-inhaled GB0139 to be generally well-tolerated and it inhibited galectin-3 in the lungs in a dose-dependent manner.

In our clinical, preclinical and in vitro testing to date, we have demonstrated that GB0139 can directly target galectin-3 in the lungs and markedly lowers the systemic plasma levels of biomarkers of fibrosis in IPF patients. In our Phase 1/2a trial in both healthy volunteers and IPF patients, GB0139 was generally well-tolerated, showed consistent and tight pharmacokinetics measured as plasma levels of the compound, and showed target engagement with the inhibition of galectin-3 in the lungs of IPF patients in a dose-dependent manner. Our clinical trials completed to date have found that orally inhaled GB0139 also decreased systemic levels of a range of plasma biomarkers, such as the glycoprotein YKL-40 and PDGF, that have been linked to mortality, disease severity and/or progression in IPF.

In June 2023, we announced that we had completed dosing in the GALACTIC-1 trial, a 52-week randomized, double-blind, multicenter, parallel, placebo-controlled Phase 2b trial investigating the safety and efficacy of GB0139 in patients with IPF. The primary endpoint of the trial is to assess the annual rate of decline in forced vital capacity, or FVC, over 52 weeks, which is the regulatory endpoint identified for IPF therapy approval. Reduction in the decline of FVC is the endpoint that was accepted by the FDA for the approval of both nintedanib, marketed as Ofev® by Boehringer Ingelheim, and pirfenidone, marketed as Esbriet® by Roche/Genentech, which are the only current therapeutic treatments for IPF. We continue to expect topline results to be available in August 2023.

GB1211 (Liver Cirrhosis and Oncology Indications) – GULLIVER-2, GALLANT-1 and Providece Investigator-Initiated Trials

GB1211 is a selective oral small molecule inhibitor of galectin-3 and is chemically distinct from GB0139. We believe GB1211 has the potential to treat multiple types of fibrosis and oncology indications. GB1211 demonstrated antifibrotic and anticancer activity in multiple preclinical models and was evaluated in a Phase 1 trial in 78 healthy volunteers. In the Phase 1 trial, GB1211 was well-tolerated and showed dose-dependent pharmacokinetics.

Within the field of fibrotic diseases, our initial target indication for GB1211 is liver cirrhosis, a severe, progressive disease that ultimately leads to liver failure and for which there are limited treatment options and no FDA-approved disease modifying therapeutics available. During the fourth quarter of 2022, at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting® 2022, we announced topline results from our Phase 1b/2a GULLIVER-2 trial in patients with decompensated liver cirrhosis showing statistically significant reductions in ALT ($p<0.0005$), AST ($p<0.005$) and GGT ($p<0.05$), with encouraging reductions for ALP ($p<0.09$), after 12 weeks of treatment. These findings suggest that GB1211 provided liver cell protection and improved liver status, further supporting clinical development in severe liver disease. The consistency of the reductions in liver enzymes shown in this severe form of liver cirrhosis, the progressive improvement we observed over 12 weeks and the favorable safety profile observed in the GULLIVER-2 trial lead us to believe that a broader study in patients with compensated and/or decompensated cirrhosis could show broader clinical activity, providing a potential regulatory path to approval as the first FDA-approved therapy in liver cirrhosis. Our next step in the development of GB1211 for the treatment of liver cirrhosis and other liver diseases is to conduct a long-term, randomized, placebo-controlled Phase 2a trial in patients with decompensated NASH cirrhosis, which will evaluate efficacy and tolerability at additional dose levels. We plan to initiate this trial in early 2024, subject to obtaining additional financing or collaborating with a third party.

GB1211 is also being studied in oncology. Many tumors overexpress galectin-3, which mechanistically is linked to several cancer promoting mechanisms, including those linked to programmed cell death receptor 1 (PD-1) or its ligand, PD-L1 resistance and chemotherapy resistance, and may ultimately lead to worse clinical outcomes. Galectin-3 inhibition has the potential to both directly reduce tumor growth as well as increase the immune mediated eradication of tumors and is believed to increase T-cell recruitment and activation in the tumor microenvironment. In an animal model, we observed that oral administration of our galectin-3 inhibitors reduced human and mouse lung adenocarcinoma growth and blocked metastasis. Treatment with one of our galectin-3 inhibitors also potentiated the activity of a PD-L1 immune checkpoint inhibitor. The mechanisms at work include checkpoint inhibitor-type mechanisms (inhibition of TGF-β signaling, LAG-3, T-cell receptor, interferon gamma) and mechanisms potentially enhancing PD-1/PD-L1 activity, as evidenced by preclinical data that we presented at the 2022 American Society of Clinical Oncology Annual Meeting showing that GB1211 reversed a galectin-3 induced blockage of the checkpoint inhibitors atezolizumab and pembrolizumab and exhibited synergistic activity with these checkpoint inhibitors. Furthermore, in the clinic, a retrospective study showed that patients with high tumor staining for galectin-3 were resistant to treatment with pembrolizumab, an anti-PD-1 antibody approved for the treatment of NSCLC, and, by contrast, patients with low galectin-3 had a good response to pembrolizumab and a reduction in tumor volume. Thus, galectin-3 could be a biomarker for anti-PD-1/PD-L1 resistance and, therefore, also be a marker for patients who may benefit from galectin-3 inhibition, which could enable a biomarker-based therapy. We believe the emerging data of galectin-3 as a checkpoint inhibitor resistance mechanism supports a key role for our oral galectin-3 inhibitor candidates in cancer therapy.

Our initial target indication for GB1211 in oncology is non-small cell lung cancer, or NSCLC, a cancer indication with high unmet medical need. In the fourth quarter of 2021, we announced that we had entered into a clinical trial supply agreement with F. Hoffmann-La Roche Ltd, or Roche, for our Phase 2a trial of GB1211 in combination with atezolizumab, marketed by Roche as Tecentriq®, a PD-L1 checkpoint inhibitor for the first-line treatment of NSCLC, which we refer to as the GALLANT-1 trial. This randomized, double blind, placebo-controlled trial is examining the effect of GB1211 and atezolizumab on tumor shrinkage based on RECIST criteria, as well as secondary endpoint measures such as overall survival and progression-free survival. We also plan to analyze how plasma galectin-3 levels and tumor galectin-3 correlate with tumor response.

We recently completed Part A of the GALLANT-1 trial, an open-label study to select the dose of GB1211 to be used in future trials to evaluate the safety and tumor shrinkage of the combination of GB1211 and checkpoint inhibitors. The Safety Review Committee, or SRC, for the GALLANT-1 trial recently reviewed the results from Part A and recommended that we continue at the 100 mg twice daily dose of GB1211 in Part B and in combination with checkpoint inhibitors in future oncology trials.

In connection with completing Part A of the GALLANT-1 trial, we conducted an interim safety analysis of twelve evaluable patients treated in Part A of the trial where GB1211 exhibited a favorable safety and tolerability profile. In the second quarter of 2022, we initiated dosing in Part A of the trial with GB1211 200 mg and atezolizumab. In the seven evaluable patients who received GB1211 200 mg twice daily in combination with atezolizumab, we observed eight serious adverse events, of which four of these serious adverse events were determined not to be related to either GB1211 200 mg or atezolizumab. One case of grade 1 hyperthyroidism was attributed solely to atezolizumab and one case of grade 4 hypocellular bone marrow was determined to be related

to both GB1211 200 mg and atezolizumab. The last two of these serious adverse events were autoimmune-type skin rashes (showing perivascular lymphocytic infiltrates), one of which was a grade 3 case of autoimmune pemphigus determined to be related solely to atezolizumab and the other was a grade 4 case of skin rash determined to be related to both GB1211 200 mg and atezolizumab. As a result of these skin reactions and in accordance with the protocol, we reduced the GB1211 dose to 100 mg twice daily for the second patient cohort. The skin reactions were similar to those historically observed with atezolizumab and described in the label. Both reactions responded to therapy with glucocorticosteroids and were clinically manageable. Interestingly, inflammatory and perivascular lymphocytic infiltrates were observed in both skin reactions, and could signal an exaggerated immune activation, something often observed with checkpoint inhibitor therapy and associated with improved clinical outcomes. Because a central aspect of the mechanism of action design for GB1211 in combination with a checkpoint inhibitor is to remove galectin-3 from the lymphocytes and the tumor cells, and thereby increase lymphocyte-based tumor killing, we believe this could also be a positive signal of enhanced lymphocyte activation. Eleven grade 1 or 2 adverse events were determined to be related to both GB1211 200 mg and atezolizumab and six grade 1 or 2 adverse events were determined to be solely attributed to GB1211 200 mg. One grade 4 adverse event of skin reaction was determined to be related to both GB1211 200 mg and atezolizumab and one grade 3 adverse event of fatigue was determined to be solely attributed to GB1211 200 mg.

Following the dose reduction referred to above, five additional evaluable patients received GB 1211 100 mg twice daily in combination with atezolizumab. In this cohort, we observed two serious adverse events, neither of which were determined to be related to GB1211 100 mg or atezolizumab. Seven grade 1 or 2 adverse events were determined to be related to both GB1211 100 mg and atezolizumab and one grade 2 adverse event of nausea was determined to be solely attributed to GB1211 100 mg. Importantly, we did not observe any autoimmune-type skin rashes in the 100 mg cohort.

We have enrolled thirteen patients in Part A of the GALLANT-1 trial. Currently, five patients are continuing to receive GB1211 (100 mg: four; 200 mg: one) in combination with atezolizumab and will continue to be followed. Eight patients discontinued treatment as a result of disease progression, adverse reactions or withdrawal of consent. However, of these eight patients, five received treatment for less than four weeks: two withdrew consent, one reported major malnutrition and two had autoimmune skin rashes as mentioned above.

One patient in the GALLANT-1 trial who has been in treatment for 35 weeks with both GB1211 200 mg twice daily and atezolizumab showed a partial response, which is defined by the RECIST criteria (version 1.1) to be shrinkage of at least 30% of the tumor, at weeks 18, 24 and 30. As of the week 30 study visit, the tumor shrinkage pursuant to RECIST criteria was greater than 70%. Of the three patients who have been treated for at least six weeks with GB1211 100 mg in combination with atezolizumab, one patient who has been in treatment for 26 weeks with GB1211 100 mg twice daily and atezolizumab also showed a partial response at weeks 6, 12, 18 and 24. As of the week 24 study visit, the tumor shrinkage pursuant to RECIST criteria also exceeded 70%. Another patient in this cohort has shown stable disease for at least six weeks. These three patients and two other recently enrolled patients continue to receive treatment with GB1211 and atezolizumab.

In October 2022, we expanded our focus on additional oncology indications and entered into an agreement with Providence Portland Medical Center's EACRI to evaluate the safety and efficacy of GB1211 in combination with pembrolizumab in an investigator-initiated trial in metastatic melanoma and HNSCC patients. Galecto has committed to supply GB1211 for this Phase 2 trial. The randomized, double-blind placebo controlled, investigator-initiated Phase 2 trial is expected to evaluate whether the addition of GB1211 increases the response rate of pembrolizumab in metastatic melanoma and HNSCC patients. The study is designed to evaluate GB1211 in combination with the standard therapeutic dose of pembrolizumab in patients with unresectable or metastatic melanoma or recurrent or metastatic HNSCC progressing during or after platinum-containing chemotherapy. In addition to monitoring for toxicity and clinical response, blood and tumor samples will be obtained to assess immunologic measures relevant to galectin-3 biology and checkpoint inhibition. This trial is expected to begin in the second half of 2023 and topline results could be reported as early as 2025.

GB2064 (Myelofibrosis) – MYLOX-1 Trial

GB2064 is a selective oral small molecule inhibitor of LOXL2 that we are initially developing for the treatment of myelofibrosis, a malignant disease of the bone marrow in which progressive fibrosis reduces the ability to form blood cells in the bone marrow. Myelofibrosis is one of several types of cancer and multiple fibrotic diseases in which expression of LOXL2 is significantly increased. Unlike current treatment options for myelofibrosis, we believe that GB2064 has the potential to be a disease-modifying therapy as it is designed to have a direct impact on the fibrotic process and slow the progression of the disease.

We are currently conducting a Phase 2a MYLOX-1 trial examining GB2064 in myelofibrosis in which the primary endpoint is safety and secondary endpoints include measurements of drug levels in the bone marrow and grade of fibrosis, improvement of anemia and/or thrombocytopenia and assessment of spleen and liver size. In the third quarter of 2022, we announced results from a planned intermediate assessment of the first five patients who had completed at least six months of treatment with

GB2064. Four of the five patients experienced a ≥ 1-grade reduction in collagen fibrosis of the bone marrow, an improvement suggesting that GB2064 could impact the progression of the disease and potentially be disease modifying. All four patients who experienced a ≥ 1-grade reduction in collagen fibrosis also showed stable hematological parameters (hemoglobin, white blood cell count, and thrombocytes) and stable spleen volume over the six month treatment period, and none required transfusion. As of the date of the planned intermediate assessment, the most commonly observed treatment-related adverse events were gastrointestinal in nature and were manageable in most patients with standard therapy. In the five patients who completed at least six months of treatment with GB2064 and valid bone marrow biopsies, there were no treatment-related serious adverse events, while in the entire trial population, the only possibly treatment-related serious adverse event was a case of fall.

We have enrolled and treated 18 patients in the MYLOX-1 trial, of which two patients continue to receive treatment and four patients are currently in the extension phase because their treating physician deemed them to be clinically responsive to treatment with GB2064. The data received to date from the MYLOX-1 trial suggest that inhibiting LOXL2 may be a way to reduce tissue collagen levels in multiple fibrosis and oncology indications. Four evaluable patients have shown a ≥ 1 grade reduction in collagen fibrosis, which we believe has not been shown with any FDA-approved therapy. Because the trial has already exceeded the pre-defined target of a ≥ 1 grade reduction in collagen fibrosis in at least three out of 16 evaluable patients, we believe that MYLOX-1 has reached the dual goal of confirming LOXL2 as an attractive fibrosis target and demonstrating that GB2064 has clinically meaningful antifibrotic activity. Accordingly, we have determined to stop enrolling additional patients in the trial and will continue following the remaining patients. We continue to expect to report topline results in the second half of 2023. Given that we have already shown bone marrow collagen reduction and a manageable clinical tolerability profile, we are beginning to plan for next steps in clinical development, which we expect could include combining GB2064 with another myelofibrosis treatment.

Financial Overview

Our product candidates GB0139, GB1211 and GB2064 are in Phase 2 of clinical development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of these product candidates. Our operations to date have been financed primarily from our initial public offering, or IPO, the issuance of common stock through our ATM Program, the issuance of convertible preferred shares and convertible notes. Since inception, we have had significant operating losses. Our net loss was $10.7 million and $23.7 million for the three and six months ended June 30, 2023, respectively. Our net loss was $16.9 million and $33.8 million for the three and six months ended June 30, 2022, respectively.As of June 30, 2023, we had an accumulated deficit of $241.5 million and $52.1 million in cash, cash equivalents and marketable securities.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our prepaid expenses, accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue. In particular, we expect our expenses to continue as we further our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any current or future product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities of $52.1 million as of June 30, 2023 will be sufficient to fund our operating expenditures and capital expenditure requirements into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

To date, we have not had any products approved for sale and, therefore, have not generated any product revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Economic uncertainty in various global markets, including the U.S. and Europe, caused by political instability and conflict, such as the ongoing conflict in Ukraine, have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused inflation globally. Our business, financial condition and results of operations could be materially and adversely affected by further negative impact on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen.

Although, to date, our business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such instability could impact our business and results of operations. The extent and duration of these market disruptions, whether as a result of the military conflict between Russia and Ukraine and effects of the Russian sanctions, geopolitical tensions, record inflation or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this report.

Components of Operating Results

Operating Expenses

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

Research and Development

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

- personnel costs, which include salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with consultants, and third-party contract organizations that conduct research and development activities on our behalf;
- costs related to sponsored research service agreements;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials;
- laboratory supplies and equipment used for internal research and development activities; and
- acquired in-process research and development programs.

We expense all research and development costs in the periods in which they are incurred, including for acquired in-process research and development. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We have historically met the requirements to receive a tax credit in Denmark of up to $0.9 million per year for losses resulting from research and development costs of up to approximately $4.1 million per year. The tax credit is reported as a reduction to research and development expense in the condensed consolidated statements of operations. We recorded a tax credit of $0.8 million for each of the six month periods ended June 30, 2023 and 2022.

Our direct research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. The majority of our clinical spending in the six month period ended June 30, 2023 and 2022 was on GB0139.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful enrollment and completion of our Phase 2 clinical trials for GB0139, GB2064 and GB1211, and any clinical trials for future product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, regulatory authorities in Europe, Medicines and Healthcare products Regulatory Agency, or MHRA, Health Canada or other regulatory agencies of the IND applications, clinical trial applications and/or other regulatory filings for GB0139, GB2064, GB1211 and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies; obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to continue for the foreseeable future as we continue to implement our business strategy, which includes advancing GB0139, GB2064 and GB1211 through clinical development and other product candidates further into clinical development, expanding our research and development efforts, including hiring additional personnel to support further clinical development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to continue as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services and facility-related fees not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and stock-based compensation expense, for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect our general and administrative expenses to continue over the next several years to support our continued research and development activities, manufacturing activities and continued costs of operating as a public company. These expenses will likely include continued costs related to the hiring of additional personnel, legal, regulatory and other fees, director and officer insurance premiums and investor relations costs associated with our continued operations.

Other Income (Expense), Net

Our other income (expense), net is comprised of:

- Interest income: The interest income earned on our cash, cash equivalents, restricted cash and marketable securities are recorded in our statements of operations.

- Foreign exchange: The functional currency of our subsidiaries in Denmark and Sweden is the Euro. Transactions denominated in currencies other than the Euro result in exchange gains and losses that are recorded in our statements of operations.

Results of Operations

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

The following sets forth our results of operations for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Change	
	2023	2022	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	$ 8,089	$ 13,707	$ (5,618)	-41.0%
General and administrative	3,070	3,414	(344)	-10.1%
Total operating expenses	$ 11,159	$ 17,121	$ (5,962)	-34.8%
Loss from operations	(11,159)	(17,121)	5,962	-34.8%
Other income, net	415	234	181	77.4%
Net loss	$ (10,744)	$ (16,887)	$ 6,143	-36.4%

Research and development expenses

Research and development expenses were comprised of:

	Three Months Ended June 30,		Change	
	2023	2022	Amount	Percent
	(in thousands)			
Preclinical studies and clinical trial-related activities	$ 3,345	$ 8,775	$ (5,430)	-61.9%
Chemistry, manufacturing and control	603	1,283	(680)	-53.0%
Personnel	2,538	2,401	137	5.7%
Consultants and other costs	1,603	1,248	355	28.4%
Total research and development expenses	$ 8,089	$ 13,707	$ (5,618)	-41.0%

Research and development expenses were $8.1 million for the three months ended June 30, 2023, compared to $13.7 million for the three months ended June 30, 2022. The decrease of $5.6 million was primarily related to decreased clinical trial-related expenses of $5.4 million due to timing of clinical trial activities and decreased chemistry, manufacturing and control costs of $0.7 million, offset by increased other research and development costs of $0.4 million and increased personnel costs of $0.1 million.

General and administrative expenses

General and administrative expenses were $3.1 million for the three months ended June 30, 2023, compared to $3.4 million for the three months ended June 30, 2022. The decrease of $0.3 million was primarily related to decreased insurance costs.

Other income (expense), net

Other income (expense), net for the three months ended June 30, 2023 was $0.4 million, compared to $0.2 million for the three months ended June 30, 2022. The increase of $0.2 million was primarily due to an increase in net interest income, offset by a decrease in foreign exchange transaction gain (loss), net.

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

The following sets forth our results of operations for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,		Change	
	2023	2022	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	$ 18,451	$ 26,942	$ (8,491)	-31.5%
General and administrative	6,200	7,118	(918)	-12.9%
Total operating expenses	$ 24,651	$ 34,060	$ (9,409)	-27.6%
Loss from operations	(24,651)	(34,060)	9,409	-27.6%
Other income, net	913	235	678	288.5%
Net loss	$ (23,738)	$ (33,825)	$ 10,087	-29.8%

Research and development expenses

Research and development expenses were comprised of:

	Six Months Ended June 30,		Change	
	2023	2022	Amount	Percent
	(in thousands)			
Preclinical studies and clinical trial-related activities	$ 8,291	$ 16,708	$ (8,417)	-50.4%
Chemistry, manufacturing and control	1,563	3,069	(1,506)	-49.1%
Personnel	5,066	4,929	137	2.8%
Consultants and other costs	3,531	2,236	1,295	57.9%
Total research and development expenses	$ 18,451	$ 26,942	$ (8,491)	-31.5%

Research and development expenses were $18.5 million for the six months ended June 30, 2023, compared to $26.9 million for the six months ended June 30, 2022. The decrease of $8.5 million was primarily related to decreased clinical trial-related expenses of $8.4 million due to timing of clinical trial activities and decreased chemistry, manufacturing and control costs of $1.5 million, offset by increased other research and development costs of $1.3 million and increased personnel costs of $0.1 million.

General and administrative expenses

General and administrative expenses were $6.2 million for the six months ended June 30, 2023, compared to $7.1 million for the six months ended June 30, 2022. The decrease of $0.9 million was primarily related to decreased insurance costs of $0.5 million and decreased net other general administrative costs of $0.4 million.

Other income (expense), net

Other income (expense), net for the six months ended June 30, 2023 was $0.9 million, compared to $0.2 million for the six months ended June 30, 2022. The increase of $0.7 million was primarily due to an increase in net interest income.

Liquidity and Capital Resources

Sources of Liquidity

Our operations to date have been financed primarily through our IPO, the issuance of common stock through our ATM Program (as defined below), the issuance of convertible preferred shares and convertible notes. Since inception, we have had significant operating losses. On November 2, 2020, we completed our IPO in which we raised $86.3 million in net proceeds. On November 4, 2021, we filed with the SEC, and the SEC declared effective on November 12, 2021, a registration statement on Form S-3, or the Registration Statement, which registers the offering, issuance and sale of up to $200.0 million of our common stock, preferred stock, debt securities, warrants, subscription rights and/or units of any combination thereof. Simultaneous with the filing of the Registration Statement, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, as sales agent, to provide for the issuance and sale of up to $50.0 million of our common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus, or the ATM Program. During the three and six months ended June 30, 2023, we sold an aggregate of 1,348,425 shares and 1,369,507 shares, respectively, of our common stock under the ATM Program at a weighted average selling price of $2.09 per share and $2.07 per share, respectively. During the three and six months ended June 30, 2022, we sold an aggregate of 80,306 shares of our common stock under the ATM Program at a weighted average selling price of $1.98 per share.

Our net losses were $10.7 million and $23.7 million for the three and six months ended June 30, 2023, respectively. Our net losses were $16.9 million and $33.8 million for the three and six months ended June 30, 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $241.5 million and $52.1 million in cash, cash equivalents and marketable securities. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (16,983)	$ (21,637)
Net cash provided by (used in) investing activities	4,465	(10,258)
Net cash provided by financing activities	2,705	18
Net decrease in cash, cash equivalents and restricted cash	$ (9,813)	$ (31,877)

Net Cash Used in Operating Activities

Cash used in operating activities of $17.0 million during the six months ended June 30, 2023 was primarily attributable to our net loss of $23.7 million together with non-cash items of $2.9 million principally with respect to stock-based compensation and a net increase of $3.8 million in components of our working capital.

Cash used in operating activities of $21.6 million during the six months ended June 30, 2022 was primarily attributable to our net loss of $33.8 million together with non-cash items of $3.6 million principally with respect to stock-based compensation and a net increase of $8.6 million in components of our working capital.

Net Cash Used in Investing Activities

Cash provided by investing activities of $4.5 million during the six months ended June 30, 2023 was the result of $26.5 million in proceeds from the sale of marketable securities, offset by $22.0 million for the purchase of marketable securities.

Cash used in investing activities of $10.3 million during the six months ended June 30, 2022 was the result of $30.4 million in proceeds from the sale of marketable securities, offset by $40.7 million for the purchase of marketable securities.

Net Cash Provided by Financing Activities

Cash provided by financing activities of $2.7 million during six months ended June 30, 2023 was the result of net proceeds from the issuance of our common stock.

Cash provided by financing activities of $0.02 million during six months ended June 30, 2022 was the result of net proceeds from the issuance of our common stock.

Funding Requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses; costs related to third-party clinical research, manufacturing and development services; costs relating to the build-out of our headquarters and other offices, our laboratories and our manufacturing facility; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; clinical costs; manufacturing costs; legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities of $52.1 million as of June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders, will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

We may be unable to raise additional funds or enter into other arrangements when needed, on favorable terms, or at all. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial services industry or economy in general. Volatility in equity capital markets, including market events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or the financial services industry generally, may adversely affect the market price of our equity securities, which may in turn materially limit our ability to fund our business through public or private sales of equity securities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs. Furthermore, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill other obligations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

- the progress, costs and results of our ongoing Phase 2 clinical trials of GB0139, GB2064 and GB1211, as well as the progress, costs and results for other preclinical and clinical trials for any future product candidates;
- the scope, progress, results and costs of discovery, research, preclinical development, laboratory testing and clinical trials for our current and future product candidates;
- the impacts of rising inflation and interest rates, geopolitical instability, changes in international trade relationships and conflicts;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates and the terms of such arrangements;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations; and
- the costs of continuing to operate as a public company.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited interim condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Costs

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include, the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs, CMOs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the condensed consolidated statements of operations. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Stock-based Compensation

We have issued stock-based compensation awards through the granting of stock options, which generally vest over a four-year period. We account for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*, or ASC 718. In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award.

We use a Black-Scholes option pricing model to determine fair value of our stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of stock options, the expected volatility based on the historical volatility of a publicly traded set of peer companies and the expected risk-free interest rate based on the implied yield on a U.S. Treasury security. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, stock-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions for future grants, share-based compensation cost could be materially impacted in future periods.

The fair value of our awards in the six months ended June 30, 2023 has been estimated using Black-Scholes based on the following assumptions: expected term of 6.0 years; expected volatility of 91.0%; risk-free interest rate of 3.8%; and no expectation of dividends. The fair value of our awards in the six months ended June 30, 2022 has been estimated using Black-Scholes based on the following assumptions: expected term of 6.0 years; expected volatility of 90.0%; risk-free interest rate of 1.7%; and no expectation of dividends.

We will continue to use judgment in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes model, the amount of stock-based compensation expense we recognize in our consolidated financial statements includes stock option forfeitures as they occurred. We recognize forfeitures as they occur, and the compensation expense is reversed in the period that the forfeiture occurs.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in

the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that our net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce our net deferred tax assets.

We recognize tax benefits from uncertain tax positions only if (based on the technical merits of the position) it is more likely than not that the tax positions will be sustained on examination by the tax authority. The tax benefits recognized in the financial statements from such positions are measured based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. We do not believe there will be any material changes in its unrecognized tax positions over the next 12 months. We have not incurred any interest or penalties. In the event we are assessed interest or penalties at some point in the future, they will be classified in the financial statements as a component of income tax expense.

We operate in multiple jurisdictions, both within and outside the United States, and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the extent to which our deferred tax assets may be realized and adjust the valuation allowance accordingly.

Recently Adopted Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our consolidated financial statements for the six months ended June 30, 2023 and 2022 appearing elsewhere in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company, or EGC, under the Jumpstart our Business Startups Act of 2012, or the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited consolidated financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of the completion of our IPO, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year before that time, or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period.

We are also a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time, we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. Since we intend to retain and continue to use our equipment, furniture, fixtures and office equipment, computer hardware and software and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expense and use of our resources. We continue to monitor the impact of inflation on these costs in order to minimize its effects through productivity improvements and cost reductions. There can be no assurance, however, that our operating results will not be affected by inflation in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

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

Changes in Internal Control

There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which could materially affect our business, financial condition, or results of operations. There have been no material changes in or additions to the risk factors referred to in the previous sentence.

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

Use of proceeds from registered securities

On November 2, 2020, we completed our IPO in which we issued and sold 6,342,207 shares of common stock, $0.00001 par value per share, including 675,540 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-249369), which was filed with the SEC on October 7, 2020 and subsequently amended and declared effective on October 28, 2020, or the Prospectus. The underwriters of the offering were BofA Securities, Inc., SVB Leerink LLC, Credit Suisse Securities (USA) LLC and Kempen & Co U.S.A, Inc.

We raised $86.3 million in net proceeds after deducting underwriting discounts and commissions of $6.7 million and other offering expenses of $2.1 million payable by us. No underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors of officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of June 30, 2023, $36.9 million of the net proceeds from our IPO have been used for general working capital purposes, including the funding of our clinical development programs. We have invested the unused net proceeds from the offering in money market accounts and marketable debt securities. We expect to use the net proceeds from the offering described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 30, 2020, to fund our clinical development programs, including for GB0139, GB1211 and GB2064.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Not Applicable.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer 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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

† This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

Galecto, Inc.

Date: July 31, 2023

By: /s/ Hans T. Schambye

Hans T. Schambye, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: July 31, 2023

By: /s/ Jonathan Freve

Jonathan Freve
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Hans T. Schambye, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2023 of Galecto, Inc.;

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

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

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

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statement for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 31, 2023

By: /s/ Hans T. Schambye

Hans T. Schambye, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Jonathan Freve, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2023 of Galecto, Inc.;

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

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

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

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statement for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 31, 2023

By: /s/ Jonathan Freve

Jonathan Freve
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Hans T. Schambye, the Chief Executive Officer, and Jonathan Freve, the Chief Financial Officer, of Galecto, Inc. (the "Company"), hereby certify, that, to their knowledge:

(1) the Quarterly Report on Form 10-Q for the period ended June 30, 2023 (the "Report") of the Company 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: July 31, 2023

By: /s/ Hans T. Schambye

Hans T. Schambye, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: July 31, 2023

By: /s/ Jonathan Freve

Jonathan Freve
Chief Financial Officer
(Principal Financial and Accounting Officer)