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, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39655

GALECTO, INC.
(Exact Name of Registrant as Specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	GLTO	The Nasdaq 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 October 30, 2024, the registrant had 1,316,989 shares of common stock, $0.00001 par value per share, outstanding.

Table of Contents

		Page
	PART I. FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	4
	Condensed Consolidated Balance Sheets	4
	Condensed Consolidated Statements of Operations and Comprehensive Loss	5
	Condensed Consolidated Statements of Changes in Stockholders' Equity	6
	Condensed Consolidated Statements of Cash Flows	8
	Notes to Unaudited Interim Condensed Consolidated Financial Statements	9
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	29
Item 4.	Controls and Procedures	30
	PART II. OTHER INFORMATION	
Item 1.	Legal Proceedings	31
Item 1A.	Risk Factors	31
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	31
Item 3.	Defaults Upon Senior Securities	32
Item 4.	Mine Safety Disclosures	32
Item 5.	Other Information	32
Item 6.	Exhibits	33
Signatures		34

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 plans and expectations following the completion of our strategic alternative review process resulting in a renewed focus on GB1211 and the addition of BRM-1420 from Bridge Medicines LLC ("Bridge Medicines") and our ability to execute successfully on our strategic realignment and realigned focus;
- the success, cost and timing of our development activities and planned initiation and completion of clinical trials of our current fibrosis and oncology product candidates, including BRM-1420, GB1211 and any future product candidates;
- our need to raise additional funding;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our 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 establish an adequate safety or efficacy profile for our current or future product candidates that we may pursue;
- the implementation of our strategic plans for our business, including the successful integration of BRM-1420 into our pipeline;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the rate and degree of market acceptance and clinical utility for our current or future product candidates we may develop;
- our estimates about the size of our market opportunity;
- our estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- our financial performance and liquidity;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to maintain adequate internal controls over financial reporting;
- the effects of global economic uncertainty and financial market volatility caused by economic effects of rising inflation and interest rates, geopolitical instability, changes in international trade relationships and conflicts, such as the ongoing conflict between Russia and Ukraine and the current armed conflict in Israel and the Gaza Strip, 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, 2023. 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, 2024	December 31, 2023
Assets	(unaudited)	
Current assets		
Cash and cash equivalents	$ 19,678	$ 21,465
Marketable securities	—	11,686
Prepaid expenses and other current assets	1,500	3,623
Total current assets	21,178	36,774
Operating lease right-of-use asset	32	247
Equipment, net	62	78
Other assets, non-current	2,104	1,128
Total assets	$ 23,376	$ 38,227
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 503	$ 1,702
Accrued expenses and other current liabilities	1,938	4,128
Total current liabilities	2,441	5,830
Operating lease liabilities, non-current	—	66
Total liabilities	2,441	5,896
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, par value of $0.00001 per share; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued or outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, par value of $0.00001 per share; 300,000,000 shares authorized at September 30, 2024 and December 31, 2023; 1,253,843 and 1,084,508 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	291,053	288,036
Accumulated deficit	(270,783)	(256,085)
Accumulated other comprehensive income	665	380
Total stockholders' equity	20,935	32,331
Total liabilities and stockholders' equity	$ 23,376	$ 38,227

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,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 1,093	$ 2,551	$ 5,390	$ 21,002
General and administrative	2,747	3,304	8,800	9,504
Restructuring costs	—	2,728	968	2,728
Total operating expenses	3,840	8,583	15,158	33,234
Loss from operations	(3,840)	(8,583)	(15,158)	(33,234)
Other income, net				
Interest income, net	146	473	616	1,349
Foreign exchange transaction gain (loss), net	(182)	(26)	(107)	11
Total other income, net	(36)	447	509	1,360
Loss before income tax expense	(3,876)	(8,136)	(14,649)	(31,874)
Income tax expense	7	—	49	—
Net loss	$ (3,883)	$ (8,136)	$ (14,698)	$ (31,874)
Net loss per common share, basic and diluted	$ (3.39)	$ (7.50)	$ (13.30)	$ (30.19)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,144,978	1,084,191	1,104,849	1,055,679
Other comprehensive income, net of tax				
Currency translation gain	468	127	251	117
Unrealized gain on marketable securities	—	56	34	173
Other comprehensive income, net of tax	468	183	285	290
Total comprehensive loss	$ (3,415)	$ (7,953)	$ (14,413)	$ (31,584)

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)

Three Months Ended September 30, 2024	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' 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

Three Months Ended September 30, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at June 30, 2023	1,080,876	$ —	$ 285,311	$ (241,474)	$ (137)	$ 43,700
Stock-based compensation expense	—	—	1,464	—	—	1,464
Issuance of common stock; net of issuance costs	3,632	—	171	—	—	171
Other comprehensive income, net	—	—	—	—	183	183
Net loss	—	—	—	(8,136)	—	(8,136)
Balance at September 30, 2023	1,084,508	$ —	$ 286,946	$ (249,610)	$ 46	$ 37,382

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)

Nine Months Ended September 30, 2024	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' 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

Nine Months Ended September 30, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2022	1,026,096	$ —	$ 279,733	$ (217,736)	$ (244)	$ 61,753
Stock-based compensation expense	—	—	4,337	—	—	4,337
Issuance of common stock; net of issuance costs of $0.2 million	58,412	—	2,876	—	—	2,876
Other comprehensive income, net	—	—	—	—	290	290
Net loss	—	—	—	(31,874)	—	(31,874)
Balance at September 30, 2023	1,084,508	$ —	$ 286,946	$ (249,610)	$ 46	$ 37,382

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (14,698)	$ (31,874)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation	16	246
Stock-based compensation	2,931	4,337
Issuance of common stock in connection with vesting of restricted stock units	86	—
Amortization of premiums and discounts on marketable securities	70	(406)
Amortization of right of use lease asset	219	355
Accretion of lease liability	9	40
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,121	812
Other assets, noncurrent	(974)	(141)
Accounts payable	(1,199)	1,127
Accrued expenses and other current liabilities	(2,040)	445
Operating lease liabilities	(228)	(378)
Net cash used in operating activities	(13,687)	(25,437)
Cash flows from investing activities:		
Purchases of marketable securities	—	(25,937)
Proceeds from sale of marketable securities	11,650	38,687
Net cash provided by investing activities	11,650	12,750
Cash flows from financing activities:		
Proceed from issuance of common stock, net of issuance costs	—	2,876
Net cash provided by financing activities	—	2,876
Net decrease in cash and cash equivalents	(2,037)	(9,811)
Effect of exchange rate changes on cash and cash equivalents	250	103
Cash and cash equivalents, beginning of period	21,465	32,786
Cash and cash equivalents, end of period	$ 19,678	$ 23,078
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ —	$ —
Supplemental disclosures of non-cash activities:		
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ —

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, 2024, the Company's wholly owned subsidiaries were PharmAkea, Inc., a Delaware corporation ("PharmAkea"), 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 experienced financial and legal advisors, a comprehensive strategic alternative review process began immediately and evaluated a broad range of options to maximize shareholder 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 Asset 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 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"). For additional details, see Note 14 to the Company's unaudited interim condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

As a result of the conclusion of the strategic alternatives review process, the Company's focus is now on the development of GB1211 and the addition of BRM-1420 from Bridge Medicines. As part of the strategic alternative review process, the Company determined not to further advance GB2064, its LOXL-2 inhibitor candidate, at this time.

Risks and Uncertainties

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

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

Liquidity and Management Plans

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

As of September 30, 2024, the Company had an accumulated deficit of $270.8 million from recurring losses since inception in 2011. The Company has incurred recurring losses and has not generated revenue as no products have obtained the necessary regulatory approval in order to market 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, 2024 and 2023 of $13.7 million and $25.4 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, 2024 were $3.9 million and $14.7 million, respectively. Net losses incurred for the three and nine months ended September 30, 2023 were $8.1 million and $31.9 million, respectively.

As of September 30, 2024, the Company's cash and cash equivalents amounted to $19.7 million, current assets amounted to $21.2 million and current liabilities amounted to $2.4 million. At December 31, 2023, the Company's cash, cash equivalents and marketable securities amounted to $33.2 million, current assets amounted to $36.8 million and current liabilities amounted to $5.8 million.

In September 2023, the Company announced the Restructuring Plan (as defined below) to reduce the Company's operations to preserve financial resources, resulting in a reduction of the Company's workforce by up to 29 people, or approximately 70% of the Company's then existing headcount. In May 2024, the Company's Board of Directors approved an additional reduction of eight employees in an effort to conserve cash resources. As of June 30, 2024, the Company incurred $4.4 million in charges relating to these reductions in workforce, consisting primarily of cash-based expenses related to employee severance and notice period payments, benefits and related costs. These activities were substantially complete as of June 30, 2024 and the Company did not incur any restructuring costs for the three months ended September 30, 2024.

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, 2024 and for the three and nine months ended September 30, 2024 and 2023, and related interim information contained within the notes to the interim condensed consolidated financial statements, are unaudited. In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's audited consolidated financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company's financial position as of September 30, 2024, results of operations, statement of stockholders' equity for the three and nine months ended September 30, 2024 and 2023 and its cash flows for the nine months ended September 30, 2024 and 2023. 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, 2023, as filed with the Securities and Exchange Commission on March 8, 2024 (the "2023 Consolidated Financial Statements"). The results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

For the nine months ended September 30, 2024, there have been no material changes to the significant accounting policies as disclosed in Note 2 to the 2023 Consolidated Financial Statements.

Recently Issued Accounting Standards

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

3. INVESTMENTS

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

The Company had no available-for-sale investments as of September 30, 2024. A summary of the Company's available-for-sale investments as of December 31, 2023 consisted of the following (in thousands):

	At December 31, 2023			
Marketable securities:	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Corporate bonds	$ 11,720	$ —	$ (34)	$ 11,686
Total	$ 11,720	$ —	$ (34)	$ 11,686

4. PROPERTY AND EQUIPMENT, NET

Property and equipment as of September 30, 2024 consisted of the following (in thousands):

	September 30, 2024	**December 31, 2023**
Equipment	$ 107	$ 107
Less: accumulated depreciation	(45)	(29)
Equipment, net	$ 62	$ 78

Depreciation expense for the three and nine months ended September 30, 2024 was $6,000 and $16,000, respectively. Depreciation expense for the three and nine months ended September 30, 2023 was $211,000 and $246,000, respectively.

5. FAIR VALUE MEASUREMENTS

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

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

A summary of the assets that are measured at fair value as of September 30, 2024 and December 31, 2023 is as follows (in thousands):

		Fair Value Measurement at September 30, 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)]	$ 8,856	$ 8,856	$ —	$ —
Debt securities	—	—	—	—
Total	$ 8,856	$ 8,856	$ —	$ —

		Fair Value Measurement at December 31, 2023		
Assets:	**Carrying Value**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds[(1)]	$ 13,610	13,610	—	—
Debt securities	11,686	—	11,686	—
Total	$ 25,296	$ 13,610	$ 11,686	$ —

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

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	September 30, 2024	December 31, 2023
Research and development tax credit receivable	$ 949	$ 1,438
Prepaid insurance costs	89	774
Value-added tax refund receivable	256	280
Contract research and development costs	73	1,046
Other	133	85
Total prepaid expenses and other current assets	$ 1,500	$ 3,623

7. LEASES

The Company has the following operating leases:

Location	Primary Use	Lease Expiration Date	Renewal Option
Copenhagen, Denmark	Corporate headquarters	November 2024	None

The Company has no finance leases and has elected to apply the short-term lease exception to all leases of one year or less. Rent expense for the three and nine months ended September 30, 2024 was $0.05 million and $0.2 million, respectively. Rent expense for the three and nine months ended September 30, 2023 was $0.2 million and $0.5 million, respectively.

Quantitative information regarding the Company's leases for the three and nine months ended September 30, 2024 and 2023 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost	**2024**	**2023**	**2024**	**2023**
Operating lease cost (in thousands)	$ 49	$ 135	$ 192	$ 411
Other Information				
Operating cash flows paid for amounts included in the measurement of lease liabilities (in thousands)	$ 50	$ 121	$ 190	$ 394
Operating lease liabilities arising from obtaining right-of-use assets (in thousands)	$ —	$ —	$ —	$ —

As of September 30, 2024 and December 31, 2023, the weighted average remaining lease term for operating leases was 0.2 years and 0.9 years, respectively.

As of September 30, 2024 and December 31, 2023, the weighted average discount rate for operating leases was 8% for both periods.

Operating lease liabilities at September 30, 2024 are as follows (in thousands):

Future Lease Payments	Operating Leases
2024 (excluding the period ended September 30, 2024)	$ 33
2025	—
2026	—
2027	—
2028	—
Total lease payments	33
Less: imputed interest	(1)
Total lease liabilities	$ 32

8. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	September 30, 2024	December 31, 2023
Employee compensation costs	$ 809	$ 987
Contract research and development costs	247	685
Restructuring costs	230	1,734
Operating lease liabilities, current	32	183
Other liabilities	620	539
Total accrued expenses and other current liabilities	$ 1,938	$ 4,128

9. COMMITMENTS AND CONTINGENCIES

During the three and nine months ended September 30, 2024, there were no material changes to the Company's commitments and contingencies as disclosed in Note 9 of the 2023 Consolidated Financial Statements. Further, the Company's commitments related to lease agreements are disclosed in Note 7 to the Company's unaudited interim condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

10. STOCK-BASED COMPENSATION

Employee Equity Plan

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

In October 2020, the Company's Board of Directors and stockholders approved the 2020 Equity Incentive Plan ("2020 Equity Plan"). Following the adoption of the 2020 Equity Plan, no further options are available to be issued under the 2020 Plan. Stock-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 will cumulatively increase by 5 percent of the number of shares of common stock issued and outstanding on January 1st each year until 2030. At September 30, 2024, the Company had 164,785 shares available for future grant under the 2020 Equity Plan.

The following table sets forth the activity for the Company's stock options during the nine months ended September 30, 2024:

	Number of Options	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2023	275,478	$ 114.40	6.7	$ —
Granted	4,320	12.25	—	130
Cancelled	(97,593)	103.56	—	—
Outstanding at September 30, 2024	182,205	$ 117.78	6.3	$ —
Vested and expected to vest at September 30, 2024	172,493	$ 116.87	6.3	$ —
Vested and exercisable at September 30, 2024	160,204	$ 126.10	6.0	$ —

The weighted-average grant date fair value of all stock-based awards granted for the nine months ended September 30, 2024 was $9.47 per share. The intrinsic value at September 30, 2024 and December 31, 2023 was based on the closing price of the Company's common stock on these dates of $12.15 and $18.00 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, 2024, 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 nine months ended September 30, 2024.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, 2024, the Company recognized $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, 2024:

	Restricted Stock Units	Weighted-average grant date fair value
Total nonvested units at December 31, 2023	—	$ —
Granted	34,200	17.75
Vested	(6,828)	17.75
Cancelled	(10,772)	17.75
Total nonvested units at September 30, 2024	16,600	$ 17.75

Stock-Based Compensation

The grant date fair value of stock-based awards vested during the nine months ended September 30, 2024 and 2023 was $3.0 million and $5.0 million, respectively. Total unrecognized compensation expense related to unvested options granted under the Company's stock-based compensation plan was $0.8 million at September 30, 2024, which is expected to be recognized over a weighted average period of 1.2 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,	
	2024	2023	2024	2023
Research and development	$ 70	$ 712	$ 887	$ 2,082
General and administrative	611	752	2,044	2,255
Total stock-based compensation	$ 681	$ 1,464	$ 2,931	$ 4,337

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,	
	2024	2023
Risk-free interest rate	4.2%	3.8%
Expected term (in years)	5.3	6.0
Expected volatility	99.3%	91.0%
Expected dividend yield	—	—

11. RESTRUCTURING ACTIVITIES

In September 2023, the Company's Board of Directors approved a restructuring plan (the "Restructuring Plan") to reduce the Company's operating costs and better align its workforce with the needs of its business. The Restructuring Plan eliminated approximately 70% of the Company's workforce. In May 2024, the Company's Board of Directors approved an additional reduction of eight employees in an effort to conserve cash resources (the "May RIF").

Employees affected by the Restructuring Plan and the May RIF obtained involuntary termination benefits pursuant to a one-time benefit arrangement. For employees who have no requirements to provide future service, the Company recognized the liability for the termination benefits in full at fair value at the time of termination. For employees who are required to render services beyond a minimum retention period to receive their one-time termination benefits, the Company recognized the termination benefits ratably over their future service periods. For the Restructuring Plan, the Company recorded employee termination benefit charges during the year ended December 31, 2023 of $3.4 million and has included such charges as operating expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss. For the May RIF, the Company recorded employee termination benefit charges during the three and nine months ended September 30, 2024 of $1.0 million and has included such charges as operating expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Restructuring costs pertaining to the Restructuring Plan and the May RIF consist of the following (in thousands):

		Nine Months Ended September 30, 2024
Balance at December 31, 2022	$	—
Restructuring expenses incurred		3,448
Payments		(1,593)
Non-cash charges		(121)
Balance at December 31, 2023		1,734
Restructuring expenses incurred		968
Payments		(2,472)
Balance at September 30, 2024	$	230

The Company incurred an impairment charge related to a leased facility of $0.03 million during the year ended December 31, 2023 resulting from the Restructuring Plan.

In September 2023, the Board of Directors approved arrangements designed to provide that the Company will have the continued dedication and commitment of its remaining employees, including executives, determined to be key to the Company's planned go-forward operations. The Board of Directors approved, and management implemented, a retention program for employees remaining with the Company which includes cash retention bonuses totaling $1.2 million for certain retained employees, provided that they remain within the Company through various requisite service periods. As a result, these cash retention bonuses are being accrued over the requisite service period. The Company's arrangement with its Chief Executive Officer specified that he was only entitled to a cash bonus upon the timely achievement of certain corporate and strategic milestones for the Company, which were not achieved by September 30, 2024. During the period ended September 30, 2024, the Company's retention accrual was $0.2 million. During the year ended December 31, 2023, the Company's retention accrual was $0.4 million.

12. INCOME TAXES

As a result of the Company's history of net operating losses ("NOL"), the Company continues to maintain a full valuation allowance against its domestic net deferred tax assets. For the three and nine months ended September 30, 2024, the Company recognized an income tax expense of $0.04 million, primarily due to foreign income tax expense.

13. 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,	
	2024	2023	2024	2023
Net loss	$ (3,883)	$ (8,136)	$ (14,698)	$ (31,874)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,144,978	1,084,191	1,104,849	1,055,679
Net loss per common share, basic and diluted	$ (3.39)	$ (7.50)	$ (13.30)	$ (30.19)

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,	
	2024	2023
Stock options to purchase common stock	182,206	292,010
Restricted stock units	16,600	—

14. SUBSEQUENT EVENTS

On October 7, 2024, the Company entered into an Asset Purchase Agreement (the "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 acquired assets (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 newly designated Series A non-voting convertible preferred stock, par value $0.00001 per share (the "Preferred Stock") and (b) assumed specified liabilities. The closing of the Asset Purchase occurred on October 7, 2024. The total cost of the Asset Purchase was $4.4 million, including the fair value of the common stock, the fair value of the convertible preferred stock, the assumed specified liabilities and transaction costs.

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. Each share of Preferred Stock is convertible into 1,000 shares of common stock at the election of the holder of such Preferred Stock, subject to, and contingent upon, the approval by the Company's stockholders to approve, for purposes of the Nasdaq Stock Market Rules, the issuance of the Company's common stock upon conversion of the Preferred Stock (the "Stockholder Approval"). Furthermore, on the third business day following the Company's receipt of Stockholder Approval, each outstanding share of Preferred Stock shall, subject to certain beneficial ownership limitations, automatically convert into 1,000 shares of common stock upon the conversion terms set forth in the Certificate of Designation. 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, issue additional shares of Preferred Stock, consummate certain transactions prior to Stockholder Approval, amend or terminate the support agreements entered into by the Company's directors and officers, or amend or fail to comply with certain provisions of the Purchase Agreement.

Carl Goldfischer, Chairman of the Company's Board of Directors is also the Executive Chairman of Bridge Medicines.

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, 2023, 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, 2023, filed with the United States Securities and Exchange Commission (the "SEC"), on March 8, 2024. 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, 2023 and in other SEC filings.

Overview

We are a clinical-stage biotechnology company developing novel small molecule therapeutics that are designed to target the biological processes that lie at the heart of cancer and fibrotic diseases. Our strategy is to focus on diseases without disease-modifying treatment options and where there is a high unmet medical need. We are concentrating on the development of small molecule inhibitors for the treatment of cancer and severe liver diseases.

In September 2023, we announced a corporate restructuring 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 with Bridge Medicines pursuant to which we acquired global rights to Bridge Medicines' BRM-1420 program, a novel dual ENL-YEATS and 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, our focus is now on the development of GB1211 and the addition of BRM-1420 from Bridge Medicines. As part of the strategic alternative review process, we determined not to further advance GB2064, our LOXL-2 inhibitor candidate, at this time.

BRM-1420

We are developing BRM-1420, a preclinical dual inhibitor of ENL-YEATS and FLT3 for multiple molecularly defined subsets of AML, pursuant to a license agreement with Rockefeller University. Preclinical models have demonstrated that BRM1420 is active against MLL-r, NPM1m, cKIT+ and FLT3+ driven AML, and we believe that BRM-1420 has the potential to be further developed to become a treatment option for other tumor types. We anticipate that a small molecule ENL-YEATS/FLT3 inhibitor such as BRM-1420 may have the potential to address a broader AML patient population, including those with high-risk genetic mutations. We plan to submit an investigational new drug application ("IND") to test BRM-1420 in AML in late 2025 or early 2026.

Background on ENL-YEATS and FLT3

The chromatin reader protein eleven-nineteen leukemia (ENL; encoded by the *MLLT1* gene) has been identified as a potential therapeutic target in a subset of leukemias. ENL binds to acetylated histone through a protein domain called the YEATS domain. The human genome encodes four YEATS domain-containing proteins: ENL, AF9, GAS41, and YEATS2. These proteins have been found in nuclear complexes with a variety of molecular functions spanning chromatin remodeling, histone modification, and transcription, and they have been increasingly implicated in cancer. In leukemia, ENL and its paralog, AF9, are frequently fused with the mixed lineage leukemia protein (MLL1, also known as KMT2A) as a result of chromosomal translocations. ENL acts as a "reader" for acetylation on histone H3 lysine residues 9, 18 and 27, epigenetic marks associated with gene activation. Once bound to acetylated histones, ENL can stabilize transcription machinery on target genes, leading to increased gene expression and the growth of leukemia cells. Deletion of ENL or disruption of its binding to acetylated histones has been shown to decrease leukemia burden and increase survival in mouse models of leukemia. In contrast, loss of ENL has shown to have minimal effects on the survival of normal hemopoietic stem cells in culture.

Fms-like tyrosine kinase 3 (FLT3), a member of the receptor tyrosine kinase family, is widely expressed in hematopoietic progenitor cells and is overexpressed on the majority of AML blasts. Upon binding to the FLT3 ligand, FLT3 receptors activate and dimerize, leading to conformational change, cellular proliferation, and inhibition of apoptosis and differentiation. Mutations in FLT3 are the most common genomic alteration in AML, identified in approximately one-third of newly diagnosed adult patients.

Background on Target Indication and Subsets

We are targeting multiple molecularly defined subsets of AML, a rare, fast-growing cancer of the blood and bone marrow that occurs when abnormal blood cells, called blasts, rapidly multiply in the bone marrow and blood. AML is a complex and heterogeneous disease characterized by uncontrolled clonal expansion of hematopoietic progenitor cells that involves cytogenetic and epigenetic changes. Patient outcomes in AML have slowly improved over time, though for many patients mortality remains high.

BRM-1420 is designed to target acute leukemias with rearrangements in the KMT2A gene as well as other oncogenic driver mutations, such as NPM1. KMT2A rearrangements are seen in 5-10% of adult leukemias and 70-80% of infant leukemias. The prognosis of KMT2A rearranged leukemias appears to be worse than that of AML patients with normal cytogenetics.

MEN1 Mutations. Acute leukemias driven by rearrangement of the mixed lineage leukemia 1 gene (KMT2Ar) or mutation of the nucleophosmin gene (NPM1) require the chromatin adapter protein menin, encoded by the MEN1 gene, to sustain aberrant leukemogenic gene expression programs. Somatic mutations in MEN1 were 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. The MEN1 mutation, or menin-resistant, population within AML represents a potential market for BRM-1420.

Preclinical Data

Bridge Medicines, prior to our acquisition, conducted a number of preclinical *in vitro* and *in vivo* studies of BRM-1420 which suggest that it is a potent and selective inhibitor of cell proliferation in MLLr cell lines, with durable anti-tumor activity. BRM-1420 has shown effects on key genetic drivers of leukemogenesis and maintenance, including HOXA9 and MEIS1. 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 BRM-1420 is active against several molecular drivers of AML, including MLL-r, NPM1m, cKIT+, FLT3+ and TET2+. *In vitro* modeling of BRM-1420 in combination with AML standard of care therapies and menin inhibitors in several relevant cell lines showed synergistic or additive effects. BRM-1420 has demonstrated promising tolerability in rat and dog toxicology studies performed to date at encouraging exposure multiples.

GB1211

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

GALLANT-1 Trial

During the fourth quarter of 2022, we announced topline results from our Phase 1b/2a trial of GB1211 that was focused on safety and effect on liver function and fibrosis biomarkers in patients with decompensated liver cirrhosis. These topline results showed statistically significant reductions in ALT ($p<0.0005$), AST ($p<0.005$) and GGT ($p<0.05$), with encouraging reductions for ALP ($p<0.09$), after 12 weeks of treatment. In this trial, GB1211 exhibited a favorable safety and tolerability profile in patients with decompensated liver cirrhosis.

During the third quarter of 2023, we completed Part A of the GALLANT-1 trial, which investigated GB1211 in combination with atezolizumab, a PD-L1 checkpoint inhibitor, for the treatment of first-line non-small cell lung cancer (NSCLC). Four patients in Part A of the GALLANT-1 trial (100 mg: three; 200 mg: one) showed a partial response according to RECIST criteria (version 1.1). One patient receiving GB1211 at 200 mg twice daily, alongside atezolizumab, 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 recently 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. One patient, currently treated for over 90 weeks, demonstrated tumor shrinkage exceeding 80%, consistently recorded during multiple study visits at weeks 36, 42, 48, 54, 60, 66, 72, 78, and 84. This patient is still being treated in the extension phase of the trial.

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 (EACRI). 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.

Financial Overview

We will incur significant expenses relating to our development of BRM-1420 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, to provide for the issuance and sale of up to $50.0 million of our common stock from time to time in "at-the-market" offerings under a registration statement on Form S-3 that the SEC declared effective on November 12, 2021 (the "Registration Statement") 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 $3.9 million and $14.7 million for the three and nine months ended September 30, 2024, respectively. Our net loss was $8.1 million and $31.9 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $270.8 million and $19.7 million in cash and cash equivalents, respectively.

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:

- advance our fibrosis and oncology product candidates, including BRM-1420 and GB1211, and any future product candidates through clinical development, and, if successful, later-stage clinical trials;
- advance our preclinical development programs into clinical development;
- experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain, including delays and economic uncertainty in various global markets caused by geopolitical instability and conflict;
- increase the amount of research and development activities to discover and develop product candidates;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts, general and administrative functions and our operations as a public company;
- 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 BRM-1420. 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 $19.7 million as of September 30, 2024 will be sufficient to fund our operating expenditures and capital expenditure requirements through at least the next twelve months from the filing date of this Quarterly Report on Form 10-Q. 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. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or other operations.

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 beyond the restructurings implemented in September 2023 and May 2024.

Economic uncertainty in various global markets, including the United States and Europe, caused by political instability and conflict, such as the ongoing conflict in Ukraine and in Israel, 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 conflict between Russia and Ukraine and effects of the Russian sanctions, current armed conflict in Israel and the Gaza Strip, geopolitical tensions, record inflation or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this report.

Components of Operating Results

Operating Expenses

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

Research and Development

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

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

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

We have historically met the requirements to receive a tax credit in Denmark of up to $0.8 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 $0.8 million during both nine-month periods ended September 30, 2024 and 2023. We anticipate that we will be eligible to receive this credit in 2024 and 2025.

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 in the consolidated statements of operations. 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. There was no RDEC recorded during the three and nine months ended September 30, 2023. We anticipate that we will be eligible to receive this credit in 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 U.S. Food and Drug Administration (the "FDA"), European Medicines Agency (the "EMA"), Medicines and Healthcare products Regulatory Agency ("MHRA"), Health Canada or other regulatory agencies of IND applications, clinical trial applications, and/or other regulatory filings for BRM-1420, 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 and accounting, business operations and other administrative functions. We expect our general and administrative expenses to continue over the next several years to support our continued research and development activities, manufacturing activities and continued costs of operating as a public company, however we anticipate these expenses will be lower than our general and administrative expenses prior to announcing the initiation of our strategic alternative review. These expenses will likely include continued costs related to the hiring of additional personnel, legal, regulatory and other fees, director and officer insurance premiums and investor relations costs associated with our continued operations.

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. We anticipate that our restructuring costs will decrease in the near future compared to prior periods due to the restructuring costs being incurred in the periods ended June 30, 2024 and December 31, 2023 and that the execution of the Restructuring Plan is substantially complete. We did not incur any restructuring costs in the three month period ended September 30, 2024.

Other Income (Expense), Net

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

•Interest income: The interest income earned on our cash, cash equivalents and marketable securities 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, 2024 and 2023

The following sets forth our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	$ 1,093	$ 2,551	$ (1,458)	-57.2%
General and administrative	2,747	3,304	(557)	-16.9%
Restructuring costs	-	2,728	(2,728)	-100.0%
Total operating expenses	$ 3,840	$ 8,583	$ (4,743)	-55.3%
Loss from operations	(3,840)	(8,583)	4,743	-55.3%
Other income, net	(36)	447	(483)	-108.1%
Loss before income tax expense	(3,876)	(8,136)	4,260	-52.4%
Income tax expense	7	—	7	0.0%
Net loss	$ (3,883)	$ (8,136)	$ 4,253	-52.3%

Research and development expenses

Research and development expenses were comprised of:

	Three Months Ended September 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Preclinical studies and clinical trial-related activities	$ 472	$ (971)	$ 1,443	-148.6%
Personnel	248	1,280	(1,032)	-80.6%
Chemistry, manufacturing and control	88	496	(408)	-82.3%
Consultants and other costs	285	1,746	(1,461)	-83.7%
Total research and development expenses	$ 1,093	$ 2,551	$ (1,458)	-57.2%

Research and development expenses were $1.1 million for the three months ended September 30, 2024, compared to $2.6 million for the three months ended September 30, 2023. The decrease of $1.5 million was primarily related to decreased chemistry, manufacturing and control costs of $0.4 million, decreased personnel costs of $1.0 million and decreased consulting related costs and other research and development costs of $1.5 million, offset by increased clinical trial-related expenses of $1.4 million.

General and administrative expenses

General and administrative expenses were $2.7 million for the three months ended September 30, 2024, compared to $3.3 million for the three months ended September 30, 2023. The decrease of $0.6 million was primarily related to decreased personnel costs of $0.5 million and decreased net other general administrative costs of $0.1 million.

Restructuring costs

There were no restructuring costs for the three months ended September 30, 2024. Restructuring costs were $2.7 million for the three months ended September 30, 2023. The restructuring costs in 2023 were related to the Restructuring Plan.

Other income (expense), net

Other income (expense), net for the three months ended September 30, 2024 was $(0.04) million, compared to $0.5 million for the three months ended September 30, 2023. The decrease of $0.5 million was primarily due to decreased interest income, net resulting from lower investable balances, offset by increased foreign exchange transaction loss, net.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following sets forth our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		Change	
	2024	2023	Amount	Percent
		(in thousands)		
Operating expenses				
Research and development	$ 5,390	$ 21,002	$ (15,612)	-74.3%
General and administrative	8,800	9,504	(704)	-7.4%
Restructuring costs	968	2,728	(1,760)	-64.5%
Total operating expenses	$ 15,158	$ 33,234	$ (18,076)	-54.4%
Loss from operations	(15,158)	(33,234)	18,076	-54.4%
Other income, net	509	1,360	(851)	-62.6%
Loss before income tax expense	(14,649)	(31,874)	17,225	-54.0%
Income tax expense	49	-	49	0.0%
Net loss	$ (14,698)	$ (31,874)	$ 17,176	-53.9%

Research and development expenses

Research and development expenses were comprised of:

	Nine Months Ended September 30,		Change	
	2024	2023	Amount	Percent
		(in thousands)		
Personnel	$ 2,233	$ 6,346	$ (4,113)	-64.8%
Preclinical studies and clinical trial-related activities	1,358	7,320	(5,962)	-81.4%
Chemistry, manufacturing and control	378	2,059	(1,681)	-81.6%
Consultants and other costs	1,421	5,277	(3,856)	-73.1%
Total research and development expenses	$ 5,390	$ 21,002	$ (15,612)	-74.3%

Research and development expenses were $5.4 million for the nine months ended September 30, 2024, compared to $21.0 million for the nine months ended September 30, 2023. The decrease of $15.6 million was primarily related to decreased clinical trial-related expenses of $6.0 million due to discontinued clinical trial activities and decreased chemistry, manufacturing and control costs of $1.7 million, decreased personnel costs of $4.1 million and decreased consulting related costs and other research and development costs of $3.9 million.

General and administrative expenses

General and administrative expenses were $8.8 million for the nine months ended September 30, 2024, compared to $9.5 million for the nine months ended September 30, 2023. The decrease of $0.7 million was primarily related to decreased personnel costs of $1.1 million and decreased net other general administrative costs of $0.3 million, offset by increased legal increased legal costs relating to our exploration of strategic alternatives of $0.7 million.

Restructuring costs

Restructuring costs were $1.0 million for the nine months ended September 30, 2024, compared to $2.7 million for the nine months ended September 30, 2023. The decrease of $1.7 million was primarily related to the May RIF costs incurred in 2024 compared to the Restructuring Plan costs incurred in 2023.

Other income (expense), net

Other income (expense), net for the nine months ended September 30, 2024 was $0.5 million, compared to $1.4 million for the nine months ended September 30, 2023. The decrease of $0.9 million was primarily due to decreased interest income, net resulting from lower investable balances and increased foreign exchange transaction loss, net.

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 the three and nine months ended September 30, 2024, we had no sales under the ATM Program. During the three and nine months ended September 30, 2023, we sold an aggregate of 3,632 shares and 58,412 shares, respectively, of our common stock under the ATM Program at a weighted average selling price of $63.50 per share and $52.50 per share, respectively.

Our net losses were $3.9 million and $14.7 million for the three and nine months ended September 30, 2024, respectively. Our net losses were $8.1 million and $31.9 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $270.8 million and $19.7 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,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (13,687)	$ (25,437)
Net cash provided by investing activities	11,650	12,750
Net cash provided by financing activities	—	2,876
Net decrease in cash and cash equivalents	$ (2,037)	$ (9,811)

Net Cash Used in Operating Activities

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.

Cash used in operating activities of $25.4 million during the nine months ended September 30, 2023 was primarily attributable to our net loss of $31.9 million, together with non-cash items of $4.6 million principally with respect to stock-based compensation, and a net increase of $1.9 million in components of our working capital.

Net Cash Provided by Investing Activities

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.

Cash provided by investing activities of $12.8 million during the nine months ended September 30, 2023 was the result of $38.7 million in proceeds from the sale of marketable securities, offset by $25.9 million for the purchase of marketable securities.

Net Cash Provided by Financing Activities

We had no financing activities for the nine months ended September 30, 2024. Cash provided by financing activities of $2.9 million during nine months ended September 30, 2023 was the result of net proceeds from the issuance of our common stock under the ATM Program.

Funding Requirements

We expect to incur significant costs as we implement our development plans for GB1211 and BRM-1420 and we will require substantial additional capital to finance our 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; and general overhead costs. Based on current estimates of our expenses going forward, we believe that our existing cash and cash equivalents of

$19.7 million as of September 30, 2024 will be sufficient to fund our operating expenditures and capital expenditure requirements through at least the next twelve months from the filing date of this Quarterly Report on Form 10-Q. 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.

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 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 renewed focus on GB1211 and the addition of BRM-1420 from Bridge Medicines 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 BRM-1420, 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 unaudited interim condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited interim condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the related disclosures of assets and liabilities at the date of the unaudited interim condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, 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 substantial expenses associated with 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 significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs, CMOs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided by CROs, 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 condensed consolidated statements of operations. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services 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 significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

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

Stock-Based Compensation

We have issued stock-based compensation awards through the granting of stock options and restricted stock units, 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 included as compensation expense over the vesting period during which service is provided in exchange for the award.

We use a Black-Scholes option pricing model to determine fair value of our stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common 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. 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, 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. The fair value of our awards in the nine months ended September 30, 2023 has been estimated using Black-Scholes based on the following assumptions: expected term of 6.0 years; expected volatility of 91.0%; risk-free interest rate of 3.8%; and no expectation of dividends.

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

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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

We recognize tax benefits from uncertain tax positions only if (based on the technical merits of the position) it is more likely than not that the tax positions will be sustained on examination by the tax authority. The tax benefits recognized in the financial statements from such positions are measured based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. We do not believe there will be any material changes in 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, 2024 and 2023 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 an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in

the JOBS Act. As a result, our condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

We are also a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time, we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our annual reports 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, 2024. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, 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, 2024.

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

Changes in Internal Control 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, 2023, 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 other than the updates to the risk factors set forth below.

Pursuant to our recently announced conclusion of our strategic review process, our focus is now on the development of GB1211 and the addition of BRM-1420 from Bridge Medicines. If we fail to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected.

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 with Bridge Medicines pursuant to which we 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 acquired assets. As a result of the conclusion of the strategic alternatives review process, our focus is now on the development of GB1211 and the addition of BRM-1420 from Bridge Medicines. As part of the strategic alternative review process, we determined not to further advance GB2064, our LOXL-2 inhibitor candidate, at this time.

We believe this realigned strategic focus is the best way to optimize our financial and other resources to advance our business. However, there is no assurance that we will be successful at executing on this strategy. If we are unable to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected.

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 of officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of September 30, 2024, $70.0 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 BRM-1420 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 and nine months ended September 30, 2024, none of our officers or directors adopted, modified or terminated any such trading arrangements.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed with the SEC on September 5, 2024).
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 1, 2024 By: /s/ Hans T. Schambye
Hans T. Schambye, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 1, 2024 By: /s/ Lori Firmani
Lori Firmani
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)