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, 2025

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 Capital 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 3, 2025, the registrant had 1,327,212 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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (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," "contemplate," "project," "continue," "potential," "ongoing," "goal," or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements regarding:

- our need to raise significant additional funding;
- our ability to successfully execute on our realigned strategic focus with GB3226 and GB1211;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our product candidates, and our ability to continue as a going concern;
- the success, cost and timing of our product development activities and planned initiation and completion of clinical trials of our current oncology and liver disease product candidates, including GB3226 and GB1211, and any future product candidates;
- our ability to retain the continued service of our directors, officers, key employees and consultants;
- our ability to maintain the listing of our common stock on the Nasdaq Stock Market LLC;
- 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 and execution 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 expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- our financial performance and liquidity;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting;
- the effects of global economic uncertainty and financial market volatility caused by economic effects of volatility in inflation and interest rates, tariffs and changes in economic policies, geopolitical instability, changes in international trade relationships and conflicts, such as the ongoing conflicts between Russia and Ukraine or Israel and Hamas, on any of the foregoing or other aspects of our business or operations; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, the reasons described elsewhere in this Quarterly Report on Form 10-Q and those set forth in Part I, Item 1A - "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in Part II, Item 1A "Risk Factors" in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025. 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, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 7,606	$ 14,175
Prepaid expenses and other current assets	2,180	2,664
Total current assets	9,786	16,839
Operating lease right-of-use asset	72	73
Equipment, net	41	57
Other assets, noncurrent	837	163
Total assets	$ 10,736	$ 17,132
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 520	$ 377
Accrued expenses and other current liabilities	2,103	820
Total current liabilities	2,623	1,197
Operating lease liabilities, noncurrent	57	61
Other liabilities, noncurrent	49	43
Total liabilities	2,729	1,301
Commitments and contingencies (Note 8)		
Mezzanine equity		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized at September 30, 2025 and December 31, 2024; 159 and 161 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	1,341	1,360
Stockholders' equity		
Common stock, par value of $0.00001 per share; 300,000,000 shares authorized at September 30, 2025 and December 31, 2024; 1,327,212 and 1,316,989 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	292,470	291,898
Accumulated deficit	(286,627)	(277,524)
Accumulated other comprehensive income	823	97
Total stockholders' equity	8,007	15,831
Total liabilities and stockholders' equity	$ 10,736	$ 17,132

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,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 1,416	$ 1,093	$ 3,559	$ 5,390
General and administrative	1,740	2,747	5,617	8,800
Restructuring costs	—	—	—	968
Total operating expenses	3,156	3,840	9,176	15,158
Loss from operations	(3,156)	(3,840)	(9,176)	(15,158)
Other income (loss), net				
Interest income, net	42	146	166	616
Foreign exchange transaction loss, net	(19)	(182)	(87)	(107)
Total other income (loss), net	23	(36)	79	509
Loss before income tax expense	(3,133)	(3,876)	(9,097)	(14,649)
Income tax expense	—	(7)	(6)	(49)
Net loss	$ (3,133)	$ (3,883)	$ (9,103)	$ (14,698)
Net loss per common share, basic and diluted	$ (2.36)	$ (3.39)	$ (6.88)	$ (13.30)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,327,039	1,144,978	1,323,886	1,104,849
Other comprehensive income, net of tax				
Currency translation gain	14	468	726	251
Unrealized gain on marketable securities	—	—	—	34
Other comprehensive income, net of tax	14	468	726	285
Total comprehensive loss	$ (3,119)	$ (3,415)	$ (8,377)	$ (14,413)

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

GALECTO, INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

	Mezzanine Equity		Stockholders' Equity					
Three Months Ended	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
September 30, 2025	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at June 30, 2025	159	$ 1,341	1,324,560	$ —	$ 292,297	$ (283,494)	$ 809	$ 10,953
Stock-based compensation expense	—	—	—	—	164	—	—	164
Issuance of common stock in connection with vesting of restricted stock units	—	—	2,652	—	9	—	—	9
Other comprehensive income, net	—	—	—	—	—	—	14	14
Net loss	—	—	—	—	—	(3,133)	—	(3,133)
Balance at September 30, 2025	159	$ 1,341	1,327,212	$ —	$ 292,470	$ (286,627)	$ 823	$ 8,007

	Mezzanine Equity		Stockholders' Equity					
Three Months Ended	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
September 30, 2024	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at June 30, 2024	—	$ —	1,084,840	$ —	$ 290,291	$ (266,900)	$ 197	$ 23,588
Stock-based compensation expense	—	—	—	—	681	—	—	681
Issuance of common stock in connection with vesting of restricted stock units	—	—	5,945	—	81	—	—	81
Round-up shares from the 1-for-25 reverse split effective August 29, 2024	—	—	163,058	—	—	—	—	—
Other comprehensive income, net	—	—	—	—	—	—	468	468
Net loss	—	—	—	—	—	(3,883)	—	(3,883)
Balance at September 30, 2024	—	$ —	1,253,843	$ —	$ 291,053	$ (270,783)	$ 665	$ 20,935

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

GALECTO, INC.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

	Mezzanine Equity		Stockholders' Equity					
Nine Months Ended	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
September 30, 2025	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2024	161	$ 1,360	1,316,989	$ —	$ 291,898	$ (277,524)	$ 97	$ 15,831
Stock-based compensation expense	—	—	—	—	515	—	—	515
Conversion of Series A Preferred Stock	(2)	(19)	2,201	—	19	—	—	—
Issuance of common stock in connection with vesting of restricted stock units			8,022	—	38	—	—	38
Other comprehensive income, net	—	—	—	—	—	—	726	726
Net loss	—	—	—	—	—	(9,103)	—	(9,103)
Balance at September 30, 2025	159	$ 1,341	1,327,212	$ —	$ 292,470	$ (286,627)	$ 823	$ 8,007

	Mezzanine Equity		Stockholders' Equity					
Nine Months Ended	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
September 30, 2024	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2023	—	$ —	1,084,507	$ —	$ 288,036	$ (256,085)	$ 380	$ 32,331
Stock-based compensation expense	—	—	—	—	2,931	—	—	2,931
Issuance of common stock in connection with vesting of restricted stock units	—	—	6,278	—	86	—	—	86
Round-up shares from the 1-for-25 reverse split effective August 29, 2024	—	—	163,058	—	—	—	—	—
Other comprehensive income, net	—	—	—	—	—	—	285	285
Net loss	—	—	—	—	—	(14,698)	—	(14,698)
Balance at September 30, 2024	—	$ —	1,253,843	$ —	$ 291,053	$ (270,783)	$ 665	$ 20,935

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (9,103)	$ (14,698)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation	16	16
Stock-based compensation	515	2,931
Issuance of common stock in connection with vesting of restricted stock units	38	86
Amortization of premiums and discounts on marketable securities	—	70
Amortization of right of use lease asset	11	219
Accretion of lease liability	5	9
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	482	2,121
Other assets, noncurrent	(671)	(974)
Accounts payable	143	(1,199)
Accrued expenses and other current liabilities	1,281	(2,040)
Operating lease liabilities	(15)	(228)
Other liabilities, noncurrent	6	—
Net cash used in operating activities	(7,292)	(13,687)
Cash flows from investing activities:		
Proceeds from sale of marketable securities	—	11,650
Net cash provided by investing activities	—	11,650
Net decrease in cash and cash equivalents	(7,292)	(2,037)
Effect of exchange rate changes on cash and cash equivalents	723	250
Cash and cash equivalents, beginning of period	14,175	21,465
Cash and cash equivalents, end of period	$ 7,606	$ 19,678
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ 5	$ —

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

GALECTO, INC.
Notes to the Condensed Consolidated Financial Statements
(Unaudited)

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 focus is on the development of small molecule inhibitors for the treatment of cancer and severe liver diseases.

As of September 30, 2025, the Company's wholly owned subsidiaries were PharmAkea, Inc., a Delaware corporation, Galecto Securities Corporation, a Massachusetts corporation, and Galecto Biotech AB, a Swedish company. Galecto Biotech ApS, a Danish operating company, is a wholly-owned subsidiary of Galecto Biotech AB.

Strategic Shift in Business Strategy

In September 2023, the Company undertook an organizational restructuring and determined to conduct a comprehensive exploration of strategic alternatives. In consultation with financial and legal advisors, a comprehensive strategic alternative review process began immediately and evaluated a broad range of options to maximize stockholder value through broad outreach to life sciences companies and a thorough process of evaluation of prospective strategic partners. This review of strategic alternatives resulted in the execution of the Bridge Purchase Agreement (as defined below) in October 2024 with Bridge Medicines LLC ("Bridge Medicines") to acquire the global rights to Bridge Medicines' BRM-1420 program, a novel dual ENL-YEATS and FMS-like tyrosine kinase 3 ("FLT3") inhibitor for multiple genetic subsets of acute myeloid leukemia ("AML"), and assumed certain of Bridge Medicines' liabilities associated with the acquired assets (the "Asset Purchase").

As a result of the conclusion of the strategic alternatives review process, the Company's focus is now on the development of GB3226 (formerly known as BRM-1420) and GB1211. As part of the strategic alternative review process, the Company determined not to further advance GB2064, its LOXL-2 inhibitor candidate.

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.

Going Concern, Liquidity and Management Plans

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these financial statements are issued. Based on current estimates of the Company's expenses going forward, the Company expects that its existing cash and cash equivalents of $7.6 million as of September 30, 2025 will be insufficient to allow the Company to fund its current operating plan through at least the next twelve months from the issuance of these financial statements. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of at least one year from the date these financial statements are issued. The Company has developed plans to mitigate this risk, which primarily consist of raising additional capital through some combination of equity or convertible debt financings and/or potential new collaborations, but there can be no assurances any such financing will be available when needed, on acceptable terms, or at all. If the Company is unable to secure adequate additional funding, it will need to reevaluate

its operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back, or eliminate some or all of its development programs, relinquish rights to its intellectual property on less favorable terms than it would otherwise choose, or cease operations entirely. These actions could materially impact the Company's business, results of operations, and future prospects and the value of shares of its common stock, and investors may lose all or a part of their investment. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from the Company's discovery and product development efforts.

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, and sales of the Company's common stock in "at-the-market" offerings.

As of September 30, 2025, the Company had an accumulated deficit of $286.6 million from recurring losses since inception in 2011. The Company has incurred recurring losses and has not generated revenue as none of the Company's products have obtained the necessary regulatory approval in order to market such 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, 2025 and 2024 of $7.3 million and $13.7 million, respectively, and current projections indicate that the Company will have continued negative cash flows for the foreseeable future as it continues to fund operating expenses. Net losses incurred for the three and nine months ended September 30, 2025 were $3.1 million and $9.1 million, respectively. Net losses incurred for the three and nine months ended September 30, 2024 were $3.9 million and $14.7 million, respectively.

As of September 30, 2025, the Company's cash and cash equivalents amounted to $7.6 million, current assets amounted to $9.8 million and current liabilities amounted to $2.6 million. At December 31, 2024, the Company's cash and cash equivalents amounted to $14.2 million, current assets amounted to $16.8 million, and current liabilities amounted to $1.2 million.

Reverse Stock Split

On August 29, 2024, the Company effected a 1-for-25 reverse stock split of its issued and outstanding common stock. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split. All fractional shares resulting from the reverse stock split were rounded up to the nearest whole number.

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, 2025 and for the three and nine months ended September 30, 2025 and 2024, and related 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, 2025, results of operations, statement of stockholders' equity for the three and nine months ended September 30, 2025 and 2024 and its cash flows for the nine months ended September 30, 2025 and 2024. 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, 2024, as filed with the U.S. Securities and Exchange Commission (the "SEC") on March 19, 2025 (the "2024 Consolidated Financial Statements"). The results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

For the nine months ended September 30, 2025, there have been no material changes to the significant accounting policies as disclosed in Note 2 to the 2024 Consolidated Financial Statements.

Recently Issued Accounting Standards

In December 2023, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2023-09, *Income Taxes*, Accounting Standards Codification ("ASC") 740: *Improvements to Income Tax Disclosures*, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 became effective for fiscal years beginning after December 15, 2024. The Company is currently assessing the potential impact of adopting ASU 2023-09 on its financial statements and financial statement disclosures.

The Company reviewed all other recently issued accounting pronouncements and has concluded they are not applicable or not expected to be significant to the accounting for its operations.

3. PROPERTY AND EQUIPMENT, NET

Property and equipment as of September 30, 2025 consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Equipment	$ 108	$ 107
Less: accumulated depreciation	(67)	(50)
Equipment, net	$ 41	$ 57

Depreciation expense for the three and nine months ended September 30, 2025 was $6,000 and $16,000, respectively. Depreciation expense for the three and nine months ended September 30, 2024 was $6,000 and $16,000, respectively.

4. 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.

A summary of the assets that are measured at fair value as of September 30, 2025 and December 31, 2024 is as follows (in thousands):

		Fair Value Measurement at September 30, 2025		
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)]	$ 1,557	$ 1,557	$ —	$ —
Total	$ 1,557	$ 1,557	$ —	$ —

		Fair Value Measurement at December 31, 2024		
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)]	$ 5,926	$ 5,926	$ —	$ —
Total	$ 5,926	$ 5,926	$ —	$ —

(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.

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	September 30, 2025	December 31, 2024
Contract research and development costs	$ 1,017	$ 1,103
Research and development tax credit receivable	964	836
Prepaid insurance costs	56	590
Value-added tax refund receivable	28	45
Other	115	90
Total prepaid expenses and other current assets	$ 2,180	$ 2,664

6. LEASES

The Company has the following operating leases:

Location	Primary Use	Lease Expiration Date	Renewal Option
Copenhagen, Denmark	Corporate headquarters	November 2029	None

The Company has no finance leases and has elected to apply the short-term lease exception to all leases with durations of one year or less. Rent expense for the three and nine months ended September 30, 2025 was $5,000 and $15,000, respectively. Rent expense for the three and nine months ended September 30, 2024 was $49,000 and $192,000, respectively.

Quantitative information regarding the Company's leases for the three and nine months ended September 30, 2025 and 2024 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost	2025	2024	2025	2024
Operating lease cost (in thousands)	$ 5	$ 49	$ 15	$ 192
Other Information				
Operating cash flows paid for amounts included in the measurement of lease liabilities (in thousands)	$ 5	$ 50	$ 15	$ 190
Operating lease liabilities arising from obtaining right-of-use assets (in thousands)	$ —	$ —	$ —	$ —

As of September 30, 2025 and December 31, 2024, the weighted average remaining lease term for operating leases was 4.2 years and 4.9 years, respectively.

As of September 30, 2025 and December 31, 2024, the weighted average discount rate for operating leases was 8% for both periods.

Operating lease liabilities at September 30, 2025 are as follows (in thousands):

Future Lease Payments	Operating Leases
2025 (excluding the period ended September 30, 2025)	$ 5
2026	20
2027	20
2028	20
2029	20
Total lease payments	85
Less: imputed interest	(13)
Total lease liabilities	$ 72

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	September 30, 2025	December 31, 2024
Employee compensation costs	$ 1,229	$ 204
Contract research and development costs	487	117
Operating lease liabilities, current	15	12
Other liabilities	372	487
Total accrued expenses and other current liabilities	$ 2,103	$ 820

8. COMMITMENTS AND CONTINGENCIES

During the three and nine months ended September 30, 2025, there were no material changes to the Company's commitments and contingencies as disclosed in Note 9 of the 2024 Consolidated Financial Statements. Further, the Company's commitments related to lease agreements are disclosed in Note 6.

9. STOCKHOLDERS' EQUITY

Series A Non-Voting Convertible Preferred Stock

In October 2024, the Company entered into an Asset Purchase Agreement (the "Bridge Purchase Agreement") with Bridge Medicines pursuant to which the Company acquired global rights to Bridge Medicines' BRM-1420 program, a novel dual ENL-YEATS and FLT3 inhibitor for multiple genetic subsets of AML, and assumed certain of Bridge Medicines' liabilities associated with the Asset Purchase. As consideration to Bridge Medicines for the Asset Purchase, the Company (a) issued to Bridge Medicines (i) 62,594 shares of the Company's common stock and (ii) 160.562 shares of the Company's Series A non-voting convertible preferred stock, par value $0.00001 per share (the "Preferred Stock"), and (b) assumed specified liabilities.

The terms of the Preferred Stock are as set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock (the "Certificate of Designation"). Each share of Preferred Stock is convertible into 1,000 shares of common stock at the election of the holder of such Preferred Stock. Except as required by law, the Preferred Stock has no voting rights, provided that the Company shall not, without the affirmative vote or written consent of the holders of majority of then outstanding Preferred Stock, among other things, alter or change adversely the power, preferences or rights given to the Preferred Stock, amend the Certificate of Designation, or issue additional shares of Preferred Stock.

On June 18, 2025, the Company's stockholders approved, for purposes of the Nasdaq Listing Rules, the issuance of the Company's common stock upon conversion of the Preferred Stock (the "Stockholder Approval"). On the third business day following the Company's receipt of the Stockholder Approval, certain outstanding shares of Preferred Stock were, subject to certain beneficial ownership limitations, automatically converted into 1,000 shares of common stock upon the conversion terms set forth in the Certificate of Designation. As a result, on June 23, 2025, 2.201 shares of Preferred Stock were automatically converted into 2,201 shares of the Company's common stock.

Employee Equity Plans

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 are entitled to exercise the vested portion of the stock option during the term of the grant.

In October 2020, as part of the Company's initial public offering, 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-based awards granted under the 2020 Equity Plan generally vest over a four-year period and expire ten years from the grant date. Shares available for grant under the 2020 Equity Plan cumulatively increase by 5% of the number of shares of common stock issued and outstanding on January 1st each year until 2030. At September 30, 2025, the Company had 174,141 shares remaining 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, 2025:

	Number of Options	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2024	222,079	$ 78.37	7.2	$ —
Granted	39,440	5.38	—	—
Cancelled	(20,387)	137.39	—	—
Outstanding at September 30, 2025	241,132	$ 61.44	7.6	$ —
Vested and expected to vest at September 30, 2025	241,132	$ 61.44	7.6	$ —
Vested and exercisable at September 30, 2025	127,768	106.73 $	6.3	$ —

The weighted-average grant date fair value of all stock-based awards granted for the nine months ended September 30, 2025 was $4.24 per share. The intrinsic value at September 30, 2025 and December 31, 2024 was based on the closing price of the Company's common stock on these dates of $3.72 and $4.65 per share, respectively.

In November 2022, the Company's Board of Directors approved the 2022 Inducement Plan (the "Inducement Plan"), which allows for the grant of equity awards to be made to new employees where the equity award is a material inducement to an employee entering into employment with the Company. The Inducement Plan was adopted by the Company's Board of Directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). A total of 10,000 shares of the Company's common stock have been reserved for issuance under the Inducement Plan. As of September 30, 2025, no shares have been issued under the Inducement Plan.

Restricted Stock Units

In January 2024, the Company granted 34,200 restricted stock units ("RSUs") to its employees under the 2020 Equity Plan. The weighted average grant date fair value of the time-based RSUs was $17.75 for the year ended December 31, 2024. There were no RSUs granted during the three or nine months ended September 30, 2025. The RSUs vest 33% after one-year from the grant date and 17% every six-months thereafter, subject to continued service to the Company through the applicable vesting dates. For the three and nine months ended September 30, 2025, the Company recognized a $24,000 and $70,000 expense related to the RSUs, respectively. For the three and nine months ended September 30, 2024, the Company recognized a $99,000 and $193,000 expense related to the RSUs, respectively.

The following table sets forth the activity for the Company's RSUs during the nine months ended September 30, 2025:

	Restricted Stock Units	Weighted-average grant date fair value
Total nonvested units at December 31, 2024	15,600	$ 17.75
Granted	—	—
Vested	(7,800)	17.75
Cancelled	—	—
Total nonvested units at September 30, 2025	7,800	$ 17.75

Stock-Based Compensation

The grant date fair value of stock-based awards vested during the nine months ended September 30, 2025 and 2024 was $589,000 and $2,955,000, respectively. Total unrecognized compensation expense related to unvested options granted under the Company's stock-based compensation plan was $904,000 at September 30, 2025, 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,	
	2025	2024	2025	2024
Research and development	$ 3	$ 70	$ 13	$ 887
General and administrative	161	611	502	2,044
Total stock-based compensation	$ 164	$ 681	$ 515	$ 2,931

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 stock, 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,	
	2025	2024
Risk-free interest rate	4.4%	4.2%
Expected term (in years)	5.9	5.3
Expected volatility	95.9%	99.3%
Expected dividend yield	—	—

10. INCOME TAXES

As a result of the Company's history of net operating losses, the Company continues to maintain a full valuation allowance against its domestic net deferred tax assets. For the three months ended September 30, 2025, the Company recognized no income tax expense. For the nine months ended September 30, 2025, the Company recognized an income tax expense of $6,000. For the three and nine months ended September 30, 2024, the Company recognized an income tax expense of $7,000 and $49,000, respectively, primarily due to foreign income tax expense.

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,	
	2025	2024	2025	2024
Net loss	$ (3,133)	$ (3,883)	$ (9,103)	$ (14,698)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,327,039	1,144,978	1,323,886	1,104,849
Net loss per common share, basic and diluted	$ (2.36)	$ (3.39)	$ (6.88)	$ (13.30)

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

	Nine Months Ended September 30,	
	2025	2024
Stock options to purchase common stock	241,131	182,206
Restricted stock units	7,800	16,600

12. SEGMENT REPORTING

The Company has one reportable and one operating segment and manages its business activities primarily in Denmark and North America on a consolidated basis. The Company's singular focus is on the development of small molecule inhibitors for the treatment of cancer and severe liver diseases. All of the Company's tangible assets are held in Denmark and the United States.

The accounting policies of the Company are the same as those described in the summary of significant accounting policies.

The Company's chief operating decision maker ("CODM") is its chief executive officer. The CODM assesses performance for the Company and decides how to allocate resources based on net loss as reported on the consolidated statements of operations. The annual budgeting process is the primary mechanism used to make these decisions. The financial information also helps in making performance assessments using budgeted versus actual results.

The measure of segment assets is reported on the balance sheet as total consolidated assets.

13. 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, 2024, 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, 2024, filed with the SEC on March 19, 2025. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q 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, 2024 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 liver diseases. Our strategy is to focus on diseases without disease-modifying treatment options and where there is a high unmet medical need.

In September 2023, we announced a corporate restructuring restructuring (the "Restructuring Plan") that resulted in a substantial reduction of our workforce and that we had initiated a process to evaluate strategic alternatives. On October 7, 2024, we announced that we had completed our strategic alternative review process and determined to focus on oncology and severe liver diseases. In connection with this announcement, we announced that we had entered into an Asset Purchase Agreement (the "Bridge Purchase Agreement") with Bridge Medicines LLC ("Bridge Medicines"), pursuant to which we acquired global rights to Bridge Medicines' BRM-1420 program, a novel dual ENL-YEATS and FMS-like tyrosine kinase 3 ("FLT3") inhibitor for multiple genetic subsets of acute myeloid leukemia ("AML"), and assumed certain of Bridge Medicines' liabilities associated with the acquired assets. As a result of the conclusion of the strategic alternatives review process and the entry into the Bridge Purchase Agreement, our focus is now on the development of GB3226 (formerly BRM-1420) and GB1211. As part of the strategic alternative review process, we determined not to further advance GB2064, our LOXL-2 inhibitor candidate.

Based on current estimates of our expenses going forward, we believe that our existing cash and cash equivalents will be sufficient to fund the preclinical development of GB3226 into 2026, including the submission of an investigational new drug application ("IND") to the U.S. Food and Drug Administration (the "FDA"). 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. We will require substantial additional capital to finance our operations, including clinical development of any of the GB3226 and GB1211 programs identified herein. If we are unable to secure adequate additional funding, we will need to reevaluate our operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of our development programs, relinquish rights to our intellectual property on less favorable terms than we would otherwise choose, or cease operations entirely.

GB3226

We are developing GB3226, a preclinical small molecule dual inhibitor of ENL-YEATS and FLT3 for multiple molecularly defined subsets of AML, pursuant to a license agreement with Rockefeller University. We anticipate that an ENL-YEATS/FLT3 inhibitor such as GB3226 may have the potential to address a broad portion of the AML patient population, including those with high-risk genetic mutations. For instance, preclinical models have demonstrated that GB3226 is active against mixed-lineage leukemia-rearrange ("MLLr") (or KMT2Ar), NPM1m, and FLT3+ driven AML, and we believe that GB3226 has the potential to be further developed to become a treatment option for other high-risk genetic drivers of AML.

In September 2025, we received feedback from the FDA in response to our pre-IND submission for GB3226. The feedback was consistent with our plans to submit an IND application in the first quarter of 2026 and, subject to obtaining sufficient capital, to conduct a Phase 1trial for the treatment of patients with AML. The proposed first-in-human study is designed as an open-label, dose-escalation and expansion trial to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of GB3226, as well as biomarker analyses, including MYC, MEIS1, HOXA9 and FLT3, to further characterize the therapeutic potential of GB3226 in adults with relapsed or refractory AML. Furthermore, the study is designed to allow potential expansion into a Phase 2 trial following completion of the Phase 1 trial and assessment of preliminary safety, pharmacokinetic, pharmacodynamic and efficacy data. We plan to activate the Phase 2 component through a protocol amendment if the data support progression and regulatory, ethics and any other requisite approvals have been obtained. We would expect initial clinical data for the Phase 1 trial to be available in 2027.

Background on Target Indication and Subsets

We are targeting multiple molecularly defined subsets of AML, a hematologic cancer that is characterized by the clonal expansion of immature myeloid-derived cells, known as blasts, in the peripheral blood and bone marrow. While rare, AML nonetheless is the most common leukemia in adults. In 2023, there were an estimated 20,380 newly diagnosed cases of AML and it caused an estimated 11,310 deaths in the United States. Despite the many available treatments for AML, prognosis for patients remains poor, and the AML sales market is projected to expand to $10 billion by 2028.

Nucleophosmin-1 gene ("NPM1") and FLT3 mutations are among the most common genetic alterations, with each mutation present in approximately 30% of AML patients, including many patients with co-mutations. Mixed lineage leukemia-1 ("MLL") gene ("KMT2A") rearrangements represent approximately 5-10% of adult leukemias and 70-80% of infant leukemias. The prognosis of KMT2A rearranged leukemias is poor with high rates of resistance and relapse following standard of care therapies. In the aggregate, we believe GB3226 has the potential to address greater than 30% of AML cases. Initially, we plan to develop GB3226 as a treatment for AML patients with relapsed or refractory disease, including those who develop resistance to FLT3 or menin inhibitor therapy and those with other high-risk mutations.

MEN1 Mutations.

We believe that GB3226 is well-positioned to address the menin-resistant population within AML. Acute leukemias driven by rearrangement of KMT2A or mutation of NPM1 require the chromatin adapter protein menin, encoded by the MEN1 gene, to sustain aberrant leukemogenic gene expression programs. Somatic mutations in MEN1 have been identified in patients with acquired resistance to menin inhibition. Consistent with the genetic data in patients, inhibitor-menin interface mutations represent a conserved mechanism of therapeutic resistance in xenograft models and in an unbiased base-editor screen. These mutants attenuate drug-target binding by generating structural perturbations that impact small-molecule binding but not the interaction with the natural ligand MLL1, and prevent inhibitor-induced eviction of menin and MLL1 from chromatin. Inhibition of ENL and the subsequent decrease of target gene expression occurs independent of presence of menin and is not negatively impacted by MEN1 mutations, which suggests that this therapeutic resistance could potentially be addressed by GB3226.

Preclinical Data

Bridge Medicines, prior to our acquisition of GB3226, conducted a number of preclinical *in vitro* and *in vivo* studies of GB3226 that suggest it is a potent and selective inhibitor of cell proliferation in MLLr cell lines, with durable anti-tumor activity. GB3226 has shown dose-dependent effects on key genetic drivers of leukemogenesis and maintenance, including HOXA9 and MEIS1, indicating suppression of leukemic stem cell development in the bone marrow. Reductions of blasts cells in peripheral blood, bone marrow, and spleen have been demonstrated in animal models, in addition to cell cycle arrest, differentiation of blasts, and apoptosis. Preclinical studies have shown that GB3226 is active against several molecular drivers of AML, including MLL-r, NPM1m, cKIT+, FLT3+ and TET2+. *In vitro* modeling of GB3226 in combination with AML standard of care therapies and menin inhibitors in several relevant cell lines showed synergistic or additive effects. GB3226 has shown a promising tolerability profile at encouraging exposure multiples in rat and dog toxicology studies performed to date. We initiated additional IND-enabling toxicology studies in August 2025. We believe that this preclinical data demonstrates GB3226's unique dual-mechanism that promotes rapid onset (FLT3 inhibition) and duration of response (ENL-YEATS inhibition).

GB1211

GB1211 is a selective oral small molecule inhibitor of galectin-3. We believe GB1211 has the potential to treat multiple types of oncology and liver disease indications.

GALLANT-1 Trial

We enrolled a total of 13 patients in Part A of the GALLANT-1 trial (100 mg: six; 200 mg: seven). Four patients in Part A of the GALLANT-1 trial (100 mg: three; 200 mg: one) showed a partial response according to Response Evaluation Criteria in Solid Tumors ("RECIST"), criteria (version 1.1). One patient receiving GB1211 at 200 mg twice daily, alongside atezolizumab (Tecentriq®) demonstrated a sustained partial response over the course of the trial. At the 12-week mark, tumor shrinkage exceeded 70%, and this reduction was maintained throughout subsequent study visits. In accordance with local treatment guidelines, this patient was discontinued from the trial after receiving checkpoint inhibitor therapy for two consecutive years. Additionally, three of the five patients treated for at least six weeks with 100 mg of GB1211 twice daily, combined with atezolizumab, showed a partial response. We completed dosing in the extension phase of the this trial, with the final patient receiving their last dose of GB1211 in combination with atezolizumab in late October 2025. In accordance with local treatment guidelines, this patient will continue to receive checkpoint inhibitor therapy until disease progression or unacceptable toxicity. This patient, who had been treated for over 2.5 years,

demonstrated tumor shrinkage exceeding 80%, consistently recorded during all study visits between week 36 and week 138. Insights from biomarker analyses from the GALLANT-1 trial revealed a trend showing that responders had increased levels of galectin-3 at baseline, and stable or decreasing galectin-3 levels during treatment. In contrast, patients with progressive disease demonstrated increasing levels of galectin-3 during treatment. This correlation suggests that the detection of galectin-3 levels could potentially be used to select and monitor patient populations.

In the seven patients who received GB1211 200 mg twice daily in combination with atezolizumab, we observed six serious adverse events, of which three of these serious adverse events were determined not to be related to either GB1211 200 mg or atezolizumab. No serious adverse events were deemed to be solely attributed to GB1211 200 mg. One case of grade 4 hypocellular bone marrow was determined to be related to both GB1211 200 mg and atezolizumab. The other two serious adverse events were autoimmune-type skin rashes (showing perivascular lymphocytic infiltrates), one of which was a grade 3 case of autoimmune pemphigus determined to be related solely to atezolizumab and the other was a grade 4 case of skin rash determined to be related to both GB1211 200 mg and atezolizumab. In the six patients who received GB1211 100 mg twice daily in combination with atezolizumab, GB1211 and atezolizumab appeared to be well-tolerated, with predominantly Grade 1 and Grade 2 treatment-emergent adverse events observed. In this cohort, we observed two serious adverse events, neither of which were determined to be related to GB1211 100 mg or atezolizumab. Importantly, we did not observe any autoimmune-type skin rashes in the 100 mg cohort.

Investigator-Initiated Phase 2 Trial with Providence Portland Medical Center's Earle A. Chiles Research Institute

In October 2023, we announced that we did not intend to initiate Part B of the GALLANT-1 trial, which had been designed to evaluate safety and tumor shrinkage and explore tumor response rate based on RECIST criteria (version 1.1), clinical activity and immune biomarkers. While we do not intend to initiate Part B of the GALLANT-1 trial, we will continue to supply GB1211 at the recommended Phase 2 dose level of 100 mg twice daily in an investigator-initiated Phase 2 trial at Providence Portland Medical Center's Earle A. Chiles Research Institute. GB1211 will be administered in combination with the standard therapeutic dose of pembrolizumab (Keytruda®) in patients with unresectable or metastatic melanoma or recurrent or metastatic HNSCC progressing during or after platinum-containing chemotherapy. This trial is designed to evaluate (i) the safety and efficacy of GB1211, our first-in-class, oral small molecule galectin-3 inhibitor candidate, in combination with pembrolizumab, in metastatic melanoma and HNSCC patients and (ii) whether the addition of GB1211 increases the response rate of pembrolizumab in metastatic melanoma and HNSCC patients. This trial was initiated and enrolled its first patient in the second quarter of 2024 and continues to enroll patients.

Financial Overview

We will incur significant expenses relating to our development of GB3226 and GB1211. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on our advancement of these two assets, as well as partnering and/or funding additional activities in order to achieve 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 ("IPO"), the issuance of common stock through our Open Market Sale Agreement℠ with Jefferies LLC, as sales agent, which provided 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 a previously effective registration statement on Form S-3 and related prospectus (the "ATM Program"), and the issuance of convertible preferred shares and convertible notes. Since inception, we have had significant operating losses. Our net loss was $3.1 million and $9.1 million for the three and nine months ended September 30, 2025, respectively. Our net loss was $3.9 million and $14.7 million for the three and nine months ended September 30, 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $286.6 million and $7.6 million in cash and cash equivalents.

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 anticipate that our expenses will increase substantially if, and as, we:

- complete preclinical development and file an IND for GB3226;
- advance our oncology and liver disease product candidates and any future product candidates through preclinical and clinical development, and, if successful, later-stage clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize our oncology and liver disease product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to discover and develop product candidates;
- hire additional clinical development, quality control, scientific, and management personnel;

•expand our operational, financial, and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts;

•establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;

•maintain, expand, and protect our intellectual property portfolio; and

•invest in or in-license other technologies or product candidates.

We expect to continue to incur net losses for the foreseeable future as we implement our development plans for GB1211 and GB3226. In particular, we expect our expenses to gradually increase as we further our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers, and accountants, and incur other costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any current or future product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based on current estimates of our expenses going forward, we believe that our existing cash and cash equivalents of $7.6 million as of September 30, 2025 will be sufficient to fund the preclinical development of GB3226 into 2026, including the submission of an IND to the FDA. However, we will require substantial additional capital to finance our operations, including clinical development of any of our GB3226 and GB1211 programs. 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. We have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern from the issuance date of our financial statements. We will require substantial additional capital to finance our operations, including clinical development of any of our GB3226 and GB1211 programs. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date our financial statements are issued. We have developed plans to mitigate this risk, which primarily consist of raising additional capital through some combination of equity or convertible debt financings and/or potential new collaborations, but there can be no assurances any such financing will be available when needed, or on acceptable terms. If we are unable to secure adequate additional funding, we will need to reevaluate our operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back, or eliminate some or all of our development programs, relinquish rights to our intellectual property on less favorable terms than we would otherwise choose, or cease operations entirely. These actions could materially impact our business, results of operations and future prospects, and the value of shares of our common stock, and investors may lose all or a part of their investment. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our discovery and product development efforts.

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. 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 further delay, reduce, or terminate activities to reduce costs.

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

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

Components of Operating Results

Operating Expenses

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

Research and Development

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

•personnel costs, which include salaries, benefits, and stock-based compensation expense;

•expenses incurred under agreements with consultants, and third-party contract organizations that conduct research and development activities on our behalf;

•costs related to sponsored research service agreements;

•costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;

•laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials;

•laboratory supplies and equipment used for internal research and development activities; and

•acquired in-process research and development programs.

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

We have historically met the requirements to receive a tax credit in Denmark of up to $0.8 million per year for losses resulting from research and development costs of up to approximately $3.6 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 $0.7 and $0.8 million during the nine months ended September 30, 2025 and 2024, respectively. The credits are available the following year, in 2026 and 2025, respectively.

We have qualified for the R&D Expenditure Credit (the "RDEC") in United Kingdom for preclinical laboratory and in-patient clinical trials. The RDEC net tax benefit is reported as a reduction to research and development expense in the consolidated statements of operations. There was no RDEC recorded during the nine months ended September 30, 2025. We recorded an overall reduction for the RDEC, net of the UK corporation tax rate of $0.1 million during the nine months ended September 30, 2024.

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.

We expect our research and development expenses to continue for the foreseeable future as we plan to invest in research and development activities related to developing our product candidates, including investments in preclinical development, 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 completion of our preclinical studies and our Phase 2 clinical trials for our current fibrosis and oncology product candidates 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, European Medicines Agency (the "EMA"), Medicines and Healthcare products Regulatory Agency, Health Canada, or other regulatory agencies of IND applications, clinical trial applications, and/or other regulatory filings for GB3226, GB1211, and any future product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing, and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies; obtainment and maintenance of coverage, adequate pricing, and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense, and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation, or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

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

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to continue for the foreseeable future but be lower than our research and development expenses prior to announcing the initiation of our strategic alternative review, as we continue to implement our new business strategy. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that if we choose to pursue further development and testing of our product candidates, our research and development expenses will 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, accounting, business operations, and other administrative functions. We expect our general and administrative expenses to increase moderately over the next several years to support our continued research and development activities, manufacturing activities, and continued costs of operating as a public company. However, we anticipate these expenses will remain lower than our general and administrative expenses prior to announcing the initiation of our strategic alternative review in September 2023. These expenses will likely include continued costs related to consultants and the hiring of additional personnel; legal, regulatory, and other fees; director and officer insurance premiums; and other costs associated with our continued operations.

Restructuring Costs

Our restructuring costs consist primarily of expenses related to employee severance and notice period payments, benefits and related costs and other expenses, including non-cash stock-based compensation expense related to the accelerated vesting of certain share-based awards, lease commitments and legal expenses. The execution of the Restructuring Plan is substantially complete. We did not incur any restructuring costs in the three and nine month periods ended September 30, 2025.

Other Income (Expense), Net

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

- Interest income: The interest income earned on our cash and cash equivalents is 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 consolidated statements of operations.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

The following sets forth our results of operations for the three months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Change	
	2025	2024	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	$ 1,416	$ 1,093	$ 323	29.6%
General and administrative	1,740	2,747	(1,007)	-36.7%
Total operating expenses	$ 3,156	$ 3,840	$ (684)	-17.8%
Income (loss) from operations	(3,156)	(3,840)	684	-17.8%
Other income (loss), net	23	(36)	59	-163.9%
Income (loss) before income tax expense	(3,133)	(3,876)	743	-19.2%
Income tax expense	-	(7)	7	-100.0%
Net loss	$ (3,133)	$ (3,883)	$ 750	-19.3%

Research and development expenses

Research and development expenses were comprised of:

	Three Months Ended September 30,		Change	
	2025	2024	Amount	Percent
	(in thousands)			
Preclinical studies and clinical trial-related activities	$ 545	$ 472	$ 73	15.5%
Chemistry, manufacturing and control	404	88	316	359.1%
Personnel	77	248	(171)	-69.0%
Consultants and other costs	390	285	105	36.8%
Total research and development expenses	$ 1,416	$ 1,093	$ 323	29.6%

Research and development expenses were $1.4 million for the three months ended September 30, 2025, compared to $1.1 million for the three months ended September 30, 2024. The increase of $0.3 million was primarily related to increased chemistry, manufacturing, and control costs of $0.3 million, increased preclinical studies and clinical trial-related expenses of $0.1 million and increased consulting and other research and development costs of $0.1 million, offset by decreased personnel costs of $0.2 million.

General and administrative expenses

General and administrative expenses were $1.7 million for the three months ended September 30, 2025, compared to $2.7 million for the three months ended September 30, 2024. The decrease of $1.0 million was primarily related to decreased personnel costs of $0.6 million, decreased legal related costs of $0.2 million, and decreased other general administrative costs of $0.2 million.

Other income (expense), net

Other income (expense), net, for the three months ended September 30, 2025 was $23,000, compared to ($36,000) for the three months ended September 30, 2024. The increase of $59,000 was primarily due to decreased interest income, net, resulting from lower investable balances and decreased foreign exchange transaction loss, net.

Comparison of the Nine Months Ended September 30, 2025 and 2024

The following sets forth our results of operations for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,		Change	
	2025	2024	Amount	Percent
		(in thousands)		
Operating expenses				
Research and development	$ 3,559	$ 5,390	$ (1,831)	-34.0%
General and administrative	5,617	8,800	(3,183)	-36.2%
Restructuring costs	-	968	(968)	-100.0%
Total operating expenses	$ 9,176	$ 15,158	$ (5,982)	-39.5%
Loss from operations	(9,176)	(15,158)	5,982	-39.5%
Other income, net	79	509	(430)	-84.5%
Loss before income tax expense	(9,097)	(14,649)	5,552	-37.9%
Income tax expense	(6)	(49)	43	-87.8%
Net loss	$ (9,103)	$ (14,698)	$ 5,595	-38.1%

Research and development expenses

Research and development expenses were comprised of:

	Nine Months Ended September 30,		Change	
	2025	2024	Amount	Percent
		(in thousands)		
Chemistry, manufacturing and control	$ 1,417	$ 378	$ 1,039	274.9%
Preclinical studies and clinical trial-related activities	1,012	1,358	(346)	-25.5%
Personnel	226	2,233	(2,007)	-89.9%
Consultants and other costs	904	1,421	(517)	-36.4%
Total research and development expenses	$ 3,559	$ 5,390	$ (1,831)	-34.0%

Research and development expenses were $3.6 million for the nine months ended September 30, 2025, compared to $5.4 million for the nine months ended September 30, 2024. The decrease of $1.8 million was primarily related to decreased personnel costs of $2.0 million, decreased preclinical studies and clinical trial-related expenses of $0.3 million, and decreased consulting and other research and development costs of $0.5 million, offset by increased chemistry, manufacturing, and control costs of $1.0 million.

General and administrative expenses

General and administrative expenses were $5.6 million for the nine months ended September 30, 2025, compared to $8.8 million for the nine months ended September 30, 2024. The decrease of $3.2 million was primarily related to decreased personnel costs of $1.5 million, decreased legal related costs of $1.0 million, and decreased other general administrative costs of $0.7 million.

Restructuring costs

There were no restructuring costs for the nine months ended September 30, 2025. Restructuring costs were $1.0 million for the nine months ended September 30, 2024, primarily related to employee severance and notice period payments, benefits and related costs.

Other income (expense), net

Other income, net, for the nine months ended September 30, 2025 was $79,000, compared to $509,000 for the nine months ended September 30, 2024. The decrease of $430,000 was primarily due to decreased interest income, net, resulting from lower investable balances.

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, 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. During each of the three and nine months ended September 30, 2025 and 2024, we had no sales under the ATM Program.

Our net losses were $3.1 million and $9.1 million for the three and nine months ended September 30, 2025, respectively. Our net losses were $3.9 million and $14.7 million for the nine months ended September 30, 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $286.6 million and $7.6 million in cash and cash equivalents. 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,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (7,292)	$ (13,687)
Net cash provided by investing activities	—	11,650
Net cash provided by financing activities	—	—
Net decrease in cash and cash equivalents	$ (7,292)	$ (2,037)

Net Cash Used in Operating Activities

Cash used in operating activities of $7.3 million during the nine months ended September 30, 2025 was primarily attributable to our net loss of $9.1 million together with non-cash items of $0.6 million principally with respect to stock-based compensation and a net increase of $1.2 million in components of our working capital.

Cash used in operating activities of $13.7 million during the nine months ended September 30, 2024 was primarily attributable to our net loss of $14.7 million together with non-cash items of $3.3 million principally with respect to stock-based compensation and a net decrease of $2.3 million in components of our working capital.

Net Cash Provided by Investing Activities

We had no investing activities during the nine months ended September 30, 2025.

Cash provided by investing activities of $11.7 million during the nine months ended September 30, 2024 was the result of proceeds from the sale of marketable securities.

Net Cash Provided by Financing Activities

We had no financing activities during the nine months ended September 30, 2025 and 2024.

Funding Requirements

We expect to incur significant costs as we implement our development plans for GB3226 and GB1211, and we will need to obtain substantial additional funding to finance our continuing operations. Our primary uses of capital are, and we expect will continue to be, costs related to third-party clinical research, manufacturing and development services; laboratory expenses and costs for related supplies; clinical costs; manufacturing costs; compensation-related expenses; legal and other regulatory expenses; costs to operate as a public company; and general overhead costs.

Based on current estimates of our expenses going forward, we believe that our existing cash and cash equivalents of $7.6 million as of September 30, 2025 will be sufficient to fund the preclinical development of GB3226 into 2026, including the submission of an IND to the FDA. 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. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date our financial statements are issued. We have developed plans to mitigate this risk, which primarily consist of raising additional capital through some combination of equity or convertible debt financings and/or potential new collaborations, but there can be no assurances any such financing will be available when needed, or on acceptable terms. If we are unable to secure adequate additional funding, we will need to reevaluate our operating plans and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of our development programs, relinquish rights to our intellectual property on less favorable terms than we would otherwise choose, or cease operations entirely. These actions could materially impact our business, results of operations and future prospects and the value of shares of our common stock, and investors may lose all or a part of their investment. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our discovery and product development efforts. If our available cash resources are insufficient to fund our expenses and the development of our product candidates and/or completion of a transaction identified above, we may implement further cost reduction and other cash-focused measures to manage liquidity, and we may pursue a plan of liquidation or dissolution or seek bankruptcy protection. If we decide to cease operations and dissolve and liquidate our assets, it is unclear to what extent we would be able to pay our obligations. In such a circumstance and in light of our current liquidity position, it is unlikely that cash would be available for distribution to stockholders.

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our future operations through our existing cash and cash equivalents and through a combination of equity offerings, debt financings, collaborations, strategic alliances, marketing and distribution arrangements, and/or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, marketing and distribution arrangements, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements on acceptable terms when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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, both near-term and long-term, will depend on many factors, including, but not limited to:

- our new focus on GB3226 and GB1211 and our ability to execute successfully on our strategic realignment and realigned focus;
- our ability to raise additional funding;
- the initiation, progress, timing, costs, and results of preclinical studies and clinical trials for our product candidates, including GB3226, GB1211, and any other product candidates we develop in the future;

•the clinical development plans we establish for these product candidates;

•the scope, progress, results and costs of discovery, research, preclinical development, laboratory testing, and clinical trials for our current and future product candidates;

•the impacts of fluctuating interest rates, geopolitical instability, changes in international trade relationships, and conflicts;

•the number of, and development requirements for, other product candidates that we develop;

•the timelines of our clinical trials and the overall costs to finish clinical trials due to geopolitical instability and conflict;

•the outcome, timing, and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities;

•our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient and manufacture of our product candidates, and the terms of such arrangements;

•whether we are able to enter into and maintain collaboration agreements, including the terms of and timing of payments under any such agreements;

•the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;

•the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;

•the extent to which we acquire or in-license other products, product candidates, or technologies;

•the ability to receive additional non-dilutive funding, including grants from organizations and foundations;

•the effect of competing clinical, technological, and market developments;

•the cost and timing of completion of commercial-scale outsourced manufacturing activities;

•changes in economic conditions, lower consumer confidence, and volatile equity capital markets; 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 consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the related disclosures of assets and liabilities at the date of the 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, and 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 expenses associated with the development of our product candidates to conduct preclinical studies and clinical trials. Accounting for clinical trials relating to activities performed by contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other external vendors requires management to exercise 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 preclinical studies and clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided by the CRO, CMOs, and other vendors 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 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 received 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 in accordance with agreements established with our collaboration partners and third-party service providers. We make 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 awards, which generally vest over a four-year period. We account for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation* ("ASC 718"). In accordance with ASC 718, compensation cost is measured at estimated fair value and is recognized 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. 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, 2025 has been estimated using Black-Scholes based on the following assumptions: expected term of 5.9 years; expected volatility of 95.9%; risk-free interest rate of 4.4%; and no expectation of dividends. The fair value of our awards in the nine months ended September 30, 2024 has been estimated using Black-Scholes based on the following assumptions: expected term of 5.3 years; expected volatility of 99.3%; risk-free interest rate of 4.2%; and no expectation of dividends.

We will continue to use judgment in evaluating the assumptions utilized for our equity-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes model, the amount of equity-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 our 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 our 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, 2025 and 2024 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 ("EGC") under the Jumpstart Our Business Startups Act of 2012 (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 Sarbanes-Oxley Act of 2002, as amended, 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 EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We expect to remain classified as an EGC until December 31, 2025, the end of the fiscal year following the fifth anniversary of the completion of our IPO.

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 EGC, 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, 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, 2025. Based on the evaluation of our disclosure controls and procedures as of September 30, 2025, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2025.

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 in our periodic and current 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 over Financial Reporting

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, 2024 and in Part II, Item 1A "Risk Factors" in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025, 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 253,688 shares of our common stock, including 27,022 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 a registration statement 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. The underwriters of the IPO 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 or 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, 2025, $82.1 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 GB3226 and GB1211.

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.

10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended September 30, 2025, none of our officers or directors adopted, modified or terminated any such trading arrangements.

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
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 Exchange Act 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 or the Exchange Act, 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 6, 2025	By:	/s/ Hans T. Schambye **Hans T. Schambye, M.D., Ph.D.** **President, Chief Executive Officer and Director** **(Principal Executive Officer)**
Date: November 6, 2025	By:	/s/ Lori Firmani **Lori Firmani** **Interim Chief Financial Officer** **(Principal Financial and Accounting Officer)**