UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

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 **(State or other jurisdiction of incorporation or organization)**	**37-1957007** **(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** **(Address of principal executive offices)**	**02109** **(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 November 4, 2022, the registrant had 25,581,029 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;
- the success, cost and timing of our product development activities and planned initiation and completion of clinical trials of our other current fibrosis and oncology product candidates, including GB2064 and GB1211, and any future product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- 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;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations and those of our collaborators, service providers and other vendors, such as any impact on the enrollment for, or timing of, our clinical trials;
- our ability to maintain adequate internal controls over financial reporting; 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, 2021. 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)

	September 30, 2022	December 31, 2021
Assets	(unaudited)	
Current assets		
Cash and cash equivalents	$ 28,336	$ 62,563
Marketable securities	40,748	37,628
Prepaid expenses and other current assets	2,115	9,911
Total current assets	71,199	110,102
Marketable securities, non-current	6,829	9,048
Operating lease right-of-use asset	852	834
Equipment, net	338	203
Other assets, non-current	2,807	2,028
Total assets	$ 82,025	$ 122,215
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,907	$ 1,531
Accrued expenses and other current liabilities	6,951	3,013
Total current liabilities	8,858	4,544
Operating lease liabilities, non-current	440	448
Total liabilities	9,298	4,992
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued or outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, par value of $0.00001 per share; 300,000,000 shares authorized at September 30, 2022 and December 31, 2021; 25,581,029 and 25,261,832 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	278,319	273,655
Accumulated deficit	(203,667)	(156,112)
Accumulated other comprehensive loss	(1,925)	(320)
Total stockholders' equity	72,727	117,223
Total liabilities and stockholders' equity	$ 82,025	$ 122,215

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 10,494	$ 9,748	$ 37,436	$ 28,373
General and administrative	3,128	3,191	10,246	10,386
Total operating expenses	13,622	12,939	47,682	38,759
Loss from operations	(13,622)	(12,939)	(47,682)	(38,759)
Other income (expense), net				
Interest income, net	221	35	438	126
Loss on sale of marketable securities	—	—	(70)	—
Foreign exchange transaction gain (loss), net	(329)	208	(241)	290
Total other income (expense), net	(108)	243	127	416
Net loss	$ (13,730)	$ (12,696)	$ (47,555)	$ (38,343)
Net loss per common share, basic and diluted	$ (0.54)	$ (0.50)	$ (1.88)	$ (1.52)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	25,491,786	25,261,832	25,342,153	25,261,832
Other comprehensive loss, net of tax				
Currency translation loss	(344)	(369)	(1,233)	(740)
Unrealized gain (loss) on marketable securities	(82)	34	(442)	(23)
Reclassification adjustment for loss included in net income	—	—	70	—
Other comprehensive loss, net of tax	(426)	(335)	(1,605)	(763)
Total comprehensive loss	$ (14,156)	$ (13,031)	$ (49,160)	$ (39,106)

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

GALECTO, INC.

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

For the Three Months Ended September 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at June 30, 2022	25,342,138	$ —	$ 276,501	$ (189,937)	$ (1,499)	$ 85,065
Stock-based compensation expense	—	—	1,398	—	—	1,398
Issuance of common stock; net of issuance costs	238,891	—	420	—	—	420
Other comprehensive loss, net	—	—	—	—	(426)	(426)
Net loss	—	—	—	(13,730)	—	(13,730)
Balance at September 30, 2022	25,581,029	$ —	$ 278,319	$ (203,667)	$ (1,925)	$ 72,727

For the Three Months Ended September 30, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at June 30, 2021	25,261,832	$ —	$ 271,193	$ (130,007)	$ 246	$ 141,432
Stock-based compensation expense	—	—	1,219	—	—	1,219
Other comprehensive loss, net	—	—	—	—	(335)	(335)
Net loss	—	—	—	(12,696)	—	(12,696)
Balance at September 30, 2021	25,261,832	$ —	$ 272,412	$ (142,703)	$ (89)	$ 129,620

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

GALECTO, INC.

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

For the Nine Months Ended September 30, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2021	25,261,832	$ —	$ 273,655	$ (156,112)	$ (320)	$ 117,223
Stock-based compensation expense	—	—	4,222	—	—	4,222
Issuance of common stock; net of issuance costs of $0.2 million	319,197	—	442	—	—	442
Other comprehensive loss, net	—	—	—	—	(1,605)	(1,605)
Net loss	—	—	—	(47,555)	—	(47,555)
Balance at September 30, 2022	25,581,029	$ —	$ 278,319	$ (203,667)	$ (1,925)	$ 72,727

For the Nine Months Ended September 30, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2020	25,261,832	$ —	$ 269,175	$ (104,360)	$ 674	$ 165,489
Stock-based compensation expense	—	—	3,237	—	—	3,237
Other comprehensive loss, net	—	—	—	—	(763)	(763)
Net loss	—	—	—	(38,343)	—	(38,343)
Balance at September 30, 2021	25,261,832	$ —	$ 272,412	$ (142,703)	$ (89)	$ 129,620

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

GALECTO, INC.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (47,555)	$ (38,343)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation of equipment	21	13
Stock-based compensation	4,222	3,237
Amortization of premiums and discounts on marketable securities	447	731
Net loss on sale of marketable securities	70	—
Amortization of right of use lease asset	305	317
Accretion of lease liability	36	57
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	7,802	(7)
Other assets, non-current	(785)	(203)
Accounts payable	376	(871)
Accrued expenses and other current liabilities	3,919	993
Operating lease liabilities	(342)	(403)
Net cash used in operating activities	(31,484)	(34,479)
Cash flows from investing activities:		
Purchases of marketable securities	(40,656)	(84,209)
Proceeds from sale of marketable securities	38,865	21,976
Purchases of property and equipment	(155)	(227)
Net cash used in investing activities	(1,946)	(62,460)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	442	—
Net cash provided by financing activities	442	—
Net decrease in cash, cash equivalents and restricted cash	(32,988)	(96,939)
Effect of exchange rate changes on cash and cash equivalents	(1,239)	(740)
Cash and cash equivalents, beginning of period	62,563	163,836
Cash and cash equivalents, end of period	$ 28,336	$ 66,157
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ —	$ 40
Supplemental disclosures of noncash activities:		
Operating lease liabilities arising from obtaining right-of-use assets	$ 449	$ 409

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 September 30, 2022, 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 September 30, 2022, the Company had an accumulated deficit of $203.7 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 nine months ended September 30, 2022 and 2021 of $31.5 million and $34.5 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 nine months ended September 30, 2022 were $13.7 million and $47.6 million, respectively. Net losses incurred for the three and nine months ended September 30, 2021 were $12.7 million and $38.3 million, respectively.

At September 30, 2022, the Company's cash, cash equivalents and marketable securities amounted to $75.9 million and current assets amounted to $71.2 million and current liabilities amounted to $8.9 million. At December 31, 2021, the Company's cash, cash equivalents and marketable securities amounted to $109.2 million, current assets amounted to $110.1 million and current liabilities amounted to $4.5 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 development and regulatory events and its decisions in the future.

Coronavirus pandemic

The novel coronavirus ("COVID-19") and its variants, and ensuing pandemic, has continued to spread worldwide, causing many governments to implement measures to slow the spread of the outbreak. COVID-19 and its variants have had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The Company continues to monitor the impact of COVID-19 and its subvariants and assess its strategy accordingly. However, there can be no assurance that the Company will not experience additional negative impacts associated with the COVID-19 pandemic, which could decrease or delay enrollment of patients in the Company's clinical trials or otherwise cause interruptions or delays in the Company's clinical trials, programs and services, and negatively impact the Company's business, financial condition and results of operations.

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 September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021, 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 September 30, 2022, results of operations, statement of stockholders' equity for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021. 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, 2021, as filed with the Securities and Exchange Commission ("SEC") on February 17, 2022 ("2021 Consolidated Financial Statements"). The results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

For the nine months ended September 30, 2022, there have been no changes to the significant accounting policies as disclosed in Note 2 to the Company's annual consolidated financial statements for the year ended December 31, 2021.

Recently issued accounting standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. The ASU 2016-13 guidance became effective as of January 1, 2020, and must be adopted using a modified retrospective approach, with certain exceptions. This guidance is effective for public business entities that meet the definition of a SEC, excluding eligible smaller reporting companies for fiscal years beginning after December 15, 2019. For all other entities, including emerging growth companies, it is effective for fiscal years beginning after December 15, 2022. The Company has not yet adopted ASU 2016-13 and is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and financial statement disclosures.

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 September 30, 2022 and December 31, 2021 consisted of the following (in thousands):

	At September 30, 2022			
Marketable securities:	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Corporate bonds	$ 41,035	$ —	$ (287)	$ 40,748
Total	$ 41,035	$ —	$ (287)	$ 40,748
Marketable securities, non-current:				
Corporate bonds	$ 6,991	$ —	$ (162)	$ 6,829
Total	$ 6,991	$ —	$ (162)	$ 6,829

	At December 31, 2021			
Marketable securities:	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Corporate bonds	$ 37,671	$ —	$ (43)	$ 37,628
Total	$ 37,671	$ —	$ (43)	$ 37,628
Marketable securities, non-current:				
Corporate bonds	$ 9,082	$ —	$ (34)	$ 9,048
Total	$ 9,082	$ —	$ (34)	$ 9,048

The Company incurred a realized loss on an available-for sale investment during the nine months ending September 30, 2022 of $0.1 million, which is included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment as of September 30, 2022 consisted of the following (in thousands):

	September 30, 2022	**December 31, 2021**
Equipment	$ 379	$ 223
Less: accumulated depreciation	(41)	(20)
Equipment, net	$ 338	$ 203

Depreciation expense for the three and nine months ended September 30, 2022 was $6,000 and $21,000, respectively. Depreciation expense for the three and nine months ended September 30, 2021 was $8,000 and $13,000, 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 September 30, 2022 and December 31, 2021 is as follows (in thousands):

	Fair Value Measurement at September 30, 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)]	$ 13,160	$ 13,160	$ —	$ —
Debt securities	47,577	—	47,577	—
Total	$ 60,737	$ 13,160	$ 47,577	$ —

	Fair Value Measurement at December 31, 2021			
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)]	$ 49,626	49,626	—	—
Debt securities	46,676	—	46,676	—
Total	$ 96,302	$ 49,626	$ 46,676	$ —

(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):

	September 30, 2022	December 31, 2021
Contract research and development costs	$ 732	$ 5,569
Research and development tax credit receivable	724	1,682
Prepaid insurance costs	214	1,728
Value-added tax refund receivable	368	598
Other	77	334
Total prepaid expenses and other current assets	$ 2,115	$ 9,911

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	May 2023	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 nine months ended September 30, 2022 was $0.1 million and $0.4 million, respectively. Rent expense for the three and nine months ended September 30, 2021 was $0.1 million and $0.4 million, respectively.

Quantitative information regarding the Company's leases for the three and nine months ended September 30, 2022 and 2021 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost	**2022**	**2021**	**2022**	**2021**
Operating lease cost (in thousands)	$ 125	$ 130	$ 368	$ 374
Other Information				
Operating cash flows paid for amounts included in the measurement of lease liabilities (in thousands)	$ 134	$ 142	$ 368	$ 403
Operating lease liabilities arising from obtaining right-of-use assets (in thousands)	$ 449	$ 409	$ 449	$ 409

As of September 30, 2022 and December 31, 2021, the weighted average remaining lease term for operating leases was 2.0 years and 2.4 years, respectively.

As of September 30, 2022 and December 31, 2021, the weighted average discount rate for operating leases was 8% for both periods.

Operating lease liabilities at September 30, 2022 are as follows (in thousands):

Future Lease Payments	**Operating Leases**
2022 (excluding the period ended September 30, 2022)	$ 134
2023	481
2024	269
2025	47
2026	—
Total lease payments	931
Less: imputed interest	(74)
Total lease liabilities	$ 857

8. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	September 30, 2022	December 31, 2021
Contract research and development costs	$ 4,544	$ 1,575
Employee compensation costs	1,549	601
Operating lease liabilities, current	418	399
Other liabilities	440	438
Total accrued expenses and other current liabilities	$ 6,951	$ 3,013

9. COMMITMENTS AND CONTINGENCIES

There have been no material changes to the Company's commitments and contingencies since the 2021 Consolidated Financial Statements. The Company's commitments and contingencies are disclosed in Note 9 of the 2021 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 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 September 30, 2022, the Company had 853,223 options available for future grant under the 2020 Equity Plan.

The following table sets forth the activity for the Company's stock options during the nine months ended September 30, 2022:

	Number of Options	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2021	3,998,728	$ 6.51	8.3	$ 1,357,655
Granted	1,827,750	2.98	—	111,013
Cancelled	(16,250)	4.24	—	—
Outstanding at September 30, 2022	5,810,228	$ 5.41	8.1	$ 2,400
Vested and expected to vest at September 30, 2022	5,506,086	$ 5.41	8.5	$ 2,400
Vested and exercisable at September 30, 2022	2,464,125	$ 5.52	7.2	$ —

The weighted-average grant date fair value of all stock options granted for the nine months ended September 30, 2022 was $2.22. The intrinsic value at September 30, 2022 and December 31, 2021 was based on the closing price of the Company's common stock on that date of $1.89 and $3.03 per share, respectively.

Stock-based compensation

The grant date fair value of stock options vested during the nine months ended September 30, 2022 and 2021 was $5.7 million and $1.9 million, respectively. Total unrecognized compensation expense related to unvested options granted under the Company's stock-based compensation plan was $12.3 million at September 30, 2022, which is expected to be recognized over a weighted average period of 2.4 years. The Company recorded stock-based compensation expense related to the issuance of stock as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 657	$ 516	$ 1,980	$ 1,372
General and administrative	741	703	2,242	1,865
Total stock-based compensation	$ 1,398	$ 1,219	$ 4,222	$ 3,237

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:

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	1.7%	0.7%
Expected term (in years)	6.0	6.0
Expected volatility	90.0%	90.5%
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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (13,730)	$ (12,696)	$ (47,555)	$ (38,343)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	25,491,786	25,261,832	25,342,153	25,261,832
Net loss per common share, basic and diluted	$ (0.54)	$ (0.50)	$ (1.88)	$ (1.52)

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

	Three and Nine Months Ended September 30,	
	2022	2021
Stock options to purchase common stock	5,810,228	3,923,728

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, 2021, 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, 2021, filed with the United States Securities and Exchange Commission, or the SEC, on February 17, 2022. 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, 2021 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 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 and fibrotic diseases and promote cancer progression, while 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 and metastasis. Our product candidates are designed to modulate multiple disease pathways simultaneously by inhibiting the master drivers of the cancer and fibrotic cascades and may also work synergistically with and enhance the efficacy of other therapeutics. 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.

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, and have not conclusively shown an impact on survival. 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. We also observed that GB0139 decreased levels of a range of plasma biomarkers, such as YKL-40 and platelet-derived growth factor that have been linked to mortality, disease severity and/or progression in IPF. We are currently conducting a 52-week randomized, double-blind, multicenter, parallel, placebo-controlled Phase 2b trial investigating the safety and efficacy of GB0139 in patients with IPF, which we refer to as the GALACTIC-1 trial. We completed target enrollment of 141 patients during the second quarter of 2022 and expect topline results to be available in mid-2023.

GB2064 is a selective oral small molecule inhibitor of LOXL2. We are initially developing GB2064 for the treatment of myelofibrosis, a malignant disease of the bone marrow in which fibrosis reduces the ability to form blood cells. 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 trial examining GB2064 in myelofibrosis, which we refer to as the MYLOX-1 trial, and we announced results from a planned intermediate assessment in the third quarter of 2022. As part of this assessment, we evaluated results from the first five patients who had completed at least six months of treatment with GB2064 and who had repeated bone marrow biopsies. In the intermediate assessment, four out of five evaluable myelofibrosis patients who received GB2064 monotherapy for at least six months experienced a $\geq$ 1-grade reduction in collagen fibrosis of the bone marrow, an improvement suggesting that GB2064 could impact the progression of the disease and be disease modifying. All four patients who experienced a > 1-grade reduction in fibrosis score 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, sixteen patients in the MYLOX-1 trial had been dosed with GB2064, of which eight patients have completed or continue to receive treatment and eight patients have either discontinued treatment as a result of an adverse event or disease progression. 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, 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, demonstrating a generally acceptable tolerability profile from this assessment. We expect topline results to be available in the second half of 2023.

GB1211 is a selective oral small molecule inhibitor of galectin-3, is chemically distinct from GB0139 and is initially being developed for the treatment of oncology indications and liver cirrhosis. We believe GB1211 has the potential to treat multiple types of fibrosis and oncology indications. 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. We also believe that inhibiting galectin-3 could lead to an increase in the efficacy of checkpoint inhibitors in cancer patients with high galectin-3 expression, as evidenced by preclinical data that we recently 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 effects with these checkpoint inhibitors. Our initial target indication for GB1211 in oncology is non-small cell lung cancer, or NSCLC, a cancer indication with high unmet 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 planned Phase 2a trial of GB1211 in combination with atezolizumab, marketed by Roche as Tecentriq®, a programmed death-ligand 1 (PD-L1) checkpoint inhibitor for the treatment of first-line NSCLC, which we refer to as the GALLANT-1 trial. We initiated the GALLANT-1 trial in the second quarter of 2022 and expect topline results to be available in the second half of 2023.

In October 2022, we entered into an agreement with Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI) to evaluate the safety and efficacy of GB1211 in combination with pembrolizumab (Keytruda®). Galecto has committed to supply GB1211 for this Phase 2 trial. The randomized, double-blind placebo controlled, investigator-initiated Phase 2 trial will evaluate whether the addition of GB1211 increases the response rate of pembrolizumab in metastatic melanoma and head and neck squamous cell carcinoma (HNSCC) patients. The study will employ a fixed dose of GB1211 in conjunction 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 2023 and topline results of the combination are expected to be reported as early as 2025.

In fibrosis, 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 specific therapeutics available. We are currently conducting a Phase 1b/2a trial of GB1211 for liver cirrhosis, which we refer to as the GULLIVER-2 trial, that is focused on safety and effect on liver function and fibrosis biomarkers.

In November 2022, we announced topline results from the GULLIVER-2 trial that showed 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. Patients treated with GB1211 also demonstrated improvement and consistent signs of activity across biochemical liver function markers and markers of target engagement, apoptosis, and fibrosis, including reductions in galectin-3 ($p<0.05$) and CK-18 (M65) ($p<0.002$). Bilirubin, albumin, international normalized ratio (INR) and other biochemical measurements remained stable. These findings suggest that GB1211 provided liver cell protection and improved liver status, further supporting clinical development in severe liver disease. Liver enzyme (AST, ALT, and GGT) reductions were observed after seven days of treatment and continued to decrease over the 12 weeks of treatment. These liver enzyme levels remained decreased compared to baseline two weeks after the study's conclusion, indicating durable effects and a decrease in liver inflammation. The use of GB1211 in the GULLIVER-2 trial showed encouraging numerical improvements in liver health biomarkers after 12 weeks of therapy.

GB1211 exhibited a favorable tolerability profile in Child-Pugh B decompensated liver cirrhosis patients in the GULLIVER-2 trial. Five of 15 patients on GB1211 and four of 15 patients on placebo reported nine and eight treatment-emergent adverse events (TEAEs), respectively. Three serious TEAEs were observed in one patient on GB1211, but were deemed to be unrelated to GB1211.

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 convertible preferred shares and convertible notes. Since inception, we have had significant operating losses. Our net loss was $13.7 million and $47.6 million for the three and nine months ended September 30, 2022, respectively. Our net loss was $12.7 million and $38.3 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $203.7 million and $75.9 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 to increase. In particular, we expect our expenses to increase as we continue 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 increased 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 $75.9 million as of September 30, 2022 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.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked. The continued impact of these events on our business and operations are uncertain.

In response to the disruptions caused by the COVID-19 pandemic and various resulting government directives, we implemented certain measures intended to help us manage its impact, including a hybrid work-from-home strategy for administrative functions and operations. Despite our implementation of such measures, the actual and perceived effect of the COVID-19 pandemic continues to evolve. The COVID-19 pandemic has caused delays and difficulties in the initiation of and recruitment in our ongoing clinical trials of GB0139 (GALACTIC-1), GB2064 (MYLOX-1) and GB1211 (GALLANT-1 and our recently completed GULLIVER-2 trial). If COVID-19 and its variants continue to impact patient recruitment on our trials, we may not be able to maintain our planned timing for completion of enrollment in these trials, which could require further amendments to trial protocols and delay planned readouts from our trials. We cannot assure you that we will not experience additional negative impacts associated with COVID-19 and its variants, which could be significant. The COVID-19 pandemic may negatively impact our business, financial condition and results of operations, including by decreasing or delaying the enrollment of patients in our clinical trials or otherwise causing interruptions or delays in our programs and services. See "*Risk Factors—Risks Related to Managing Our Business and Operations—The global pandemic of the novel coronavirus disease, COVID-19, has, and may continue to, adversely impact our business, including our preclinical studies and clinical trials*" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 for more information regarding the potential impact of COVID-19 and its variants on our business and operations.

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 and $0.9 million for the nine month period ended September 30, 2022 and 2021, respectively.

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 nine month period ended September 30, 2022 and 2021 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 increase 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 our research and 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 increase 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 increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel, legal, regulatory and other fees, director and officer insurance premiums and investor relations costs associated with our growth and continued expansion of our 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.

- Loss on sales of marketable securities: The loss on the sales of our 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 September 30, 2022 and 2021

The following sets forth our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change	
	2022	2021	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	$ 10,494	$ 9,748	$ 746	7.7%
General and administrative	3,128	3,191	(63)	-2.0%
Total operating expenses	$ 13,622	$ 12,939	$ 683	5.3%
Loss from operations	(13,622)	(12,939)	(683)	5.3%
Other income (expense), net	(108)	243	(351)	-144.4%
Net loss	$ (13,730)	$ (12,696)	$ (1,034)	8.1%

Research and development expenses

Research and development expenses were comprised of:

	Three Months Ended September 30,		Change	
	2022	2021	Amount	Percent
	(in thousands)			
Preclinical studies and clinical trial-related activities	$ 5,897	$ 5,312	$ 585	11.0%
Chemistry, manufacturing and control	1,354	1,314	40	3.0%
Personnel	1,993	2,046	(53)	-2.6%
Consultants and other costs	1,250	1,076	174	16.2%
Total research and development expenses	$ 10,494	$ 9,748	$ 746	7.7%

Research and development expenses were $10.5 million for the three months ended September 30, 2022, compared to $9.7 million for the three months ended September 30, 2021. The increase of $0.7 million was primarily related to increased clinical trial-related expenses of $0.6 million resulting from the GALACTIC-1 Phase 2b trial and three other Phase 2 clinical trials and increased other general research and development costs of $0.2 million, offset by decreased personnel costs of $0.1 million.

General and administrative expenses

General and administrative expenses were $3.1 million for the three months ended September 30, 2022, compared to $3.2 million for the three months ended September 30, 2021. The decrease of $0.1 million was primarily related to decreased net other general administrative costs.

Other income (expense), net

Other income (expense), net for the three months ended September 30, 2022 was $(0.1) million, compared to $0.2 million other income (expense), net for the three months ended September 30, 2021. The decrease of $0.3 million was primarily due to a net foreign exchange loss, offset by an increase in net interest income.

Comparison of the Nine Months Ended September 30, 2022 and 2021

	Nine Months Ended September 30,		Change	
	2022	2021	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	$ 37,436	$ 28,373	$ 9,063	31.9%
General and administrative	10,246	10,386	(140)	-1.3%
Total operating expenses	$ 47,682	$ 38,759	$ 8,923	23.0%
Loss from operations	(47,682)	(38,759)	(8,923)	23.0%
Other income, net	127	416	(289)	-69.5%
Net loss	$ (47,555)	$ (38,343)	$ (9,212)	24.0%

Research and development expenses

Research and development expenses were comprised of:

	Nine Months Ended September 30,		Change	
	2022	2021	Amount	Percent
	(in thousands)			
Preclinical studies and clinical trial-related activities	$ 22,605	$ 14,115	$ 8,490	60.1%
Chemistry, manufacturing and control	4,423	5,708	(1,285)	-22.5%
Personnel	6,922	5,748	1,174	20.4%
Consultants and other costs	3,486	2,802	684	24.4%
Total research and development expenses	$ 37,436	$ 28,373	$ 9,063	31.9%

Research and development expenses were $37.4 million for the nine months ended September 30, 2022, compared to $28.4 million for the nine months ended September 30, 2021. The increase of $9.1 million was primarily related to increased clinical trial-related expenses of $8.5 million resulting from the GALACTIC-1 Phase 2b trial and three other Phase 2 clinical trials, increased personnel costs due to additional headcount of $0.6 million and personnel costs for non-cash stock-based compensation of $0.6 million and increased other general research and development costs of $0.7 million, offset by decreased manufacturing expenses of $1.3 million.

General and administrative expenses

General and administrative expenses were $10.2 million for the nine months ended September 30, 2022, compared to $10.4 million for the nine months ended September 30, 2021. The decrease of $0.2 million was primarily related to decreased consulting related costs of $0.9 million and decreased legal related costs of $0.5 million; offset by increased personnel costs due to additional headcount of $0.4 million and personnel costs for non-cash stock-based compensation of $0.4 million and increased other general and administrative costs of $0.4 million.

Other income (expense), net

Other income (expense), net for the nine months ended September 30, 2022 was $0.1 million, compared to other income (expense), net of $0.4 million for the nine months ended September 30, 2021. The decrease of $0.3 million was primarily due to a net foreign exchange loss, offset by 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 AgreementSM 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 nine months ended September 30, 2022, we sold an aggregate of 238,891 and 319,197 shares, respectively, of our common stock under the ATM Program at a weighted average selling price of $1.99 per share during both periods.

Our net losses were $13.7 million and $47.6 million for the three and nine months ended September 30, 2022, respectively. Our net losses were $12.7 million and $38.3 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $203.7 million and $75.9 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:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (31,484)	$ (34,479)
Net cash used in investing activities	(1,946)	(62,460)
Net cash provided by financing activities	442	—
Net decrease in cash and cash equivalents	$ (32,988)	$ (96,939)

Net Cash Used in Operating Activities

Cash used in operating activities of $31.5 million during the nine months ended September 30, 2022 was primarily attributable to our net loss of $47.6 million together with non-cash items of $5.1 million principally with respect to stock-based compensation and a net increase of $11.0 million in components of our working capital.

Cash used in operating activities of $34.5 million during the nine months ended September 30, 2021 was primarily attributable to our net loss of $38.3 million together with non-cash items of $4.4 million principally with respect to stock-based compensation, offset by a net decrease of $0.5 million in components of our working capital.

Net Cash Used in Investing Activities

Cash used in investing activities of $1.9 million during the nine months ended September 30, 2022 was the result of $40.7 million for the purchase of marketable securities and $0.1 million for the purchase of property and equipment, offset by $38.9 million in proceeds from the sale of marketable securities.

Cash used in investing activities of $62.5 million during the nine months ended September 30, 2021 was the result of $84.2 million for the purchase of marketable securities and $0.2 million for the purchase of property and equipment, offset by $21.9 million in proceeds from the sale of marketable securities.

Net Cash Provided by Financing Activities

Cash provided by financing activities of $0.4 million during nine months ended September 30, 2022 was the result of net proceeds from the issuance of our common stock. We had no financing activities for the nine months ended September 30, 2021.

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 $75.9 million as of September 30, 2022 will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. 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. 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. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Volatility in equity capital markets may adversely affect the market price of our equity securities, which may materially and adversely affect our ability to fund our business through public or private sales of equity securities. If we raise additional capital through public or private equity offerings in the future, 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. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

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 continued impacts of the ongoing COVID-19 pandemic;
- 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 nine months ended September 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. The fair value of our awards in the nine months ended September 30, 2021 has been estimated using Black-Scholes based on the following assumptions: term of 6.0 years; volatility of 90.5%; risk-free rate of 0.7%; 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 nine months ended September 30, 2022 and 2021 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 $1.07 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, 2021 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 September 30, 2022. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, 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, 2021, 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 September 30, 2022, $10.9 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.

On November 8, 2022, we announced topline results from the GULLIVER-2 trial that showed statistically significant reductions in ALT ($p<0.0005$), AST ($p<0.005$) and GGT ($p<0.05$), with encouraging reductions in ALP ($p<0.09$), after 12 weeks of treatment. Patients treated with GB1211 also demonstrated improvement and consistent signs of activity across biochemical liver function markers and markers of target engagement, apoptosis, and fibrosis, including reductions in galectin-3 ($p<0.05$) and CK-18 (M65) ($p<0.002$). Bilirubin, albumin, international normalized ratio (INR) and other biochemical measurements remained stable. These findings suggest that GB1211 provided liver cell protection and improved liver status, further supporting clinical development in severe liver disease. Liver enzyme (AST, ALT, and GGT) reductions were observed after seven days of treatment and continued to decrease over the 12 weeks of treatment. These liver enzyme levels remained decreased compared to baseline two weeks after the study's conclusion, indicating durable effects and a decrease in liver inflammation. The use of GB1211 in the GULLIVER-2 trial showed encouraging numerical improvements in liver health biomarkers after 12 weeks of therapy.

GB1211 exhibited a favorable tolerability profile in Child-Pugh B decompensated liver cirrhosis patients in the GULLIVER-2 trial. Five of 15 patients on GB1211 and four of 15 patients on placebo reported nine and eight treatment-emergent adverse events (TEAEs), respectively. Three serious TEAEs were observed in one patient on GB1211, but were deemed to be unrelated to GB1211.

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: November 8, 2022

By: /s/ Hans T. Schambye

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

Date: November 8, 2022

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 September 30, 2022 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: November 8, 2022

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 September 30, 2022 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: November 8, 2022

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 September 30, 2022 (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: November 8, 2022

By: /s/ Hans T. Schambye

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

Date: November 8, 2022

By: /s/ Jonathan Freve

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