

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40522

Monte Rosa Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

84-3766197

(I.R.S. Employer
Identification No.)

645 Summer Street, Suite 102

Boston, Massachusetts

(Address of principal executive offices)

02210

(Zip Code)

Registrant's telephone number, including area code: (617) 949-2643

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	GLUE	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 7, 2022, the registrant had 48,399,056 shares of common stock, \$0.0001 per share, outstanding.

Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, or the 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 facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, results, cost and success of our current and future research and development programs and preclinical studies, including our expectations for our GSPT1-directed MGDs;
- the initiation, timing, progress, results, cost and success of our future clinical trials, including statements regarding the period during which the results of the clinical trials will become available;
- our ability to continue to develop our proprietary protein degradation platform called QuEEN™ and to expand our proteomics and translational medicine capabilities;
- the potential advantages of our platform technology and product candidates;
- the extent to which our scientific approach and platform technology may target proteins that have been considered undruggable or inadequately drugged;
- our plans to submit IND applications to the FDA future product candidates;
- the potential benefits of strategic collaborations and our ability to enter into strategic collaborations with third parties who have the expertise to enable us to further develop our biological targets, product candidates and platform technologies;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to manufacture, including through third-party manufacturers, our product candidates for preclinical use, future clinical trials and commercial use, if approved;
- our ability to commercialize our product candidates, including our ability to establish sales, marketing and distribution capabilities;
- the rate and degree of market acceptance of our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to establish and maintain intellectual property rights covering our current and future product candidates and technologies;
- the implementation of our business model and strategic plans for our business, product candidates, and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our financial performance;
- developments in laws and regulations in the United States and foreign countries;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of the COVID-19 pandemic on our business and operations; and

- other risks and uncertainties, including those listed under the section entitled "Risk factors" and those included in "Part 1, Item 1A, Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, or our Annual Report, filed with the SEC on March 29, 2022.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect 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, those described under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. 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.

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

We have applied for various trademarks that we use in connection with the operation of our business. All other trade names, trademarks and service marks of other companies appearing in this Quarterly Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Quarterly 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. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

From time to time, we may use our website, our Twitter at @MonteRosaTx and on our LinkedIn account at [linkedin.com/company/monte-rosa-therapeutics](https://www.linkedin.com/company/monte-rosa-therapeutics) to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.monterosatx.com. Investors are encouraged to review the Investor Relations section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our Twitter posts and our LinkedIn posts are not incorporated into, and does not form a part of, this Quarterly Report.

Table of Contents

	<u>Page</u>
PART I.	
FINANCIAL INFORMATION	
Item 1. Financial Statements (Unaudited)	1
Condensed Consolidated Balance Sheets (Unaudited)	1
Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)	2
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (Unaudited)	3
Condensed Consolidated Statements of Cash Flows (Unaudited)	5
Notes to the Condensed Consolidated Financial Statements (Unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures About Market Risk	23
Item 4. Controls and Procedures	23
PART II.	
OTHER INFORMATION	
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 3. Defaults Upon Senior Securities	27
Item 4. Mine Safety Disclosures	27
Item 6. Exhibits	28
Signatures	29

Part I – Financial Information

Item 1. Financial Statements

Monte Rosa Therapeutics, Inc.

Condensed consolidated balance sheets (unaudited)

(in thousands, except share and per share amounts) (unaudited)	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 112,394	\$ 346,071
Marketable securities	159,755	—
Proceeds receivable from common stock sale	13,507	—
Other receivables	4,050	—
Prepaid expenses and other current assets	4,569	2,595
Current restricted cash	960	—
Total current assets	295,235	348,666
Property and equipment, net	19,384	12,325
Operating lease right-of-use assets	38,534	—
Restricted cash, net of current	4,302	5,338
Other long-term assets	148	—
Total assets	\$ 357,603	\$ 366,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 9,753	\$ 6,558
Accrued expenses and other current liabilities	8,972	10,080
Current portion of operating lease liability	3,065	—
Total current liabilities	21,790	16,638
Defined benefit plan liability	2,128	2,176
Operating lease liability	42,593	—
Total liabilities	66,511	18,814
Commitments and contingencies		
Stockholders' equity		
Common stock, \$0.0001 par value; 500,000,000 shares authorized, 48,528,247 shares issued and 48,372,781 shares outstanding as of September 30, 2022; and 500,000,000 shares authorized, 46,794,295 shares issued and 46,535,966 shares outstanding as of December 31, 2021	5	5
Additional paid-in capital	493,443	471,566
Accumulated other comprehensive loss	(2,602)	(2,021)
Accumulated deficit	(199,754)	(122,035)
Total stockholders' equity	291,092	347,515
Total liabilities and stockholders' equity	\$ 357,603	\$ 366,329

See accompanying notes to the condensed consolidated financial statements.

Monte Rosa Therapeutics, Inc.

Condensed consolidated statements of operations and comprehensive loss (unaudited)

(in thousands, except share and per share amounts) (unaudited)	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 21,342	\$ 15,115	\$ 60,193	\$ 39,025
General and administrative	7,020	4,753	19,702	10,470
Total operating expenses	28,362	19,868	79,895	49,495
Loss from operations	(28,362)	(19,868)	(79,895)	(49,495)
Other income (expense):				
Interest income, net	997	13	1,774	33
Foreign currency exchange gain (loss), net	63	18	293	(96)
Gain (loss) on disposal of fixed assets	(16)	—	109	—
Changes in fair value of preferred stock tranche obligations, net	—	—	—	(960)
Total other income (expense)	1,044	31	2,176	(1,023)
Net loss	\$ (27,318)	\$ (19,837)	\$ (77,719)	\$ (50,518)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.58)	\$ (0.43)	\$ (1.67)	\$ (2.85)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	46,732,353	45,987,866	46,666,000	17,751,410
Comprehensive loss:				
Net loss	\$ (27,318)	\$ (19,837)	\$ (77,719)	\$ (50,518)
Other comprehensive loss:				
Provision for pension benefit obligation	32	(535)	99	(894)
Unrealized loss on available-for-sale securities	(176)	—	(680)	—
Comprehensive loss	\$ (27,462)	\$ (20,372)	\$ (78,300)	\$ (51,412)

See accompanying notes to the condensed consolidated financial statements.

Monte Rosa Therapeutics, Inc.

Condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit) (unaudited)

(in thousands, except share amounts) (unaudited)	Common stock		Additional paid-in capital	Accumulated other comprehensiv e loss	Accumulated deficit	Total Stockholders , equity (deficit)
	Shares	Amount				
Balance—January 1, 2022	46,535,966	\$ 5	\$ 471,566	\$ (2,021)	\$ (122,035)	\$ 347,515
Restricted common stock vesting	34,505	—	—	—	—	—
Exercise of common stock options	60,240	—	153	—	—	153
Provision for pension benefit obligation	—	—	—	34	—	34
Stock-based compensation expense	—	—	2,251	—	—	2,251
Unrealized loss on available-for-sale securities	—	—	—	(146)	—	(146)
Net Loss	—	—	—	—	(23,932)	(23,932)
Balance—March 31, 2022	46,630,711	\$ 5	\$ 473,970	\$ (2,133)	\$ (145,967)	\$ 325,875
Restricted common stock vesting	34,508	—	—	—	—	—
Exercise of common stock options	19,439	—	96	—	—	96
Provision for pension benefit obligation	—	—	—	33	—	33
Stock-based compensation expense	—	—	2,873	—	—	2,873
Unrealized loss on available-for-sale securities	—	—	—	(358)	—	(358)
Net Loss	—	—	—	—	(26,469)	(26,469)
Balance—June 30, 2022	46,684,658	\$ 5	\$ 476,939	\$ (2,458)	\$ (172,436)	\$ 302,050
Restricted common stock vesting	33,850	—	—	—	—	—
Exercise of common stock options	16,047	—	79	—	—	79
Provision for pension benefit obligation	—	—	—	32	—	32
Stock-based compensation expense	—	—	3,214	—	—	3,214
Unrealized loss on available-for-sale securities	—	—	—	(176)	—	(176)
Issuance of common stock, net of issuance costs of \$714	1,638,226	—	13,211	—	—	13,211
Net Loss	—	—	—	—	(27,318)	(27,318)
Balance—September 30, 2022	48,372,781	\$ 5	\$ 493,443	\$ (2,602)	\$ (199,754)	\$ 291,092

See accompanying notes to the condensed consolidated financial statements

Monte Rosa Therapeutics, Inc.

Condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit) (unaudited) - Continued

(in thousands, except share amounts) (unaudited)	Convertible preferred stock		Common stock					Total Stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	
Balance—January 1, 2021	53,631,514	\$ 67,764	1,685,534	\$ 1	\$ 404	\$ (1,056)	\$ (48,077)	\$ (48,728)
Restricted common stock vesting	—	—	36,565	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of \$69	24,000,000	68,571	—	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of \$163	32,054,521	94,837	—	—	—	—	—	—
Provision for pension benefit obligation	—	—	—	—	—	136	—	136
Stock-based compensation expense	—	—	—	—	252	—	—	252
Net Loss	—	—	—	—	—	—	(12,276)	(12,276)
Balance—March 31, 2021	109,686,035	\$ 231,172	1,722,099	\$ 1	656	\$ (920)	\$ (60,353)	\$ (60,616)
Restricted common stock vesting	—	—	36,580	—	—	—	—	—
Exercise of common stock options	—	—	76,950	—	128	—	—	128
Conversion of convertible preferred stock into common stock	(109,686,035)	(231,172)	31,068,102	2	231,170	—	—	231,172
Issuance of common stock in connection with initial public offering, net of issuance costs of \$18,500	—	—	11,700,000	1	203,874	—	—	203,875
Provision for pension benefit obligation	—	—	—	—	—	(495)	—	(495)
Stock-based compensation expense	—	—	—	—	1,019	—	—	1,019
Net Loss	—	—	—	—	—	—	(18,405)	(18,405)
Balance—June 30, 2021	—	\$ —	44,603,731	\$ 4	436,847	\$ (1,415)	\$ (78,758)	\$ 356,678
Restricted common stock vesting	—	—	125,187	—	—	—	—	—
Issuance of common stock in connection with initial public offering, net of issuance costs of \$2.3 million	—	—	1,755,000	1	30,925	—	—	30,926
Exercise of common stock options	—	—	—	—	—	—	—	—
Provision for pension benefit obligation	—	—	—	—	—	(535)	—	(535)
Stock-based compensation expense	—	—	—	—	2,073	—	—	2,073
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	—
Net Loss	—	—	—	—	—	—	(19,837)	(19,837)
Balance—September 30, 2021	—	\$ —	46,483,918	\$ 5	469,845	\$ (1,950)	\$ (98,595)	\$ 369,305

See accompanying notes to the condensed consolidated financial statements

Monte Rosa Therapeutics, Inc.

Condensed consolidated statements of cash flows (unaudited)

(in thousands) (unaudited)	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (77,719)	\$ (50,518)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	8,338	3,344
Depreciation	2,675	1,323
Noncash lease expense	3,202	—
Net accretion of discounts/premiums on marketable securities	(685)	—
Changes in fair value of preferred stock tranche obligations	—	960
Gain (loss) on disposal of property and equipment	(109)	13
Changes in operating assets and liabilities		
Other receivables	(177)	—
Prepaid expenses and other current assets	(2,122)	(1,593)
Accounts payable	(899)	(5,446)
Accrued expenses and other current liabilities	(1,041)	6,726
Defined benefit plan liability	50	—
Right-of-use assets and operating lease liabilities	(18)	—
Net cash used in operating activities	\$ (68,505)	\$ (45,191)
Cash flows from investing activities:		
Purchases of property and equipment	(5,640)	(6,673)
Proceeds from sale of property and equipment	109	67
Purchases of marketable securities	(290,049)	—
Proceeds from maturities of marketable securities	130,300	—
Net cash used in investing activities	\$ (165,280)	\$ (6,606)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock	—	143,000
Payment of convertible preferred stock issuance costs	—	(231)
Proceeds from initial public offering, net of underwriting discount of \$17.9 million	—	237,750
Payment of initial public offering issuance costs	—	(2,950)
Payment of common stock issuance costs	(296)	—
Proceeds from exercise of employee stock options	328	128
Net cash provided by financing activities	\$ 32	\$ 377,697
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (233,753)	\$ 325,900
Cash, cash equivalents and restricted cash—beginning of period	351,409	42,863
Cash, cash equivalents and restricted cash—end of period	\$ 117,656	\$ 368,763
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	\$ 112,394	\$ 367,034
Restricted cash	5,262	1,729
Total cash, cash equivalents and restricted cash	\$ 117,656	\$ 368,763
Supplemental disclosure of noncash items		
Conversion of convertible preferred stock into common stock	\$ —	\$ 231,172
Settlement of preferred stock tranche obligation	\$ —	\$ 20,640
Common stock issuance costs in accounts payable and accrued expenses	\$ 31	\$ —
Proceeds receivable from issuance of common stock	\$ 13,507	\$ —
Reduction of right-of-use assets for lease incentives receivable	\$ 3,872	\$ —
Purchases of property and equipment in accounts payable and accrued expenses	\$ 4,750	\$ 1,909

See accompanying notes to the condensed consolidated financial statements.

Monte Rosa Therapeutics, Inc.

Notes to the condensed consolidated financial statements

(unaudited)

1. Description of business, contribution and exchange, and liquidity

Business

Monte Rosa Therapeutics, Inc. is a biotechnology company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. As used in these condensed consolidated financial statements, unless the context otherwise requires, references to the Company or Monte Rosa refer to Monte Rosa Therapeutics, Inc. and its wholly owned subsidiaries Monte Rosa Therapeutics AG and Monte Rosa Therapeutics Securities Corp. Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated under the laws of Switzerland in April 2018. Monte Rosa Therapeutics, Inc. was incorporated in Delaware in November 2019. The Company is headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland.

Reverse Stock Split

The Company's board of directors approved a one-for-3.5305 reverse stock split of its issued and outstanding common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company's preferred stock effective as of June 17, 2021. Accordingly, all share and per share amounts for all periods presented in the financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

Initial Public Offering

In June 2021 the Company completed its initial public offering, or IPO, and issued an aggregate of 11,700,000 shares of common stock at a price to the public of \$19.00 per share. The Company received aggregate net proceeds from the IPO of \$203.6 million, after deducting underwriting discounts and commissions of \$15.6 million and offering costs of \$3.1 million. In connection with the IPO, the Company granted the underwriters a 30-day option to purchase an additional 1,755,000 shares. In July 2021, the underwriters exercised the option in full and the Company issued 1,755,000 shares of common stock for aggregate net proceeds of \$31.0 million after deducting underwriter discounts and commissions of \$2.3 million.

Immediately prior to consummation of the IPO, all outstanding shares of the Company's Series A, Series A-2, Series B and Series C convertible preferred stock were converted into 31,068,102 shares of common stock. The Company's common stock began trading on the Nasdaq Global Select Market on June 24, 2021 under the symbol "GLUE".

Liquidity considerations

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 convertible preferred shares and public offerings of the Company's common stock.

The Company's continued discovery and development of its product candidates 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 and infrastructure and extensive compliance-reporting capabilities. Even if product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

As of September 30, 2022, the Company had an accumulated deficit of \$199.8 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of \$77.7 million and \$50.5 million for the nine months ended September 30, 2022 and 2021, respectively. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to develop its product candidates. The Company currently expects that its cash, cash equivalents, and marketable securities of \$272.1 million as of September 30, 2022 will be sufficient to fund operating expenses and capital requirements for at least 12 months from the date the third quarter interim condensed consolidated financial statements are issued. However, additional funding will be necessary to fund future discovery research, pre-clinical and clinical activities. The Company will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although it has been successful in raising capital in the past, there is no assurance that the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and the Company may not be able to enter into collaborations or other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or

eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect the Company's business prospects, even the ability to continue operations.

2. Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and are stated in U.S. dollars. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification and Accounting Standards Updates, or ASUs, of the Financial Accounting Standards Board, or FASB. All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Financial Information

The Company's condensed consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and pursuant to the rules and regulations of the SEC. In the Company's opinion, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Recently issued accounting pronouncements

The Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act (JOBS Act).

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. 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*, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and financial statement disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (i) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for the Company beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently assessing the impact adoption of ASU 2020-06 will have on its financial statements and disclosures.

Recently adopted accounting pronouncements

On January 1, 2022, the Company adopted Accounting Standard Update ("ASU") No. 2016-02, *Leases (Topic 842)*, and its associated amendments using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. There was no cumulative-effect adjustment recorded to retained earnings upon adoption. Under the standard, a lessee is required to recognize a lease liability and right-of-use (ROU) asset for all leases, unless the lease qualifies for the short-term lease exception. The new guidance also modified the classification criteria and requires additional disclosures to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. Consistent with current guidance, a lessee's recognition, measurement, and presentation of expenses and cash flows arising from a lease continues to depend primarily on its classification. The Company elected the package of practical expedients permitted

under the transition guidance, which allowed the Company to carryforward its historical lease classification, its assessment on whether a contract was or contains a lease, and its initial direct costs for any leases that existed prior to January 1, 2022. In addition, the Company elected the following transitional practical expedients: (1) the short-term lease exception and (2) to not separate its non-lease components for its real estate, vehicle and equipment leases. Upon the adoption of this standard, the Company recorded operating lease right-of-use assets of \$7.3 million and corresponding operating lease liabilities of \$7.4 million as of January 1, 2022. The difference between the value of the right-of-use assets and lease liabilities is due to the reclassification of existing deferred rent as of January 1, 2022.

In December 2019, the FASB issued ASU 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 fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company adopted ASU 2019-12 on January 1, 2022. The adoption of the standard was immaterial to the accompanying condensed consolidated financial statements.

3. Fair value measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	As of September 30, 2022			
	Level 1	Level 2	Level 3	Total
Current assets				
Money market funds	\$ 101,157	\$ —	\$ —	\$ 101,157
Pension plan assets	—	3,739	—	3,739
Corporate debt securities	—	83,503	—	83,503
U.S Treasury securities	—	76,252	—	76,252
Total assets measured at fair value	\$ 101,157	\$ 163,494	\$ —	\$ 264,651

Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds are based on quoted prices in active markets for identical securities. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The fair value of pension plan assets has been determined as the surrender value of the portfolio of active insured members held within the Swiss Life Collective BVG Foundation collective investment fund and are classified within Level 2 of the fair value hierarchy.

Marketable securities consist of corporate debt securities and U.S. Treasury securities which are classified as available-for-sale pursuant to ASC 320, *Investments—Debt and Equity Securities*. Marketable securities are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets. The fair values of these investments are estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities based on historical data and other observable inputs. All marketable securities have a maturity date within the next 12 months.

There were no transfers among Level 1, Level 2 or Level 3 categories in the nine months ended September 30, 2022 and 2021.

4. Marketable Securities

Marketable securities as of September 30, 2022 consisted of the following (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	\$ 83,917	\$ 5	\$ (419)	\$ 83,503
U.S Treasury securities	76,518	1	(267)	76,252
Total	\$ 160,435	\$ 6	\$ (686)	\$ 159,755

As of September 30, 2022, the Company held 27 marketable securities, 21 of which were in an unrealized loss position. The aggregate fair value of securities in a loss position is \$118.1 million. There were no individual securities that were in a

significant unrealized loss position as of September 30, 2022. The Company evaluates securities for other-than-temporary impairments based on quantitative and qualitative factors, and considers the decline in market value as of September 30, 2022, to be primarily attributable to the then current economic and market conditions. The Company neither intends to sell these investments nor concludes that it is more-likely-than-not that the Company will have to sell them before recovery of their carrying values. The Company also believes that it will be able to collect both principal and interest amounts due to it at maturity.

5. Property and Equipment, net

Property and equipment, net, consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Laboratory equipment	\$ 16,914	\$ 12,315
Computer hardware and software	491	299
Furniture and fixtures	299	443
Leasehold improvements	1,368	1,119
Construction in process	5,492	852
Total property and equipment, at cost	\$ 24,564	\$ 15,028
Less: accumulated depreciation	(5,180)	(2,703)
Property and equipment, net	\$ 19,384	\$ 12,325

Depreciation expense for the three months ended September 30, 2022 and 2021 was \$1.1 million and \$0.6 million, respectively. Depreciation expense for the nine months ended September 30, 2022 and 2021 was \$2.7 million and \$1.3 million, respectively.

6. Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (ROU) assets and operating lease liabilities in the condensed consolidated balance sheets. The Company has no finance leases as of September 30, 2022.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, management estimated the incremental borrowing rate based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

Summer Street Lease

In September 2020, the Company entered into an operating lease agreement to lease 16,748 square feet of office and laboratory space at 645 Summer Street, Boston, Massachusetts. The original term of the 645 Summer Lease expires in March 2026. On May 5, 2022, the Company entered into an Agreement for Termination of Lease (the "Lease Termination Agreement") with OPG MP Parcel Owner (DE) LLC (the "Landlord") which, subject to the Landlord executing a lease with a new tenant, provides the Company with the option to terminate the existing lease agreement (the "645 Summer Lease") for office space located at 645 Summer Street, Boston, MA. On August 8, 2022, the termination condition was met. As a result, the operating lease ROU asset and operating lease liability were reduced by \$3.7 million to \$1.3 million and \$1.4 million, respectively, and the \$1.0 million security deposit associated with the lease was reclassified from long-term restricted cash to current restricted cash on the condensed consolidated balance sheet. The 645 Summer lease will terminate on June 1, 2023, provided, however, the Company may terminate the lease as of any date between February 1, 2023 and June 1, 2023 upon providing 90 days prior notice of such date.

Klybeck Lease

In March 2021, the Company entered into an operating lease agreement for office and lab space that occupies approximately 21,422 square feet located at Hochbergerstrasse 60C, 4057 Basel, Basel-City, Switzerland. The current term of the lease expires in March 2026.

Harrison Avenue Lease

In December 2021, the Company entered into a non-cancelable lease agreement for 63,327 square feet of office and laboratory space to support its expanding operations. The term of the lease commenced on April 1, 2022 and the Company's obligation to pay rent will begin upon the earlier of (a) December 1, 2022 or (b) the date which is two (2) months following the date which Company substantially completes its tenant improvements. The initial term of the lease is 128 months following the commencement date at which point the Company has the option to extend the lease an additional 5 years. As of the lease commencement date, the Company has determined that it is not reasonably certain to exercise the option to extend the lease and has not included the extension period in the lease term. The annual base rent under the Lease is \$95.00 per square foot for the first year, which is subject to scheduled annual increases of 3%, plus certain costs, operating expenses and property management fees.

Pursuant to the terms of the Harrison Avenue Lease, the landlord will reimburse the Company For \$13 million of tenant improvements. The Company will reduce the ROU asset and record an asset for construction in progress as costs and incurred and reimbursed. These costs will be reclassified from construction in progress to leasehold improvements upon completion of the project. As of September 30, 2022 the Company had \$3.9 million receivable in reimbursable tenant improvements which is recorded as an other receivable on the condensed consolidated balance sheet.

The components of lease expense for the nine months ended September 30, 2022 are as follows (in thousands):

	Nine months ended September 30, 2022	
Operating lease expense	\$	4,857
Variable lease expense		1,128
Total lease expense	\$	5,985

The variable lease expenses generally include common area maintenance and property taxes. All lease related expenses have been recorded as research and development expense in the condensed consolidated statements of operations and comprehensive loss. There were no short-term lease costs in the nine months ended September 30, 2022.

The weighted average remaining lease term and discount rate related to the Company's leases are as follows:

	September 30, 2022
Weighted average remaining lease term (years)	9.9
Weighted average discount rate	9.8%

Supplemental cash flow information relating to the Company's leases for the nine months ended September 30, 2022 are as follows (in thousands):

	Nine months ended September 30, 2022	
Right-of-use assets obtained in exchange for operating lease obligations	\$	48,488
Cash paid for amounts included in the measurement of lease liabilities	\$	1,181

The amortization of the ROU assets for the nine months ended September 30, 2022 was \$2.4 million.

Future minimum lease payments under non-cancelable leases as of September 30, 2022 for each of the years ending December 31 are as follows (in thousands):

Undiscounted lease payments	
Remaining 2022	\$ 1,023
2023	7,373
2024	6,788
2025	6,983
2026	6,867
Thereafter	44,360
Total undiscounted minimum lease payments	73,394
Less: Imputed interest	(27,736)
Total operating lease liability	\$ 45,658

Prior to January 1, 2022, the Company accounted for its leases in accordance with ASC Topic 840, *Leases*. As of December 31, 2021, the Company was committed under operating leases for its corporate offices. The future minimum lease payments under non-cancelable operating leases as of December 31, 2021 were as follows:

2022	\$	3,160
2023		8,353
2024		8,583
2025		8,820
2026		7,298
Thereafter		44,360
Total future minimum lease payments	\$	80,574

7. Common stock

The Company's board of directors approved a one-for-3.5305 reverse stock split of its issued and outstanding common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company's preferred stock effective as of June 17, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

On September 30, 2022, the Company sold 1,638,226 shares of common stock in an at-the-market (ATM) offering for aggregate gross proceeds of \$13.9 million, or aggregate net proceeds of \$13.2 million after deducting underwriting discounts and commissions and other offering costs. The proceeds from the ATM offering were receivable as of September 30, 2022. On October 5, 2022, the transaction was settled and the cash proceeds net of underwriting costs were received.

The Company had 500,000,000 shares of common stock authorized, of which 48,528,247 shares were issued and 48,372,781 shares were outstanding as of September 30, 2022.

The holders of common stock are entitled to dividends when and if declared by the board of directors. The board of directors has not declared any dividends and the Company has not paid any dividends.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders.

The Company has issued restricted stock to founders, employees and consultants, and expense for this restricted stock is recognized on a straight-line basis (see Note 8). The restricted stock generally vests monthly over 4 years.

As of September 30, 2022, and December 31, 2021, the Company has reserved the following shares of common stock for the vesting of restricted stock and exercise of stock options:

	September 30, 2022	December 31, 2021
Options to purchase common stock	7,207,043	5,563,513
Unvested restricted common stock awards	155,466	258,329
Unvested restricted common stock units	91,000	—
	7,453,509	5,821,842

8. Stock-based compensation

2020 Stock incentive plan

The Company's 2020 Stock Option and Grant Plan, or the 2020 Plan, provided for the Company to grant stock options, restricted stock and other stock awards, to employees, non-employee directors, and consultants. Upon the effectiveness of the 2021 Plan (as defined below), no further issuances will be made under the 2020 Plan.

2021 Stock incentive plan

The Company's 2021 Stock Option and Incentive Plan, or the 2021 Plan, was approved by the Company's board of directors on May 28, 2021 and the Company's stockholders on June 17, 2021 and became effective on the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. The 2021 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2021 Plan is 4,903,145.

As of December 31, 2021, 3,658,193 shares of common stock were available for issuance under 2021 Plan. As of September 30, 2022, 4,055,464 shares were available for issuance under the 2021 Plan. Under the evergreen provision of the 2021 plan, each January 1 commencing in 2022 and thereafter automatically increases shares available for

issuance by 5% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number of shares as may be determined by the Company's compensation, nomination and corporate governance committee.

2021 Employee stock purchase plan

The Company's 2021 Employee Stock Purchase Plan, or the 2021 ESPP, was approved by the Company's board of directors on May 28, 2021 and the Company's stockholders on June 17, 2021 and became effective on the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. A total of 439,849 shares of the Company's common stock were initially reserved for issuance under the 2021 ESPP, which will be automatically increased on January 1, 2022 and will continue to increase each January 1 thereafter through January 1, 2031, by the least of (i) 439,849 shares of the Company's common stock, (ii) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, 2020 or (iii) such lesser number of shares of the Company's common stock as determined by the plan administrator of the 2021 ESPP.

As of December 31, 2021 439,849 shares of common stock remained available for issuance under the 2021 ESPP. Effective January 1, 2022 the number of shares available under the 2021 ESPP automatically increased by 439,849 shares pursuant to the evergreen provision of the 2021 ESPP. As of September 30, 2022, 879,698 shares were available for issuance under the 2021 ESPP.

Stock option activity

The following summarizes stock option activity:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding—December 31, 2021	5,563,513	\$ 7.92	9.2	\$ 70,045
Granted	1,954,775	12.76	—	—
Exercised	(95,726)	3.42	—	—
Forfeited	(215,519)	12.41	—	—
Outstanding—September 30, 2022	7,207,043	\$ 9.16	8.7	\$ 14,897
Exercisable—September 30, 2022	2,033,754	\$ 7.04	8.4	\$ 6,378

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock.

Restricted stock award activity

The following summarizes restricted stock award activity:

	Number of shares	Weighted average grant date fair value
Unvested as of December 31, 2021	258,329	\$ 0.90
Vested	(102,863)	\$ 0.77
Unvested as of September 30, 2022	155,466	\$ 0.98

The aggregate fair value of restricted stock awards that vested during the nine months ended September 30, 2022 was \$1.2 million. The aggregate fair value of restricted stock that vested during the nine months ended September 30, 2021 was \$0.2 million. The weighted average grant date fair value of restricted stock that vested during the nine months ended September 30, 2022 was \$0.77.

Restricted stock unit activity

The following summarizes restricted stock unit activity:

	Number of shares	Weighted average grant date fair value
Unvested as of December 31, 2021	—	\$ —
Granted	91,000	\$ 10.11
Unvested as of September 30, 2022	91,000	\$ 10.11

The weighted average grant date fair value of restricted stock granted during the nine months ended September 30, 2022 was \$10.11.

Stock-based compensation expense

Stock-based compensation expense is classified as follows (in thousands):

	Nine months ended September 30,			
	2022		2021	
Research and development	\$	4,289	\$	1,559
General and administrative		4,049		1,785
Total stock-based compensation expense	\$	8,338	\$	3,344

As of September 30, 2022 total unrecognized stock-based compensation cost related to unvested stock options, restricted stock awards, and restricted stock units was \$32.6 million, \$0.2 million, and \$0.8 million, respectively. The Company expects to recognize this remaining cost over a weighted average period of 2.7 years, 1.2 years, and 1.8 years, respectively.

9. Income taxes

The Company did not record a provision or benefit for income taxes during the nine months ended September 30, 2022 and 2021. The Company continues to maintain a full valuation allowance against all of its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize our deferred tax assets. The Company has considered its history of cumulative net losses incurred since inception and its lack of any commercial products. The Company has concluded that it is more likely than not that it will not realize the benefits of its deferred tax assets. The Company reevaluates the positive and negative evidence at each reporting period.

10. Net loss per common share

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net loss	\$ (27,318)	\$ (19,837)	\$ (77,719)	\$ (50,518)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.58)	\$ (0.43)	\$ (1.67)	\$ (2.85)
Weighted-average number of common shares used in computing net loss per share—basic and diluted	46,732,353	45,987,866	46,666,000	17,751,410

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

	September 30, 2022	September 30, 2021
Stock options to purchase common stock	7,207,043	5,566,421
Restricted common stock	155,466	296,929
Restricted stock units	91,000	—

11. Related parties

Versant Venture Management, LLC or Versant Venture has been a related party since inception of the Company as an investor and member of the board of directors. The Company had a service agreement with a Versant Venture discovery engine, Ridgeline Discovery, or Ridgeline. Ridgeline provided management and administrative support to facilitate start-up of the Company and provided research and development services. Expenses attributable to Ridgeline were recognized primarily in research and development expenses in the Company's condensed consolidated statements of operations and comprehensive loss. The Company paid \$0.5 million and \$7.8 million to Ridgeline during the three and nine month periods ended September 30, 2021, respectively. The consulting agreement with Ridgeline expired December 31, 2021. Transactions with Versant Venture and Ridgeline for the three and nine month periods ended September 30, 2022, were immaterial.

12. Employee retirement plans

The Company, in compliance with Swiss Law, is contracted with the Swiss Life Collective BVG Foundation for the provision of pension benefits in a defined benefit plan. All benefits are reinsured in their entirety with Swiss Life Ltd within the framework of the contract. The technical administration and management of the savings account are guaranteed by Swiss Life on behalf of the collective foundation. Insurance benefits due are paid directly to the entitled persons by Swiss Life in the name of and for the account of the collective foundation. The pension plan is financed by contributions of both employees and employer. The contract between the Company and the collective foundation can be terminated by either side. In the event of a termination, the Company would have an obligation to find alternative pension arrangements for its employees. Because there is no guarantee that the employee pension arrangements would be continued under the same conditions, there is a risk, albeit remote, that a pension obligation may fall on the Company. The pension assets are pooled for all affiliated companies; the investment of assets is done by the governing bodies of the collective foundation or by mandated parties. The risks of disability, death and longevity are reinsured in their entirety with Swiss Life Ltd. The Company recorded \$0.2 million and \$0.1 million defined benefit related expense during the three months ended September 30, 2022 and 2021, respectively. The Company recorded \$0.6 million and \$0.3 million defined benefit related expense during the nine months ended September 30, 2022 and 2021, respectively.

In February 2021, the Company adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible U.S. based employees of the Company. All employees are eligible to become participants of the plan immediately upon hire. Each active employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right, but is not obligated, to make additional contributions to this plan. The Company makes safe-harbor match contributions of 100% of the first 4% of each participant's eligible compensation. The Company recorded \$0.1 million and \$0.1 million matching 401(k) contribution related expense during the three months ended September 30, 2022 and 2021, respectively. The Company recorded \$0.4 million and \$0.2 million matching 401(k) contribution related expense during the nine months ended September 30, 2022 and 2021, respectively.

Item 2. Management's discussion and analysis of financial condition and results of operations

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in "Part I, Item 1A, Risk Factors" in our 2021 Annual Report and under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special note regarding forward-looking statements."

Overview

We are a biotechnology company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. We have developed a proprietary protein degradation platform, called QuEEN™, that enables us to rapidly identify protein targets and molecular glue degrader, or MGD, product candidates that are designed to eliminate therapeutically-relevant proteins in a highly selective manner. We believe our small molecule MGDs may give us significant advantages over existing therapeutic modalities, including other protein degradation approaches, by allowing us to target proteins that have been considered undruggable or inadequately drugged. We focus on therapeutic targets backed by strong biological and genetic rationale with the goal of discovering and developing novel precision medicines.

Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated under the laws of Switzerland in April 2018. Monte Rosa Therapeutics, Inc was incorporated in Delaware in November 2019. In 2020, Monte Rosa Therapeutics, Inc. and Monte Rosa Therapeutics AG, entities under common control since the incorporation of Monte Rosa Therapeutics, Inc., consummated a contribution and exchange agreement, or the Contribution and Exchange, whereby Monte Rosa Therapeutics, Inc. acquired the net assets and shareholdings of Monte Rosa Therapeutics AG via a one-for-one exchange of equity between Monte Rosa Therapeutics, Inc. and the shareholders of Monte Rosa Therapeutics AG in a common control reorganization. We are headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland. To date, we have been financed primarily through the issuance of convertible promissory notes, convertible preferred stock and, common stock in our initial public offering, or IPO.

Liquidity

Since inception, we have had significant operating losses. 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. To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and our convertible preferred stock to outside investors in private equity financings, as well as our initial public offering. From our inception through the date hereof, we raised an aggregate of \$493 million of gross proceeds from such transactions. Since inception, we have had significant operating losses. 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. Our net loss was \$74 million and \$35.9 million for the years ended December 31, 2021 and 2020, respectively, and our net loss was \$77.7 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of \$199.8 million and \$277.4 million in cash, cash equivalents, restricted cash and marketable securities.

Business effects of COVID-19

The ongoing COVID-19 pandemic has presented a substantial public health and economic challenge around the world with continuing impact on our employees our employees, potential patients, communities and business operations, as well as the U.S. economy and financial markets. To date, our financial conditions and operations have not been significantly impacted by the ongoing COVID-19 pandemic; however, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, liquidity and financial condition will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the emergence of variants, the actions taken to contain it or treat its impact, including vaccination efforts, and the economic impact on local, regional, national and international markets.

To date, our vendors have been able to continue to provide services and supply reagents, materials, and products and currently do not anticipate any material disruption in services or interruptions in supply. However, we are continuously assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, and our ability to hire and retain employees.

The COVID-19 pandemic has caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to partial remote work, and cancelling physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients and business partners.

We continue to monitor COVID-19 levels local to our research operations and adapt our employee working practices to ensure essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories.

For additional information on the various risks posed by the COVID-19 pandemic, please read the section entitled "Risk factors" in this Quarterly Report and Part I, Item 1A; Risk Factors" included in our 2021 Annual Report.

Components of operating results

Research and development expenses

Our research and development expenses include:

- expenses incurred under agreements with consultants, third-party service providers that conduct research and development activities on our behalf;
- personnel costs, which include salaries, benefits, pension and stock-based compensation;
- laboratory and vendor expenses related to the execution of preclinical studies;
- laboratory supplies and materials used for internal research and development activities; and
- facilities and equipment costs.

Most of our research and development expenses have been related to the development of our QuEEN™ platform and advancement of our GSPT1 program, advancement of our disclosed and undisclosed programs including for CDK2, NEK7, VAV1, and multiple sickle cell disease (SCD) targets. We have not reported program costs since our inception because we have not historically tracked or recorded our research and development expenses on a program-by-program basis. We use our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

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

We 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 manufacturing, as we advance our programs and conduct clinical trials. 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. As a result, we are unable to determine the duration and completion costs of our research and development projects, the costs of related clinical development costs or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses

Our general and administrative expenses consist primarily of personnel costs and other expenses for outside professional services, including legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and other operating costs. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, and the potential commercialization of our product candidates and development of commercial infrastructure. We also anticipate our general and administrative costs will increase and with respect to the hiring of additional personnel, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC reporting requirements, insurance and investor relations costs.

Non-operating income and (expense)

Our non-operating income and (expense) includes (i) interest earned on our investments, including marketable securities and U.S. government-backed money-market funds and marketable securities; (ii) gains and losses on transactions of our Swiss subsidiary denominated in currencies other than the U.S. Dollar; and (iii) proceeds from the sale of lab equipment.

Results of operations for the three months ended September 30, 2022 and 2021

The following sets forth our results of operations:

(in thousands)	Three months ended September 30,		
	2022	2021	Dollar change
Operating expenses:			
Research and development	\$ 21,342	\$ 15,115	\$ 6,227
General and administrative	7,020	4,753	2,267
Total operating expenses	28,362	19,868	8,494
Loss from operations	(28,362)	(19,868)	(8,494)
Other expense	1,044	31	1,013
Net loss	\$ (27,318)	\$ (19,837)	\$ (7,481)

Research and development expenses

Research and development expenses were comprised of:

(in thousands)	Three months ended September 30,		
	2022	2021	Dollar change
External research and development services	\$ 8,557	\$ 6,449	\$ 2,108
Personnel costs	6,868	5,392	1,476
Laboratory and related expenses	1,778	1,586	192
Facility costs and other expenses	4,139	1,688	2,451
Research and development expenses	\$ 21,342	\$ 15,115	\$ 6,227

As of September 30, 2022, we had 97 employees engaged in research and development activities in our facilities in the United States and Switzerland. As of September 30, 2021, we had 73 research and development employees in our facilities in the United States and Switzerland.

Most of our research and development expenses have been related to the development of our QUEEN™ platform, advancement of our GSPT1 program including IND-enabling work for MRT-2359, and the advancement of our disclosed and undisclosed programs including for CDK2, NEK7, VAV1, multiple SCD targets, and other discovery efforts. The increase for the three months ended September 30, 2022 as compared to 2021 was primarily due to the expansion of research and development activities in the United States and Switzerland including increased headcount and facilities, as well as corresponding increases in laboratory related expenses. Research and development expenses for the three months ended September 30, 2022 and 2021 included non-cash stock-based compensation expense of \$1.7 million and \$1.1 million, respectively.

General and administrative expenses

General and administrative expenses to support our business activities were comprised of:

(in thousands)	Three months ended September 30,		
	2022	2021	Dollar change
Personnel costs	\$ 3,770	\$ 2,750	\$ 1,020
Professional services	1,246	772	474
Facility costs and other expenses	2,004	1,231	773
General and administrative expenses	\$ 7,020	\$ 4,753	\$ 2,267

As of September 30, 2022 and September 30, 2021 we had 21 and 19 employees engaged in general and administrative activities, respectively, principally in our U.S. facility. Personnel and professional service costs increased in the three months ended September 30, 2022 as compared to 2021 due to an increase in stock compensation driven by the increase in our stock price. The increase in other expenses in the three months ended September 30, 2022 as compared to 2021 to support our growth and operations as a public company. General and administrative expenses for the three

months ended September 30, 2022 and 2021 included non-cash stock-based compensation expense of \$1.5 million and \$1.0 million, respectively.

Other income (expense)

Other income (expense), net was comprised of:

(in thousands)	Three months ended September 30,	
	2022	2021
Interest income, net	\$ 997	\$ 13
Foreign currency exchange gain (loss), net	63	18
Loss on disposal of fixed assets	(16)	—
Other income	\$ 1,044	\$ 31

The increase in interest and other income for the three months ended September 30, 2022 is principally attributable to interest income on marketable securities purchased in 2022.

Foreign exchange gains on transactions of our Swiss subsidiary denominated in currencies other than the U.S. dollar increased in the three months ended September 30, 2022 as compared to the three months ended September 30, 2021 principally due to the strengthening of the U.S. Dollar with respect to, principally, the Swiss franc.

Results of operations for the nine months ended September 30, 2022 and 2021

The following sets forth our results of operations:

(in thousands)	Nine months ended September 30,		Dollar change
	2022	2021	
Operating expenses:			
Research and development	\$ 60,193	\$ 39,025	\$ 21,168
General and administrative	19,702	10,470	9,232
Total operating expenses	79,895	49,495	30,400
Loss from operations	(79,895)	(49,495)	(30,400)
Other expense	2,176	(1,023)	3,199
Net loss	\$ (77,719)	\$ (50,518)	\$ (27,201)

Research and development expenses

Research and development expenses were comprised of:

(in thousands)	Nine months ended September 30,		Dollar change
	2022	2021	
External research and development services	\$ 24,778	\$ 18,436	\$ 6,342
Personnel costs	19,364	11,935	7,429
Laboratory and related expenses	5,507	4,144	1,363
Facility costs and other expenses	10,544	4,510	6,034
Research and development expenses	\$ 60,193	\$ 39,025	\$ 21,168

As of September 30, 2022, we had 97 employees engaged in research and development activities in our facilities in the United States and Switzerland. As of September 30, 2021, we had 73 employees engaged in research and development activities in our facilities in the United States and Switzerland.

Most of our research and development expenses have been related to the development of our QuEEN™ platform, advancement of our GSPT1 program including IND-enabling work for MRT-2359, and the advancement of our disclosed and undisclosed programs including for CDK2, NEK7, VAV1, multiple SCD targets, and other discovery efforts. The increase for the nine months ended September 30, 2022 as compared to 2021 was primarily due to the expansion of research and development activities in the United States and Switzerland including increased headcount and facilities, as well as corresponding increases in laboratory related expenses. Research and development expenses for the nine months ended September 30, 2022 and 2021 included non-cash stock-based compensation expense of \$4.3 million and \$1.6 million, respectively.

General and administrative expenses

General and administrative expenses to support our business activities were comprised of:

(in thousands)	Nine months ended September 30,			Dollar change
	2022	2021		
Personnel costs	\$ 10,819	\$ 6,414	\$ 4,405	
Professional services	3,616	1,960	1,656	
Facility costs and other expenses	5,267	2,096	3,171	
General and administrative expenses	\$ 19,702	\$ 10,470	\$ 9,232	

As of September 30, 2022 and September 30, 2021 we had 21 and 19 employees engaged in general and administrative activities, respectively, principally in our U.S. facility. Personnel and professional service costs increased in the nine months ended September 30, 2022 as compared to 2021 due to an increase in stock compensation driven by the increase in our stock price. The increase in other expense in the nine months ended September 30, 2022 as compared to 2021 to support our growth and operations as a public company. General and administrative expenses for the nine months ended September 30, 2022 and 2021 included non-cash stock-based compensation expense of \$4.0 million and \$1.8 million, respectively.

Other income (expense)

Other income (expense), net was comprised of:

(in thousands)	Nine months ended September 30,		
	2022	2021	
Interest income, net	\$ 1,774	\$ 33	\$ 1,741
Foreign currency exchange gain (loss), net	293	(96)	389
Gain on disposal of fixed assets	109	—	109
Changes in fair value of preferred stock tranche obligations, net	—	(960)	960
Other income (expense)	\$ 2,176	\$ (1,023)	\$ 3,199

The increase in interest and other income for the nine months ended September 30, 2022 is principally attributable to interest income on marketable securities purchased in 2022.

Foreign exchange gains on transactions of our Swiss subsidiary denominated in currencies other than the U.S. dollar increased in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 principally due to the strengthening of the U.S. Dollar with respect to, principally, the Swiss franc.

Liquidity and capital resources

Overview

We were incorporated in November 2019 in Delaware and our operations to date have been financed primarily through the issuance of convertible promissory notes, convertible preferred stock and, most recently, common stock in our IPO. As of September 30, 2022, we had \$277.4 million in cash, cash equivalents, restricted cash and marketable securities. We have incurred losses since our inception and, as of September 30, 2022, we had an accumulated deficit of \$199.8 million. 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:

(in thousands)	Nine months ended September 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (68,505)	\$ (45,191)
Investing activities	(165,280)	(6,606)
Financing activities	32	377,697
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (233,753)	\$ 325,900

Operating activities

Net cash used in operating activities of \$68.5 million during the nine months ended September 30, 2022, was attributable to our net loss of \$77.7 million and a net decrease in our working capital of \$4.2 million, offset by non-cash charges of \$13.4 million principally with respect to noncash lease expense, depreciation expense and stock-based compensation.

Net cash used in operating activities of \$45.2 million during the nine months ended September 30, 2021, was attributable to our net loss of \$50.5 million and a net decrease in our working capital of \$0.3 million, offset by non-cash charges of \$5.6 million principally with respect to changes in fair value of our preferred stock tranche obligation, depreciation expense and stock-based compensation.

Investing activities

Cash used in investing activities of \$165.3 million during the nine months ended September 30, 2022, was primarily attributable to purchases of marketable securities of \$290 million and purchases of property and equipment of \$5.6 million, offset by proceeds from the maturity of marketable securities of \$130.3 million.

For the six months ended September 30, 2021, our investing activities consisted of purchases of property and equipment of \$6.6 million, as we expanded our operations.

Financing activities

On September 30, 2022, the Company sold 1,638,226 shares of common stock in an at-the-market (ATM) offering for aggregate gross proceeds of \$13.9 million, or aggregate net proceeds of \$13.2 million after deducting underwriting discounts and commissions and other offering costs. The proceeds from the ATM offering were receivable as of September 30, 2022. On October 5, 2022, the transaction was settled and the cash proceeds net of underwriting costs were received.

Net cash provided by financing activities for the nine months ended September 30, 2021, amounted to \$377.7 million comprised principally of aggregate net proceeds upon the issuance of our Series B and Series C convertible preferred stock in February and March 2021 and the issuance of common stock in our IPO in June 2021.

Funding requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, costs relating to the build-out of our headquarters, laboratories and manufacturing facility, license payments or milestone obligations that may arise, laboratory and 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 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We base 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 do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. 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 scope, progress, results and costs of researching, developing and manufacturing our current product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our lead product candidate or any future product candidates and any products we successfully commercialize, including costs associated with building-out our manufacturing capabilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the timing, receipt and amount of sales of any future approved or cleared products, if any; and
- the impact of the COVID-19 pandemic and the corresponding responses of businesses and governments.

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. We currently have no credit facility or committed sources of capital. 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 unaudited interim condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our unaudited interim condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. However, even though we believe we have used reasonable estimates and assumptions in preparing our interim condensed consolidated financial statements, the future effects of the COVID-19 pandemic on our results of operations, cash flows, and financial position are unclear. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting policies from those described in "Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2021 Annual Report.

For a complete discussion of our significant accounting policies and recent accounting pronouncements, see Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report and Note 2 to our 2021 Annual Report.

Recently issued and adopted accounting pronouncements

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

Contractual obligations and commitments

During the nine months ended September 30, 2022, there have been no material changes to our contractual obligations and commitments from those described under "Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 29, 2022.

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

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. However, we may early adopt these standards.

We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the closing of our IPO, (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large, accelerated filer under the rules of the SEC.

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

Item 3. Quantitative and qualitative disclosures about market risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this Item 3.

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 defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective for the reasons set forth below.

Material weaknesses were identified in our internal controls of December 31, 2020, which have not been remediated as of September 30, 2022. The material weaknesses we identified were (i) we did not maintain an effective control environment as we did not maintain a sufficient complement of accounting and financial reporting resources commensurate with our financial reporting requirements, (ii) we did not maintain an effective risk assessment process, which led to improperly designed controls, (iii) we did not maintain appropriate control activities to support the appropriate segregation of duties over the review of account reconciliations and manual journal entries, and (iv) we did not document, thoroughly communicate and monitor controls processes and relevant accounting policies and procedures. These material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Remediation Plan

We are committed and are taking steps necessary to remediate the control deficiencies that constituted the above material weakness by implementing changes to our internal control over financial reporting. During the last quarter of 2020 and through September 30, 2022, we made the following enhancements to our control environment including the following:

- We added qualified finance personnel to the organization to strengthen our internal accounting team including a corporate controller and senior manager of financial reporting as well as additional qualified accounting and finance personnel who provide additional expertise and help maintain appropriate segregation of duties;
- We engaged accounting advisory consultants to provide additional depth and breadth in our technical accounting and financial reporting capabilities;
- We implemented a new ERP system which will provide a stronger internal control infrastructure for financial reporting and for our internal control procedures;
- We established a disclosure committee, ongoing senior management review, and audit committee oversight;
- We engaged internal control consultants to assist us in performing a financial reporting risk assessment as well as identifying and designing our system of internal controls necessary to mitigate the risks identified; and
- We began designing and implementing controls to mitigate control gaps in our internal control processes

Our remediation activities are continuing in 2022. In addition to the above activities, we expect to engage in additional activities including:

- Define user roles within our ERP system to ensure proper segregation of duties within our accounting systems;
- Documenting the remaining controls needed to mitigate the risks identified in our comprehensive risk assessment of our financial reporting processes; and

- Perform routine testing of the operating effectiveness of the identified controls over financial reporting including general IT controls.

Changes in Internal Control over Financial Reporting

Except for the remediation efforts of the previously identified material weakness as described above, there was no change in our internal control over financial reporting that occurred during the three months ended September 30, 2022 that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Part II – Other Information

Item 1. Legal proceedings

From time to time, we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of September 30, 2022, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, those risks and uncertainties discussed in “Part I, Item 1A, Risk Factors” in our 2021 Annual Report together with all of the other information contained in this Quarterly Report, including our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report. The risk factor disclosure in our 2021 Annual Report is qualified by the information that is described in this Quarterly Report. If any of the risks described below or in our 2021 Annual Report actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Other than as set forth below, there have been no material changes to the risk factors set forth in our 2021 Annual Report.

Risks related to our financial position and capital needs

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Since our inception, we have focused substantially all of our efforts and financial resources on developing our proprietary QuEEN™ platform, and our initial pipeline. To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and our convertible preferred stock to outside investors in private equity financings, as well as our initial public offering. From our inception through the date hereof, we raised an aggregate of \$493 million of gross proceeds from such transactions. As of September 30, 2022, our cash, cash equivalents, restricted cash and marketable securities were \$277.4 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of \$199.8 million as of September 30, 2022. For the years ended December 31, 2021 and 2020, we reported net losses of \$74 million and \$35.9 million, respectively. For the nine months ended September 30, 2022, we reported a net loss of \$77.7 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and initial pipeline programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ deficit and working capital. We expect our expenses to significantly increase in connection with our ongoing activities, as we:

- initiate and progress our planned clinical trial for MRT-2359 for the treatment of Myc-driven and other selected solid tumors in the fourth quarter of 2022;
- continue preclinical activities for our initial GSPT1, NEK7, CDK2, VAV1 and BCL11A programs;
- prepare and submit IND applications with the FDA for other current and future product candidates;
- complete preclinical studies for current or future product candidates;
- progress MGD molecules from our initial programs through lead optimization to development candidates;
- initiate and complete clinical trials for current or future product candidates;
- expand and improve the capabilities of our QuEEN™ platform;
- contract to manufacture our product candidates;
- advance research and development related activities to expand our product pipeline;

- seek regulatory approval for our product candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and future clinical trials for our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel; and
- secure facilities to support continued growth in our research, development and commercialization efforts.

In addition, if we obtain marketing approval for our current or future product candidates, we will incur significant expenses relating to sales, marketing, product manufacturing and distribution. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, including in light of the ongoing evolution of the COVID-19 pandemic, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Even if we achieve profitability, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Item 2. Unregistered sales of equity securities and use of proceeds

Recent sales of unregistered equity securities

None.

Use of proceeds from initial public offering of common stock

On June 28, 2021, we completed the IPO of our common stock pursuant to which we issued and sold 11,700,000 shares of our common stock at a public offering price of \$19.00 per share. On July 23, 2021, the underwriters exercised their option to purchase additional shares in full and we issued 1,755,000 shares of our common stock at the price of \$19.00 per share.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-256773), which was declared effective by the SEC on June 23, 2021. J.P. Morgan Securities LLC, Cowen and Company, LLC, Piper Sandler & Co. and Guggenheim Securities, LLC acted as underwriters for the IPO.

We received aggregate gross proceeds from our IPO of \$255.6 million, or aggregate net proceeds of \$234.6 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus dated June 25, 2021.

Item 3. Defaults upon senior securities

None.

Item 4. Mine safety disclosures

Not Applicable.

Item 6. Exhibits

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because 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.

** Deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

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.

Monte Rosa Therapeutics, Inc.

Date: November 10, 2022

By: _____
/s/ Markus Warmuth
Markus Warmuth
Chief Executive Officer

Date: November 10, 2022

By: _____
/s/ Ajim Tamboli
Ajim Tamboli
Chief Financial Officer

**CERTIFICATION 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**

I, Ajim Tamboli, certify that:

1. I have reviewed this Quarterly Report of Form 10-Q for the period ending September 30, 2022 of Monte Rosa Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: _____
Ajim Tamboli
Chief Financial Officer

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

In connection with the Quarterly Report of Monte Rosa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report 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 result of operations of the Company.

Date: November 10, 2022

By: _____
Markus Warmuth
Chief Executive Officer

Date: November 10, 2022

By: _____
Ajim Tamboli
Chief Financial Officer
