

**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, 2021

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39655

**GALECTO, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**Ole Maaloes Vej 3**  
**DK-2200 Copenhagen N**  
**Denmark**  
**75 State Street, Suite 100**  
**Boston, MA 02109**  
(Address of principal executive offices)

**37-1957007**  
(I.R.S. Employer  
Identification No.)

N/A

**02109**  
(Zip Code)

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.00001 per share	GLTO	The Nasdaq Global Select Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 2, 2021, the registrant had 25,261,832 shares of common stock, \$0.00001 par value per share, outstanding.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “intend,” “predict,” “seek,” “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:

- the success, cost and timing of our product development activities and planned initiation and completion of clinical trials of our lead product candidate, GB0139, including our ability to enroll patients in our ongoing Phase 2b clinical trial of GB0139 at anticipated rates and our ability to complete such trial with fewer dosage groups, as well as our other current product candidates and any future product candidates;
- the success, cost and timing of our product development activities and planned initiation and completion of our clinical trials;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop, including our expectation that the U.S. Food and Drug Administration, or the FDA, or other regulatory agencies would agree with our belief that our Phase 2b clinical trial of GB0139 may be registrational;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our heavy dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates that we may pursue;
- the implementation of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the rate and degree of market acceptance and clinical utility for our current or future product candidates we may develop;
- our estimates about the size of our market opportunity;
- our ability to use the capital we have raised in ways that increase the value of your investment;
- our expectations related to the use the capital we have raised, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to establish and maintain collaborations;
- our financial performance and liquidity;
- our ability to effectively manage our potential growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations and those of our collaborators, service providers and other vendors;
- our ability to maintain adequate internal controls over financial reporting; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, the reasons described elsewhere in this Quarterly Report on Form 10-Q and those set forth in Part I, Item 1A - “Risk Factors” in our [Annual Report on Form 10-K](#) for the fiscal year ended December 31, 2020. 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, 2021 (unaudited)	December 31, 2020
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 66,157	\$ 163,582
Marketable securities	35,987	—
Prepaid expenses and other current assets	4,864	5,713
Total current assets	<u>107,008</u>	<u>169,295</u>
Marketable securities, long-term	25,492	—
Operating lease right-of-use asset	940	885
Tax credit receivable, noncurrent	856	—
Property and equipment, net	214	—
Restricted cash	—	254
Other assets, noncurrent	1,364	1,162
Total assets	<u>\$ 135,874</u>	<u>\$ 171,596</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,981	\$ 2,851
Accrued expenses and other current liabilities	3,762	2,715
Total current liabilities	<u>5,743</u>	<u>5,566</u>
Operating lease liabilities, noncurrent	511	541
Total liabilities	<u>6,254</u>	<u>6,107</u>
<b>Commitments and contingencies (Note 9)</b>		
<b>Stockholders' equity</b>		
Preferred stock, par value of \$0.00001 per share; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, par value of \$0.00001 per share; 300,000,000 shares authorized at September 30, 2021 and December 31, 2020; 25,261,832 shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	272,412	269,175
Accumulated deficit	(142,703)	(104,360)
Accumulated other comprehensive income	(89)	674
Total stockholders' equity	<u>129,620</u>	<u>165,489</u>
Total liabilities and stockholders' equity	<u>\$ 135,874</u>	<u>\$ 171,596</u>

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,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 9,748	\$ 7,651	\$ 28,373	\$ 16,874
General and administrative	3,191	2,515	10,386	5,461
Total operating expenses	12,939	10,166	38,759	22,335
Loss from operations	(12,939)	(10,166)	(38,759)	(22,335)
Other income (expense), net				
Interest income, net	35	—	126	—
Foreign exchange transaction gain (loss), net	208	(1,485)	290	(925)
Total other income (expense), net	243	(1,485)	416	(925)
Net loss	(12,696)	(11,651)	(38,343)	(23,260)
Dividends on convertible preferred stock	—	(2,713)	—	(7,648)
Net loss attributable to common shareholders	(12,696)	(14,364)	(38,343)	(30,908)
Net loss per common share, basic and diluted	\$ (0.50)	\$ (55.25)	\$ (1.52)	\$ (118.89)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	25,261,832	259,966	25,261,832	259,966
Other comprehensive loss, net of tax				
Currency translation gain (loss)	(369)	2,331	(740)	2,136
Unrealized gain (loss) on marketable securities	34	—	(23)	—
Other comprehensive gain (loss), net of tax	(335)	2,331	(763)	2,136
Total comprehensive loss	\$ (13,031)	\$ (9,320)	\$ (39,106)	\$ (21,124)

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

## GALECTO, INC.

## Condensed Consolidated Statements of Convertible Preferred Stock and Changes in Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

For the Three Months Ended	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity		
	September 30, 2021	Shares	Amount	Shares	Amount	Shares	Amount	Shares					Amount	
Balance at June 30, 2021	—	\$ —	—	\$ —	—	\$ —	—	\$ —	25,261,832	\$ —	\$ 271,193	\$ (130,007)	\$ 246	\$ 141,432
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,219	—	—	1,219
Currency translation loss	—	—	—	—	—	—	—	—	—	—	—	—	(369)	(369)
Net unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	34	34
Net loss	—	—	—	—	—	—	—	—	—	—	—	(12,696)	—	(12,696)
Balance at September 30, 2021	—	\$ —	—	\$ —	—	\$ —	—	\$ —	25,261,832	\$ —	\$ 272,412	\$ (142,703)	\$ (89)	\$ 129,620
For the Three Months Ended	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity		
	September 30, 2020	Shares	Amount	Shares	Amount	Shares	Amount	Shares					Amount	
Balance at June 30, 2020	684,068	\$ 13,414	4,125,056	\$ 106,205	—	\$ —	—	\$ —	259,966	\$ —	\$ 1,227	\$ (81,132)	\$ (2,646)	\$ (82,551)
Issuance of Series D preferred stock, net of issuance costs of \$2,797	—	—	—	—	2,368,118	61,402	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	134	—	—	134
Currency translation gain	—	—	—	—	—	—	—	—	—	—	—	—	2,331	2,331
Net loss	—	—	—	—	—	—	—	—	—	—	—	(11,651)	—	(11,651)
Balance at September 30, 2020	684,068	\$ 13,414	4,125,056	\$ 106,205	2,368,118	\$ 61,402	—	\$ —	259,966	\$ —	\$ 1,361	\$ (92,783)	\$ (315)	\$ (91,737)

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

GALECTO, INC.

Condensed Consolidated Statements of Convertible Preferred Stock and Changes in Stockholders' Equity

(in thousands, except share amounts)

(Unaudited)

For the Nine Months Ended	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	September 30, 2021	Shares	Amount	Shares	Amount	Shares	Amount	Shares				
Balance at December 31, 2020	—	\$ —	—	\$ —	—	\$ —	25,261,832	\$ —	\$ 269,175	\$ (104,360)	\$ 674	\$ 165,489
Stock-based compensation expense	—	—	—	—	—	—	—	—	3,237	—	—	3,237
Currency translation loss	—	—	—	—	—	—	—	—	—	—	(740)	(740)
Net unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(23)	(23)
Net loss	—	—	—	—	—	—	—	—	—	(38,343)	—	(38,343)
Balance at September 30, 2021	—	\$ —	—	\$ —	—	\$ —	25,261,832	\$ —	\$ 272,412	\$ (142,703)	\$ (89)	\$ 129,620
For the Nine Months Ended	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
September 30, 2020	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	684,068	\$ 13,414	4,125,056	\$ 106,205	—	\$ —	259,966	\$ —	\$ 826	\$ (69,523)	\$ (2,451)	\$ (71,148)
Issuance of Series D preferred stock, net of issuance costs of \$2,797	—	—	—	—	2,368,118	61,402	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	535	—	—	535
Currency translation gain	—	—	—	—	—	—	—	—	—	—	2,136	2,136
Net loss	—	—	—	—	—	—	—	—	—	(23,260)	—	(23,260)
Balance at September 30, 2020	684,068	\$ 13,414	4,125,056	\$ 106,205	2,368,118	\$ 61,402	259,966	\$ —	\$ 1,361	\$ (92,783)	\$ (315)	\$ (91,737)

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,	
	2021	2020
<b>Cash flows from operating activities:</b>		
Net loss	\$ (38,343)	\$ (23,260)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation	13	—
Stock-based compensation	3,237	507
Amortization of premiums and discounts on marketable securities	731	—
Amortization of right of use lease asset	317	136
Accretion of lease liability	57	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	849	(220)
Tax credit receivable, noncurrent	(856)	(865)
Other assets, noncurrent	(203)	—
Accounts payable	(871)	1,134
Accrued expenses and other current liabilities	993	(1,019)
Operating lease liabilities	(403)	(99)
Net cash used in operating activities	<u>(34,479)</u>	<u>(23,686)</u>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(84,209)	—
Proceeds from sale of marketable securities	21,976	—
Purchases of property and equipment	(227)	—
Net cash used in investing activities	<u>(62,460)</u>	<u>—</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of Series C preferred stock, net	—	39,669
Proceeds from issuance of Series D preferred stock	—	58,727
Series D preferred stock issuance costs	—	(2,797)
Net cash provided by financing activities	<u>—</u>	<u>95,599</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>(96,939)</u>	<u>71,913</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(740)	2,136
Cash, cash equivalents and restricted cash, beginning of period	163,836	11,525
Cash, cash equivalents and restricted cash, end of period	<u>\$ 66,157</u>	<u>\$ 85,574</u>
<b>Components of cash, cash equivalents and restricted cash</b>		
Cash and cash equivalents	66,157	85,333
Restricted cash	—	241
Total cash, cash equivalents and restricted cash	<u>\$ 66,157</u>	<u>\$ 85,574</u>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for taxes	\$ 40	\$ —
<b>Supplemental disclosures of noncash activities:</b>		
Receivable on issuance of Series D preferred stock	\$ —	\$ 5,473
Operating lease liabilities arising from obtaining right-of-use assets	\$ 409	\$ 672

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

## **1. DESCRIPTION OF BUSINESS, ORGANIZATION AND LIQUIDITY**

### ***Business and Organization***

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

As of September 30, 2021, the Company's wholly owned subsidiaries were PharmAkea, Inc. or PharmAkea, Galecto Securities Corporation, and Galecto Biotech AB, a Swedish company. Galecto Biotech ApS, a Danish operating company, is a wholly-owned subsidiary of Galecto Biotech AB.

### ***Risks and uncertainties***

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

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

### ***Liquidity and management plans***

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff and raising capital, and has financed its operations primarily through the issuance of redeemable convertible preferred shares, debt financings and, most recently, the Company's initial public offering, or IPO.

As of September 30, 2021, the Company had an accumulated deficit of \$142.7 million, from recurring losses since inception in 2011. The Company has incurred recurring losses and has no sales as none of its product candidates have obtained the necessary regulatory approval for commercialization and to be marketed as approved products. The Company expects to continue to incur losses as a result of costs and expenses related to the Company's clinical development and corporate general and administrative activities. The Company had negative cash flows from operating activities during the nine months ended September 30, 2021 and 2020 of \$34.5 million and \$23.7 million, respectively, and current projections indicate that the Company will have continued negative cash flows for the foreseeable future as it continues to develop its product candidates. Net losses incurred for the three and nine months ended September 30, 2021 were \$12.7 million and \$38.3 million, respectively. Net losses incurred for the three and nine months ended September 30, 2020 were \$11.7 million and \$23.3 million, respectively.

At September 30, 2021, the Company's cash, cash equivalents and marketable securities amounted to \$127.6 million and current assets amounted to \$107.0 million and current liabilities amounted to \$5.7 million. At December 31, 2020, the Company's cash and cash equivalents amounted to \$163.6 million, current assets amounted to \$169.3 million and current liabilities amounted to \$5.6 million.

In the future, the Company will consider the following ways to fund its operations including: (1) raising additional capital through equity and/ or debt financings; (2) new commercial relationships to help fund future clinical trial costs (i.e. licensing and partnerships); (3) reducing spending on one or more research and development programs by discontinuing development; and/or (4) restructuring operations to change its overhead structure. The Company's future liquidity needs, and ability to address those needs,

will largely be determined by the success of its product candidates and key development and regulatory events and its decisions in the future.

### **Coronavirus pandemic**

The coronavirus disease 2019 pandemic, or COVID-19, which has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred. Supply chains have been disrupted and facilities and production have been suspended. Demand for certain goods and services, such as medical services and supplies, however, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on the Company's business and operations are uncertain.

In response to the impact of COVID-19, the Company has implemented certain measures intended to help the Company manage its impact and position the Company to resume operations quickly and efficiently once these restrictions are lifted, such as executing a work-from-home strategy for administrative functions and operations. The Company continues to monitor the impact of COVID-19 and assess its strategy accordingly.

Despite the Company's implementation of such measures, the actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on the Company cannot be predicted. As a result, there can be no assurance that the Company will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact the Company's business, financial condition and results of operations by decreasing or delaying the enrollment of patients in the Company's clinical trials or otherwise causing interruptions or delays in the Company's programs and services.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. The CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions include removing certain limitations on the utilization of net operating losses, increasing the loss carryback period for certain losses to five years, increasing the ability to deduct interest expense, and deferring social security payments, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act of 2017. The CARES Act has not had a material impact on the Company's financial position and results of operations.

## **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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

The accompanying interim condensed consolidated financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020, 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, 2021, results of operations, statement of convertible preferred stock and stockholders' equity for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020. 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, 2020, as filed with the Securities and Exchange Commission ("SEC") on March 29, 2021. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results expected for the full fiscal year or any interim period.

Other than noted below, for the nine months ended September 30, 2021, there have been no changes to the significant accounting policies as disclosed in Note 2 to the Company's annual consolidated financial statements for the year ended December 31, 2020.

### **Investments in Marketable Securities**

The Company invests excess cash balances in short-term and long-term marketable debt securities. The Company classifies investments in marketable debt securities as either held-to-maturity or available-for-sale based on the facts and circumstances present at the time of purchase and re-evaluates classification at each balance sheet date. All investments in marketable debt securities at each balance sheet date presented, are generally considered as available-for-sale. Marketable debt securities with maturities of twelve months or less are classified as short-term investments and marketable debt securities with maturities greater than twelve months are

classified based on their availability for use in current operations. The Company reports available-for-sale debt securities at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value), net of applicable taxes, in accumulated other comprehensive income (loss), a component of stockholders' equity. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. Realized gains and losses are determined using the specific identification method and are included in other income (expense). If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the intention to sell and, if so, marks the investment to market through a charge to the Company's condensed consolidated statements of operations and comprehensive loss.

#### Property and Equipment, Net

Property and equipment are recorded at cost. Costs associated with maintenance and repairs are expensed as incurred. Depreciation is provided using the straight-line method over the estimated useful lives:

Asset Category	Useful Life
Equipment	5-7 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of 10 years or the remaining term of the respective lease

#### **Recently issued accounting standards**

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

In December 2019, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This guidance is effective for public business entities for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. For all other entities, including emerging growth companies, it is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently evaluating the impact that the new accounting standard will have on the financial statements and disclosures.

### **3. INVESTMENTS**

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

The following table summarizes the Company's interest-bearing investments in marketable securities, by category, as of September 30, 2021 (in thousands):

	September 30, 2021
<b>Marketable securities:</b>	
Debt securities - available-for-sale	\$ 35,987
Total	\$ 35,987
<b>Marketable securities, long-term:</b>	
Debt securities - available-for-sale	\$ 25,492
Total	\$ 25,492

A summary of the Company's available-for-sale investments as of September 30, 2021 consisted of the following (in thousands):

	At September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>Marketable securities:</b>				
Corporate bonds	\$ 35,990	\$ —	\$ (3)	\$ 35,987
Total	<u>\$ 35,990</u>	<u>\$ —</u>	<u>\$ (3)</u>	<u>\$ 35,987</u>
<b>Marketable securities, long-term:</b>				
Corporate bonds	\$ 25,512	\$ —	\$ (20)	\$ 25,492
Total	<u>\$ 25,512</u>	<u>\$ —</u>	<u>\$ (20)</u>	<u>\$ 25,492</u>

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of September 30, 2021 consisted of the following (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	\$ 35,990	\$ 35,987
Due after one year through five years	25,512	25,492
Total	<u>\$ 61,502</u>	<u>\$ 61,479</u>

The Company had no investments in marketable securities as of December 31, 2020.

#### 4. PROPERTY AND EQUIPMENT, NET

Property and equipment as of September 30, 2021 consisted of the following (in thousands):

	September 30, 2021
Equipment	\$ 227
Total property and equipment	227
Less: accumulated depreciation	(13)
Property and equipment, net	<u>\$ 214</u>

Depreciation expense for the three and nine months ended September 30, 2021 was \$8,000 and \$13,000, respectively. The Company had no property and equipment as of December 31, 2020.

#### 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, 2021 and December 31, 2020 is as follows (in thousands):

	Fair Value Measurement at September 30, 2021			
	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds <sup>(1)</sup>	\$ 51,713	\$ 51,713	\$ —	\$ —
Debt securities	61,479	—	61,479	—
<b>Total</b>	<b>\$ 113,192</b>	<b>\$ 51,713</b>	<b>\$ 61,479</b>	<b>\$ —</b>

	Fair Value Measurement at December 31, 2020			
	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds <sup>(1)</sup>	\$ 142,904	142,904	—	—
<b>Total</b>	<b>\$ 142,904</b>	<b>\$ 142,904</b>	<b>\$ —</b>	<b>\$ —</b>

<sup>(1)</sup> 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, 2021	December 31, 2020
Contract research and development costs	\$ 3,330	\$ 1,620
Research and development tax credit receivable	856	1,808
Prepaid insurance costs	171	1,642
Value-added tax refund receivable	313	401
Other	194	242
Total prepaid expenses and other current assets	<u>\$ 4,864</u>	<u>\$ 5,713</u>

## 7. LEASES

The Company has an operating lease for its corporate headquarters in Copenhagen, Denmark for office space that expires in January 2025. The Company also has a lease agreement for office space in London, United Kingdom, that expires August 2022 and has a renewal option and a lease agreement for office space in Gothenburg, Sweden, that expires in September 2022. The Company also has an operating lease agreement for laboratory space in Stevenage, United Kingdom.

The Company's finance leases are immaterial both individually and in the aggregate. The Company has elected to apply the short-term lease exception to all leases of one year or less.

Quantitative information regarding the Company's leases for the three and nine months ended September 30, 2021 and 2020 was as follows:

Lease Cost	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost (in thousands)	\$ 130	\$ 65	\$ 374	\$ 136
<b>Other Information</b>				
Operating cash flows paid for amounts included in the measurement of lease liabilities (in thousands)	\$ 142	\$ 67	\$ 403	\$ 136
Operating lease liabilities arising from obtaining right-of-use assets (in thousands)	\$ 409	\$ 420	\$ 409	\$ 672

As of September 30, 2021 and December 31, 2020, the weighted average remaining lease term for operating leases was 2.6 years and 2.8 years, respectively.

As of September 30, 2021 and December 31, 2020, the weighted average discount rate for operating leases was 8% for both periods.

Operating lease liabilities are as follows at September 30, 2021 (in thousands):

Future Lease Payments	Operating Leases	
2021 (excluding the period ended September 30, 2021)	\$	118
2022		438
2023		267
2024		208
2025		17
Total lease payments		1,048
Less: imputed interest		(108)
Total lease liabilities	\$	940

## 8. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	September 30, 2021	December 31, 2020
Employee compensation costs	\$ 2,022	\$ 1,031
Contract research and development costs	925	967
Lease liabilities, current	428	374
Other liabilities	387	343
Total accrued expenses and other current liabilities	\$ 3,762	\$ 2,715

## 9. COMMITMENTS AND CONTINGENCIES

The Company's commitments and contingencies are disclosed in Note 8 of the audited consolidated financial statements as of and for the year ended December 31, 2020, filed with the SEC on March 29, 2021. There have been no material changes to the Company's commitments and contingencies since the date of such financial statements. Further, the Company's commitments related to lease agreements are disclosed in Note 7 to the Company's unaudited interim condensed consolidated financial statements.

## 10. STOCK-BASED COMPENSATION

### *Employee equity plan*

In March 2020, the Company replaced its 2013 Option Program ("2013 Plan") with its 2020 Stock Option and Grant Plan ("2020 Plan"). The 2020 Plan initially allowed the Company to award up to 1,740,325 options and the 304,142 outstanding options granted under the 2013 Plan were transferred to the 2020 Plan. Each vested option entitles the option holder to purchase a single common share in the Company. Holders of stock options are entitled to exercise the vested portion of the stock option during the term of the grant. If a qualified exit, as defined in the 2020 Plan, occurs then all of the holders' unvested options shall vest immediately. Options that are not exercised during the exercise period will automatically be forfeited. Stock options generally vest over a four-year period and expire ten years from the grant date. In September 2020, the Company approved an additional 839,494 options to be awarded under the 2020 Plan.

In October 2020, the Board of Directors and stockholders of the Company approved the 2020 Equity Incentive Plan ("2020 Equity Plan"). The 2020 Equity Plan allows the Company to award up to 1,625,858 options, as well as up to 2,512,427 outstanding options granted under the 2020 Plan at the time of approval of the 2020 Equity Plan, to the extent such outstanding options are forfeited or cancelled. No further options were available to be issued under the 2020 Plan. The 2020 Equity Plan will cumulatively increase by 5 percent of the number of shares of common stock issued and outstanding on January 1st each year. At September 30, 2021, the Company had 1,476,632 options available for future grant under the 2020 Equity Plan.

The following table sets forth the activity for the Company's stock options during the periods presented:

	Number of Options	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2019	304,142	\$ 5.58	—	—
Granted	2,235,285	4.67	—	—
Exercised	(1,016)	1.95	—	—
Outstanding at December 31, 2020	2,538,411	\$ 4.67	8.8	\$ 20,009,769
Granted	1,556,000	9.79	—	8,160
Cancelled	(170,683)	7.63	—	—
Outstanding at September 30, 2021	3,923,728	\$ 6.57	8.5	\$ 2,061,624
Vested at September 30, 2021	3,619,586	\$ 6.67	9.0	\$ 2,061,624
Exercisable at September 30, 2021	1,266,116	\$ 3.97	7.2	\$ 1,173,185

The weighted-average grant date fair value of all stock options granted for the nine months ended September 30, 2021 was \$7.23. The intrinsic value at September 30, 2021 and December 31, 2020 was based on the closing price of the Company's common stock on that date of \$3.59 per share and \$12.51 per share, respectively.

### Stock-based compensation

The grant date fair value of stock options vested during the nine months ended September 30, 2021 was \$1.9 million. Total unrecognized compensation expense related to unvested options granted under the Company's stock-based compensation plan was \$13.5 million at September 30, 2021, which is expected to be recognized over a weighted average period of 3.1 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,	
	2021	2020	2021	2020
Research and development	\$ 516	\$ 63	\$ 1,372	\$ 272
General and administrative	703	71	1,865	235
Total stock-based compensation	\$ 1,219	\$ 134	\$ 3,237	\$ 507

The fair values of the options granted were estimated based on the Black-Scholes model, using the following assumptions:

	Nine Months Ended September 30,	
	2021	2020
Risk-free interest rate	0.7%	0.4%
Expected term (in years)	6.0	6.0
Expected volatility	90.5%	89.0%
Expected dividend yield	—	—

### 11. NET LOSS PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (12,696)	\$ (11,651)	\$ (38,343)	\$ (23,260)
Dividends on convertible preferred stock	—	(2,713)	—	(7,648)
Net loss attributable to common stockholders	\$ (12,696)	\$ (14,364)	\$ (38,343)	\$ (30,908)
Net loss per common share, basic and diluted	\$ (0.50)	\$ (55.25)	\$ (1.52)	\$ (118.89)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	25,261,832	259,966	25,261,832	259,966



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

	Three and Nine Months Ended September 30,	
	2021	2020
Stock options to purchase common stock	3,923,728	1,562,246
Convertible preferred stock	-	7,177,242

## 12. SUBSEQUENT EVENTS

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

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

The following information should be read in conjunction with the unaudited interim condensed consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto for the year ended December 31, 2020, 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, 2020, filed with the United States Securities and Exchange Commission, or the SEC, on March 29, 2021.

This report contains forward-looking statements that are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, or PSLRA, with the intention of obtaining the benefits of the "safe harbor" provisions of the PSLRA. Forward-looking statements involve risks and uncertainties. In this Quarterly Report on Form 10-Q, words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution our readers that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those expressed or implied by the forward-looking statements contained in this Quarterly Report on Form 10-Q.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

### Overview

We are a clinical-stage biotechnology company developing therapeutics that are designed to target the biological processes that lie at the heart of fibrosis and cancer. While our initial focus has been on the development of small-molecule inhibitors of galectin-3 and the collagen cross-linking enzyme lysyl oxidase-like 2, or LOXL2, which play key roles in regulating fibrosis, we are also advancing our compounds for the treatment of cancer (initially in non-small cell lung cancer, or NSCLC, and myelofibrosis). We believe our product candidates are distinct from the current generation of antifibrotic and anti-cancer agents and have the potential to significantly improve patients' clinical outcomes and enhance their quality of life.

Our most advanced product candidate, GB0139, is an inhaled small molecule inhibitor of galectin-3. We are developing GB0139 for the treatment of severe fibrotic lung diseases such as idiopathic pulmonary fibrosis, or IPF, a life-threatening progressive fibrotic disease of the lung. While there are currently two approved therapies for the treatment of lung fibrosis, they have only been shown to have a modest impact on the progression of the disease, and both therapies have been associated with significant side effects leading to poor therapeutic adherence. In our clinical trials completed to date, we found orally inhaled GB0139 to be generally well-tolerated and that the compound inhibited galectin-3 in the lungs, in a dose-dependent manner, and that it decreased levels of a range of plasma biomarkers, such as YKL-40 and PDGF, that have been linked to mortality, severity and/or progression in IPF. We are currently conducting a 52-week randomized, double-blind, multicenter, parallel, placebo-controlled Phase 2b trial investigating the safety and efficacy of GB0139 in up to 210 patients with IPF, which we refer to as the GALACTIC-1 trial. We continue to recruit patients in this trial and expect that topline results will be available by mid-2023.

Our product candidate portfolio includes GB2064, a selective small molecule oral inhibitor of LOXL2 that we initially plan to develop for the treatment of myelofibrosis, a malignant disease of the bone marrow in which fibrosis reduces the ability to form blood cells. The LOXL2 mechanism may also be important in other solid and liquid tumor types as well as fibrotic diseases. We initiated a Phase 2a trial examining GB2064 for the treatment of myelofibrosis, referred to as the MYLOX-1 trial, in the third quarter of 2021, and we expect that interim results from the MYLOX-1 trial will be available in the first half of 2022 and topline results will be available by the end of 2022.

Our product candidate portfolio also includes a second and distinct galectin-3 inhibitor, GB1211, a potent small molecule selective oral galectin-3 inhibitor that we are developing for the treatment of cancer (initially in NSCLC) and fibrosis (initially in liver cirrhosis). In November 2021, we announced that we had entered into a clinical trial supply agreement with Roche for our planned Phase 2a trial of GB1211 in combination with Tecentriq®, a PD-L1 checkpoint inhibitor, for the treatment of NSCLC, which we refer to as the GALLANT-1 trial. We expect to initiate the GALLANT-1 trial in the first half of 2022 and expect that topline results from this trial will be available by mid-2023.

We also initiated a Phase 1b/2a trial of GB1211 for liver cirrhosis, which we refer to as the GULLIVER-2 trial, in the third quarter of 2021. This trial is focused on safety and effect on liver function and fibrosis biomarkers. We expect that topline results from this trial will be available in the second half of 2022.

Our most advanced product candidate, GB0139, is in Phase 2b clinical development and our other product candidates and research initiatives are in early stages of clinical and preclinical development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our operations to date have been financed primarily from our initial public offering, or IPO, the issuance of convertible preferred shares and convertible notes. Since inception, we have had significant operating losses. Our net loss was \$12.7 million and \$38.3 million for the three and nine months ended September 30, 2021, respectively. Our net loss was \$11.7 million and \$23.3 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$142.7 million and \$127.6 million in cash, cash equivalents and marketable securities.

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

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities of \$127.6 million as of September 30, 2021 will be sufficient to fund our operating expenditures and capital expenditure requirements into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

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

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

In response to the impact of COVID-19, we have implemented certain measures intended to help us manage its impact and position ourselves to resume operations quickly and efficiently once these restrictions are lifted, such as executing a work-from-home strategy for administrative functions and operations.

Despite our implementation of such measures, the actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on us cannot be predicted. To date, the COVID-19 pandemic has caused delays in certain of our studies, including (i) recruitment of patients in our ongoing Phase 2b GALACTIC-1 trial for GB0139, which has resulted in certain trial protocol amendments and increased costs and (ii) initiation of our planned clinical trials of GB2064 (MYLOX-1) and GB1211 (GALLANT-1 and GULLIVER-2). With respect to our GALACTIC-1 trial, due to the continued impact of the COVID-19 pandemic on screening and recruitment, we have added more investigator sites and have expanded the number of countries in which we are recruiting. As of the date of this report we have continued to randomize and enroll patients at a rate consistent with our forecasts even though we have experienced lower patient screen rates. If COVID-19 continues to impact patient screen rates, we may not be able to maintain our planned timing for enrollment, which could require further amendments to the trial protocol. We cannot assure you that

we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact our business, financial condition and results of operations by decreasing or delaying the enrollment of patients in our clinical trials or otherwise causing interruptions or delays in our programs and services. See “Risk Factors—Risks Related to Managing Our Business and Operations—The global pandemic of the novel coronavirus disease, COVID-19, has, and may continue to, adversely impact our business, including our preclinical studies and clinical trials” in our [Annual Report on Form 10-K](#) for the fiscal year ended December 31, 2020 for more information regarding the potential impact of COVID-19 on our business and operations.

## Components of Operating Results

### Operating Expenses

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

#### Research and Development

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

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

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

From time to time, we obtain grants from public and private funds for our research and development projects. The grant income for a given period is recognized as a cost reimbursement and is typically based on the time and the costs that we have spent on the specific project during that period. We have no grant income for the three and nine months ended September 30, 2021 and 2020.

We have historically met the requirements to receive a tax credit in Denmark of up to \$0.9 million per year for losses resulting from research and development costs of up to approximately \$4.0 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 \$0.9 million and \$0.8 million for the nine month period ended September 30, 2021 and 2020, respectively.

Our direct research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. The majority of our clinical spending in the three and nine month period ended September 30, 2021 and 2020 was on GB0139.

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

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

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

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

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing GB0139 through clinical development and other product candidates further into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages

of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

#### *General and Administrative Expenses*

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

#### **Other Income (Expense), Net**

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

- Interest income: The interest income earned on our cash, cash equivalents, restricted cash and marketable securities are recorded in our statements of operations.
- Foreign exchange: The functional currency of our subsidiaries in Denmark and Sweden is the Euro. Transactions denominated in currencies other than the Euro result in exchange gains and losses that are recorded in our statements of operations.

### **Results of Operations**

#### **Comparison of the Three Months Ended September 30, 2021 and 2020**

The following sets forth our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Change	
	2021	2020	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	\$ 9,748	\$ 7,651	\$ 2,097	27.4%
General and administrative	3,191	2,515	676	26.9%
Total operating expenses	\$ 12,939	\$ 10,166	\$ 2,773	27.3%
Loss from operations	(12,939)	(10,166)	(2,773)	27.3%
Other income (expense), net	243	(1,485)	1,728	-116.4%
Net loss	\$ (12,696)	\$ (11,651)	\$ (1,045)	9.0%

## Research and development expenses

Research and development expenses were comprised of:

	Three Months Ended September 30,		Change Amount
	2021	2020	
	(in thousands)		
Preclinical studies and clinical trial-related activities	\$ 5,312	\$ 3,210	\$ 2,102
Chemistry, manufacturing and control	1,314	2,150	(836)
Personnel	2,046	1,068	978
Consultants and other costs	1,076	1,223	(147)
Total research and development expenses	<u>\$ 9,748</u>	<u>\$ 7,651</u>	<u>\$ 2,097</u>

Research and development expenses were \$9.7 million for the three months ended September 30, 2021, compared to \$7.7 million for the three months ended September 30, 2020. The increase of \$2.0 million was primarily related to an increase in clinical trial-related expenses of \$2.1 million resulting from the GALACTIC-1 trial and the commencement of two new clinical trials; and increased personnel costs due to additional headcount of \$0.5 million and personnel costs for non-cash stock-based compensation of \$0.5 million; offset by a decrease in manufacturing expenses of \$0.8 million and other research and development related expenses of \$0.2 million.

## General and administrative expenses

General and administrative expenses were \$3.2 million for the three months ended September 30, 2021, compared to \$2.5 million for the three months ended September 30, 2020. The increase of \$0.7 million was primarily related to an increase in insurance costs of \$0.5 million; increased personnel costs due to additional headcount of \$0.4 million; non-cash stock-based compensation of \$0.6 million; offset by a decrease in accounting costs of \$0.6 million; and other general and administrative costs of \$0.2 million.

## Other income (expense), net

Other income (expense), net for the three months ended September 30, 2021 and 2020 were a net income of \$0.2 million for the three months ended September 30, 2021, compared to a net expense of \$1.5 million for the three months ended September 30, 2020. The increase of \$1.7 million was due to the following:

- Net interest income was \$35,000 for the three months ended September 30, 2021. There was no interest income for the three months ended September 30, 2020.
- Net foreign exchange gains were \$0.2 million for the three months ended September 30, 2021 and net foreign exchange losses were \$1.5 million for the three months ended September 30, 2020.

## Comparison of the Nine Months Ended September 30, 2021 and 2020

The following sets forth our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Change	
	2021	2020	Amount	Percent
	(in thousands)			
Operating expenses				
Research and development	\$ 28,373	\$ 16,874	\$ 11,499	68.1%
General and administrative	10,386	5,461	4,925	90.2%
Total operating expenses	<u>\$ 38,759</u>	<u>\$ 22,335</u>	<u>\$ 16,424</u>	<u>73.5%</u>
Loss from operations	(38,759)	(22,335)	(16,424)	73.5%
Other income (expense), net	416	(925)	1,341	-145.0%
Net loss	<u>\$ (38,343)</u>	<u>\$ (23,260)</u>	<u>\$ (15,083)</u>	<u>64.8%</u>

## Research and development expenses

Research and development expenses were comprised of:

	Nine Months Ended September 30,		Change Amount
	2021	2020	
	(in thousands)		
Preclinical studies and clinical trial-related activities	\$ 14,115	\$ 6,629	\$ 7,486
Chemistry, manufacturing and control	5,708	4,513	1,195
Personnel	5,748	2,793	2,955
Consultants and other costs	2,802	2,939	(137)
Total research and development expenses	\$ 28,373	\$ 16,874	\$ 11,499

Research and development expenses were \$28.4 million for the nine months ended September 30, 2021, compared to \$16.9 million for the nine months ended September 30, 2020. The increase of \$11.5 million was primarily related to an increase in clinical trial-related expenses of \$7.5 million resulting from the GALACTIC-1 trial and the commencement of two new clinical trials; increased CMC activities to prepare for these clinical trials of \$1.2 million; increased personnel costs due to additional headcount of \$1.8 million and personnel costs for non-cash stock-based compensation of \$1.1 million; offset by a decrease in other research and development costs of \$0.1 million.

## General and administrative expenses

General and administrative expenses were \$10.4 million for the nine months ended September 30, 2021, compared to \$5.5 million for the nine months ended September 30, 2020. The increase of \$4.9 million was primarily related to an increase in insurance costs of \$1.5 million and increased personnel costs due to additional headcount of \$1.4 million as well as non-cash stock-based compensation of \$1.6 million; consultant costs of \$0.5 million; and other general and administrative costs of \$0.7 million; offset by a decrease in accounting costs of \$0.8 million.

## Other income (expense), net

Other income (expense), net for the nine months ended September 30, 2021 and 2020 were net income of \$0.4 million for the nine months ended September 30, 2021, compared to a net loss of \$0.9 million for the nine months ended September 30, 2020. The increase of \$1.3 million was due to the following:

- Net interest income was \$0.1 million for the nine months ended September 30, 2021. There was no interest income for the nine months ended September 30, 2020.
- Net foreign exchange gains were \$0.3 million for the nine months ended September 30, 2021 and net foreign exchange losses were \$0.9 million for the nine months ended September 30, 2020.

## Liquidity and Capital Resources

### Sources of Liquidity

Our operations to date have been financed primarily through our IPO, the issuance of convertible preferred shares and convertible notes. On November 2, 2020, we completed our IPO in which we issued and sold 6,342,207 shares of common stock at a public offering price of \$15.00 per share, including 675,540 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, resulting in net proceeds of \$86.3 million after deducting underwriting discounts and commissions and estimated offering expenses. Since inception, we have had significant operating losses. Our net losses were \$12.7 million and \$38.3 million for the three and nine months ended September 30, 2021, respectively. Our net losses were \$11.7 million and \$23.3 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$142.7 million and \$127.6 million in cash, cash equivalents and marketable securities. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.



## Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (34,479)	\$ (23,686)
Net cash used in investing activities	(62,460)	—
Net cash provided by financing activities	—	95,599
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ (96,939)	\$ 71,913

### Net Cash Used in Operating Activities

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

Cash used in operating activities of \$23.7 million during the nine months ended September 30, 2020 was primarily attributable to our net loss of \$23.3 million together with non-cash items of \$0.6 million principally with respect to stock-based compensation, offset by a net decrease of \$1.1 million in our working capital.

### Net Cash Used in Investing Activities

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

We had no investing activities for the nine months ended September 30, 2020.

### Net Cash Provided by Financing Activities

We had no financing activities for the nine months ended September 30, 2021.

Cash provided by financing activities of \$95.6 million for the nine months ended September 30, 2020 was comprised of net proceeds of \$39.7 million from the sale and issuance of our Series C convertible preferred shares in January 2020 and net proceeds of \$55.9 million from the issuance of our Series D convertible preferred stock in September 2020.

## Funding Requirements

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

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities of \$127.6 million as of September 30, 2021 will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements

when needed on favorable terms or at all. If we raise additional capital through public or private equity offerings in the future, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

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

- the impacts of the COVID-19 pandemic;
- the progress, costs and results of our ongoing Phase 2b clinical trial of GB0139 in IPF, Phase 2a trial of GB 2064 in myelofibrosis and Phase 1b/2a trial of GB1211 in liver cirrhosis, and our planned trials for GB1211 and our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our ongoing Phase 2b clinical trial of GB0139;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates and the terms of such arrangements;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations; and
- the costs of operating as a public company.

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

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited interim condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed

consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

## **Research and Development Costs**

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

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

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

During 2019, we acquired the right to develop and commercialize PharmAkea's product candidate PAT-1251, which we now refer to as GB2064. GB2064 is in clinical development and has not achieved regulatory approval for marketing and absent obtaining such approval, has no alternative future use. As such, the costs of acquiring GB2064 were immediately expensed as purchased in-process research and development costs in our consolidated statements of operations.

## ***Stock-based Compensation***

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

We use a Black-Scholes option pricing model to determine fair value of our stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of stock options, the expected volatility based on the historical volatility of a publicly traded set of peer companies and the expected risk-free interest rate. 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, 2021 has been estimated using Black-Scholes based on the following assumptions: expected term of 6.0 years; expected volatility of 90.5%; risk-free interest rate of 0.7%; and no expectation of dividends. The fair value of our awards in the nine months ended September 30, 2020 has been estimated using Black-Scholes based on the following assumptions: term of 6.0 years; volatility of 89.0%; risk-free rate of 0.4%; 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.

For grants of options we made in June 2020, we employed a market approach and utilized the market-adjusted back-solve method for inferring the equity value predicated on the closing of the final tranche of our Series C convertible preferred shares in January 2020, and we allocated value among different classes of equity securities under a Black-Scholes option pricing methodology, or OPM. This method was selected as we concluded that the recent financing transaction was an arm's-length transaction. We then applied an adjustment for market performance of the composite of multiple biotechnology indexes which was 0.4% from the period of January 1, 2020 through April 30, 2020. Furthermore, as of the valuation date the development timelines were long (the current Phase 2b clinical trial was expected to last up to 18 additional months) and future liquidity events were difficult to forecast. Application of the OPM back-solve method involves making assumptions for the expected time to liquidity, volatility and risk-free rate and then solving for the value of equity such that the value for the most recent financing equals the amount paid. We assumed a 1.7-year estimated term, 80% volatility rate and a risk-free rate of 0.19%. We then reflected a discount for lack of marketability of 33% derived from our then-current estimates of the time to a liquidity event. With the aid of the April 30, 2020 third-party valuation and after consideration of macroeconomic and company-specific developments during the first half of 2020, our board of directors determined the fair market value of our common shares to be \$1.95 per share for the options granted on June 24, 2020.

### **Income Taxes**

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

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

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

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

### **Recently Adopted Accounting Pronouncements**

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our consolidated financial statements for the nine months ended September 30, 2021 and 2020 appearing elsewhere in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of September 30, 2021:

	Payments due by period (in thousands)				
	Total	Less than one year	One to three years	Three to five years	More than five years
Leases	\$ 1,048	\$ 489	\$ 490	\$ 69	\$ —
Total contractual obligations	\$ 1,048	\$ 489	\$ 490	\$ 69	\$ —

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We have not included our payment obligations under these contracts in the table, as these contracts generally provide for termination upon notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate the timing of if and when they will occur. We could also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

### **Off-Balance Sheet Arrangements**

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

### **Emerging Growth Company Status**

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

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

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of the completion of our IPO, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before that time, or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1.0 billion of non-convertible debt over a three-year period.

### **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 chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, 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 management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our chief executive officer and chief financial officer concluded that, as a result of material weaknesses in our internal control over financial reporting, included in our [Annual Report on Form 10-K](#) filed with the SEC on March 29, 2021, our disclosure controls and procedures were not effective as of September 30, 2021.

***Changes in Internal Control***

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

**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, 2020, which could materially affect our business, financial condition, or results of operations. There have been no material changes in or additions to the risk factors referred to in the previous sentence.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.***Use of proceeds from registered securities*

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

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

As of September 30, 2021, we have not used the net proceeds from our initial public offering. We have invested the unused net proceeds from the offering in money market accounts and marketable debt securities. We expect to use the net proceeds from the offering described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 30, 2020, to fund our clinical development programs, including for GB0139, GB1211 and GB2064.

*Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers*

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not Applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
31.1*	<a href="#"><u>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.</u></a>
31.2*	<a href="#"><u>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.</u></a>
32.1†	<a href="#"><u>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.</u></a>
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Filed herewith.

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



**SIGNATURES**

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

Galecto, Inc.

Date: November 4, 2021

By: \_\_\_\_\_ /s/ Hans T. Schambye  
**Hans T. Schambye, M.D., Ph.D.**  
**President, Chief Executive Officer and Director**  
**(Principal Executive Officer)**

Date: November 4, 2021

By: \_\_\_\_\_ /s/ Jonathan Freve  
**Jonathan Freve**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**



**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)  
OF THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Jonathan Freve, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2021 of Galecto, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2021

By: \_\_\_\_\_ /s/ Jonathan Freve

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

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

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

- (1) the Quarterly Report on Form 10-Q for the period ended September 30, 2021 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2021

By: \_\_\_\_\_  
/s/ Hans T. Schambye  
**Hans T. Schambye, M.D., Ph.D.**  
**President, Chief Executive Officer and Director**  
**(Principal Executive Officer)**

Date: November 4, 2021

By: \_\_\_\_\_  
/s/ Jonathan Freve  
**Jonathan Freve**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**