

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

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: 001-36112

MACROGENICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

9704 Medical Center Drive
Rockville, Maryland
(Address of principal executive offices)

06-1591613

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

20850
(Zip code)

301-251-5172

(Registrant's telephone number, including area code)

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 \$0.01 per share | MGNX | 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 and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

| | | | |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input checked="" type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input 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 October 31, 2022, 61,475,221 shares of the registrant's common stock, par value \$0.01 per share, were outstanding.

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FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs and other information that is not historical information. Many of these statements appear, in particular, under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report on Form 10-Q. Forward-looking statements can often be identified by the use of terminology such as "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. The following uncertainties and factors, among others (including those set forth under "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2021 and "Part II, Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q), could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
 - our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales and the availability of financing to fund the development of our product candidates;
 - our plans to develop and commercialize our product candidates;
 - the outcomes of our ongoing and planned clinical trials and the timing of those outcomes, including when clinical trials will be initiated or completed, and when data will be reported or regulatory filings will be made;
 - the timing of and our ability to obtain and maintain regulatory approvals for our product candidates and the labeling for any approved products;
 - our ability to realize expected cost savings from our restructuring plan;
 - our expectations regarding commercial prospects of or product revenues from MARGENZA and our product candidates if approved;
 - the severity and duration of the impact of the COVID-19 global pandemic, geopolitical tensions, and macroeconomic conditions on our business, operations, clinical programs, manufacturing, financial results and other aspects of our business;
 - our expectations regarding product candidates currently being developed by our collaborators;
 - our ability to enter into new collaborations or to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives;
 - the potential benefits and future operation of our existing collaborations;
 - our ability to recover the investment in our manufacturing capabilities;
 - the rate and degree of market acceptance and clinical utility of our products;
 - our commercialization, marketing and manufacturing capabilities and strategy;
 - significant competition in our industry;
 - costs of litigation and the failure to successfully defend lawsuits and other claims against us and our expectations regarding the outcome of any regulatory or legal proceedings;
 - economic, political and other risks associated with our international operations;
 - our ability to receive research funding and achieve anticipated milestones under our collaborations;
 - our ability to protect and enforce patents and other intellectual property;
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- costs of compliance and our failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;
- loss or retirement of key members of management;
- failure to successfully execute our growth strategy, including any delays in our planned future growth; and
- our failure to maintain effective internal controls.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

MACROGENICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

| | <u>September 30, 2022</u> | <u>December 31, 2021</u> |
|---|---------------------------|--------------------------|
| | <u>(unaudited)</u> | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 83,993 | \$ 123,469 |
| Marketable securities | 39,623 | 120,147 |
| Accounts receivable | 13,837 | 10,386 |
| Inventory, net | 1,086 | 4,388 |
| Prepaid expenses and other current assets | 9,273 | 21,170 |
| Total current assets | <u>147,812</u> | <u>279,560</u> |
| Property, equipment and software, net | 31,993 | 37,676 |
| Other non current assets | 15,542 | 18,009 |
| Total assets | <u>\$ 195,347</u> | <u>\$ 335,245</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,619 | \$ 15,500 |
| Accrued expenses and other current liabilities | 33,321 | 33,755 |
| Deferred revenue | 7,085 | 20,646 |
| Lease liabilities | 5,021 | 4,677 |
| Total current liabilities | <u>50,046</u> | <u>74,578</u> |
| Deferred revenue, net of current portion | 5,084 | — |
| Lease liabilities, net of current portion | 17,001 | 20,791 |
| Other non current liabilities | 258 | 258 |
| Total liabilities | <u>72,389</u> | <u>95,627</u> |
| Stockholders' equity: | | |
| Common stock, \$0.01 par value -- 125,000,000 shares authorized, 61,462,189 and 61,307,428 shares outstanding at September 30, 2022 and December 31, 2021, respectively | 615 | 613 |
| Additional paid-in capital | 1,228,952 | 1,213,002 |
| Accumulated other comprehensive loss | (113) | (61) |
| Accumulated deficit | (1,106,496) | (973,936) |
| Total stockholders' equity | <u>122,958</u> | <u>239,618</u> |
| Total liabilities and stockholders' equity | <u>\$ 195,347</u> | <u>\$ 335,245</u> |

See notes to consolidated financial statements.

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|----------------------------------|--------------------|---------------------------------|---------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Revenues: | | | | |
| Collaborative and other agreements | \$ 35,674 | \$ 11,986 | \$ 59,630 | \$ 54,338 |
| Product sales, net | 4,371 | 3,591 | 12,623 | 7,681 |
| Contract manufacturing | 1,142 | — | 5,134 | — |
| Government agreements | 547 | 85 | 1,455 | 1,281 |
| Total revenues | 41,734 | 15,662 | 78,842 | 63,300 |
| Costs and expenses: | | | | |
| Cost of product sales | 3,007 | 1,665 | 3,235 | 1,704 |
| Cost of manufacturing services | 136 | — | 2,358 | — |
| Research and development | 48,191 | 49,823 | 161,373 | 158,724 |
| Selling, general and administrative | 15,355 | 17,161 | 45,277 | 47,431 |
| Total costs and expenses | 66,689 | 68,649 | 212,243 | 207,859 |
| Loss from operations | (24,955) | (52,987) | (133,401) | (144,559) |
| Other income | 142 | 101 | 841 | 466 |
| Net loss | (24,813) | (52,886) | (132,560) | (144,093) |
| Other comprehensive loss: | | | | |
| Unrealized gain (loss) on investments | 213 | (4) | (52) | 4 |
| Comprehensive loss | \$ (24,600) | \$ (52,890) | \$ (132,612) | \$ (144,089) |
| Basic and diluted net loss per common share | \$ (0.40) | \$ (0.86) | \$ (2.16) | \$ (2.42) |
| Basic and diluted weighted average common shares outstanding | 61,459,831 | 61,169,754 | 61,390,143 | 59,494,836 |

See notes to consolidated financial statements.

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share amounts)

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--------------------------------|--------------|--------|----------------------------------|------------------------|--|----------------------------------|
| | Shares | Amount | | | | |
| Balance, December 31, 2021 | 61,307,428 | \$ 613 | \$ 1,213,002 | \$ (973,936) | \$ (61) | \$ 239,618 |
| Share-based compensation | — | — | 5,224 | — | — | 5,224 |
| Stock plan related activity | 25,646 | — | 37 | — | — | 37 |
| Unrealized loss on investments | — | — | — | — | (222) | (222) |
| Net loss | — | — | — | (66,443) | — | (66,443) |
| Balance, March 31, 2022 | 61,333,074 | 613 | 1,218,263 | (1,040,379) | (283) | 178,214 |
| Share-based compensation | — | — | 5,350 | — | — | 5,350 |
| Stock plan related activity | 125,716 | 2 | 262 | — | — | 264 |
| Unrealized loss on investments | — | — | — | — | (43) | (43) |
| Net loss | — | — | — | (41,304) | — | (41,304) |
| Balance, June 30, 2022 | 61,458,790 | 615 | 1,223,875 | (1,081,683) | (326) | 142,481 |
| Share-based compensation | — | — | 5,077 | — | — | 5,077 |
| Stock plan related activity | 3,399 | — | — | — | — | — |
| Unrealized gain on investments | — | — | — | — | 213 | 213 |
| Net loss | — | — | — | (24,813) | — | (24,813) |
| Balance, September 30, 2022 | 61,462,189 | \$ 615 | \$ 1,228,952 | \$ (1,106,496) | \$ (113) | \$ 122,958 |

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|--------------|--------|----------------------------------|------------------------|--|----------------------------------|
| | Shares | Amount | | | | |
| Balance, December 31, 2020 | 56,244,771 | \$ 562 | \$ 1,067,150 | \$ (771,821) | \$ (7) | \$ 295,884 |
| Share-based compensation | — | — | 5,243 | — | — | 5,243 |
| Issuance of common stock, net of offering costs | 3,622,186 | 36 | 98,164 | — | — | 98,200 |
| Stock plan related activity | 144,249 | 2 | 2,456 | — | — | 2,458 |
| Unrealized gain on investments | — | — | — | — | 18 | 18 |
| Net loss | — | — | — | (51,272) | — | (51,272) |
| Balance, March 31, 2021 | 60,011,206 | 600 | 1,173,013 | (823,093) | 11 | 350,531 |
| Share-based compensation | — | — | 6,113 | — | — | 6,113 |
| Stock plan related activity | 122,241 | 1 | 2,345 | — | — | 2,346 |
| Unrealized loss on investments | — | — | — | — | (10) | (10) |
| Net loss | — | — | — | (39,935) | — | (39,935) |
| Balance, June 30, 2021 | 60,133,447 | 601 | 1,181,471 | (863,028) | 1 | 319,045 |
| Share-based compensation | — | — | 6,309 | — | — | 6,309 |
| Issuance of common stock, net of offering costs | 958,467 | 10 | 19,630 | — | — | 19,640 |
| Stock plan related activity | 162,779 | 2 | (668) | — | — | (666) |
| Unrealized loss on investments | — | — | — | — | (4) | (4) |
| Net loss | — | — | — | (52,886) | — | (52,886) |
| Balance, September 30, 2021 | 61,254,693 | \$ 613 | \$ 1,206,742 | \$ (915,914) | \$ (3) | \$ 291,438 |

See notes to consolidated financial statements.

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

| | Nine Months Ended September 30, | |
|---|--|-------------------|
| | 2022 | 2021 |
| Cash flows from operating activities | | |
| Net loss | \$ (132,560) | \$ (144,093) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 8,634 | 8,306 |
| Amortization of premiums and discounts on marketable securities | 740 | 1,267 |
| Stock-based compensation | 15,697 | 17,714 |
| Other non-cash items | 2,882 | 1,602 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (3,452) | 9,322 |
| Inventory | 419 | (5,582) |
| Prepaid expenses and other current assets | 11,898 | (1,080) |
| Other non current assets | 2,468 | 5,146 |
| Accounts payable | (10,897) | (1,931) |
| Accrued expenses and other current liabilities | (184) | 7,744 |
| Lease liabilities | (3,447) | (2,701) |
| Deferred revenue | (8,477) | 14,507 |
| Other non current liabilities | — | 258 |
| Net cash used in operating activities | <u>(116,279)</u> | <u>(89,521)</u> |
| Cash flows from investing activities | | |
| Purchases of marketable securities | (75,457) | (164,780) |
| Proceeds from sale and maturities of marketable securities | 155,190 | 146,550 |
| Purchases of property, equipment and software | (3,230) | (4,826) |
| Net cash provided by (used in) investing activities | <u>76,503</u> | <u>(23,056)</u> |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock, net of offering costs | — | 117,818 |
| Proceeds from stock option exercises and ESPP Purchases | 314 | 5,722 |
| Taxes paid related to net share settlement of equity awards | (14) | (1,563) |
| Net cash provided by financing activities | <u>300</u> | <u>121,977</u> |
| Net change in cash and cash equivalents | (39,476) | 9,400 |
| Cash and cash equivalents at beginning of period | 123,469 | 181,131 |
| Cash and cash equivalents at end of period | <u>\$ 83,993</u> | <u>\$ 190,531</u> |
| Supplemental Cash Flow Information | | |
| Property, equipment and software included in accounts payable or accruals | <u>\$ 295</u> | <u>\$ 69</u> |

See notes to consolidated financial statements.

MACROGENICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Nature of Operations

Description of the business

MacroGenics, Inc. (the Company) is incorporated in the state of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics designed to modulate the human immune response for the treatment of cancer. The Company has a pipeline of product candidates being evaluated in clinical trials sponsored by the Company or its collaborators. These product candidates include multiple immuno-oncology programs, some of which were created primarily using the Company's proprietary, antibody-based technology platforms. The Company believes its product candidates have the potential, if approved for marketing by regulatory authorities, to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents. In March 2021, the Company and its commercialization partner commenced U.S. marketing of MARGENZA[®] (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Liquidity

The Company's multiple product candidates currently under development will require significant additional research and development efforts that include extensive preclinical studies and clinical testing, and regulatory approval prior to commercial use.

The future success of the Company is dependent on its ability to identify and develop its product candidates, and ultimately upon its ability to attain profitable operations. The Company has devoted substantially all of its financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital, and accordingly, its ability to execute its future operating plans.

As a biotechnology company, the Company has primarily funded its operations with proceeds from the sale of its common stock in equity offerings, revenue from its multiple collaboration agreements, and contracts from the National Institute of Allergy and Infectious Diseases (NIAID). Management regularly reviews the Company's available liquidity relative to its operating budget and forecast to monitor the sufficiency of the Company's working capital. The Company plans to meet its future operating requirements by generating revenue from current and future strategic collaborations or other arrangements, and product sales. The Company anticipates continuing to draw upon available sources of capital, including equity and debt instruments, to support its product development activities. If the Company is unable to enter into new arrangements or to perform under current or future agreements or obtain additional capital, the Company will assess its capital resources and may be required to delay, reduce the scope of, or eliminate one or more of its product research and development programs or clinical studies, reduce other operating expenses, and/or downsize its organization. It is considered probable that the Company can successfully implement efforts to manage uncommitted spending and carry out necessary cost saving measures, including from the Company's corporate restructuring plan announced in August 2022. Therefore, based on the Company's most recent cash flow forecast, the Company believes its current resources are sufficient to fund its operating plans for a minimum of twelve months from the date that this Quarterly Report on Form 10-Q was filed.

Similar to the other risk factors pertinent to the Company's business, the COVID-19 pandemic and geopolitical tensions, including the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, and related global slowdown of economic activity, decades-high inflation, rising interest rates and a potential recession in the United States might unfavorably impact the Company's ability to generate such additional funding. Given the uncertainty in the rapidly changing market and economic conditions related to these uncertainties, the Company will continue to evaluate the nature and extent of the impact of these uncertainties on its business and financial position.

Basis of Presentation

The accompanying unaudited interim consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of the Company believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

The accompanying unaudited interim consolidated financial statements include the accounts of MacroGenics, Inc. and its wholly owned subsidiaries, MacroGenics UK Limited and MacroGenics Limited. All intercompany accounts and transactions have been eliminated in consolidation. These consolidated financial statements and related notes should be read in conjunction with the financial statements and notes thereto included in the Company's 2021 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 24, 2022.

2. Summary of Significant Accounting Policies

During the nine months ended September 30, 2022, there have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Recent Accounting Pronouncements

There were no new accounting pronouncements that were issued or became effective since the issuance of the Company's 2021 Annual Report on Form 10-K that had, or are expected to have, a material impact on its consolidated financial position, results of operations or cash flows.

3. Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses. The carrying amount of accounts receivable, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of their short-term nature. The Company accounts for recurring and non-recurring fair value measurements in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures* (ASC 820). ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820 hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1 - Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.
- Level 2 - Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.
- Level 3 - Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity - e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC 820 hierarchy. There were no transfers between levels during the periods presented.

Financial assets measured at fair value on a recurring basis were as follows (in thousands):

| | Fair Value Measurements at September 30, 2022 | | |
|--|---|-------------------|-----------------|
| | Total | Level 1 | Level 2 |
| Assets: | | | |
| Money market funds | \$ 71,398 | \$ 71,398 | \$ — |
| U.S. Treasury securities | 33,163 | 33,163 | — |
| Corporate debt securities | 6,460 | — | 6,460 |
| Total assets measured at fair value ^(a) | <u>\$ 111,021</u> | <u>\$ 104,561</u> | <u>\$ 6,460</u> |

| | Fair Value Measurements at December 31, 2021 | | |
|--|--|------------------|------------------|
| | Total | Level 1 | Level 2 |
| Assets: | | | |
| Money market funds | \$ 17,202 | \$ 17,202 | \$ — |
| U.S. Treasury securities | 81,132 | 81,132 | — |
| Government-sponsored enterprises | 7,734 | — | 7,734 |
| Corporate debt securities | 37,280 | — | 37,280 |
| Total assets measured at fair value ^(b) | <u>\$ 143,348</u> | <u>\$ 98,334</u> | <u>\$ 45,014</u> |

(a) Total assets measured at fair value at September 30, 2022 includes approximately \$71.4 million reported in cash and cash equivalents on the consolidated balance sheet.

(b) Total assets measured at fair value at December 31, 2021 includes approximately \$23.2 million reported in cash and cash equivalents on the consolidated balance sheet.

4. Marketable Securities

The following tables summarize the Company's marketable debt securities (in thousands):

| | September 30, 2022 | | | |
|---------------------------|--------------------|------------------------|-------------------------|------------------|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| U.S. Treasury securities | \$ 33,257 | \$ — | \$ (94) | \$ 33,163 |
| Corporate debt securities | 6,479 | — | (19) | 6,460 |
| Total | <u>\$ 39,736</u> | <u>\$ —</u> | <u>\$ (113)</u> | <u>\$ 39,623</u> |

| | December 31, 2021 | | | |
|----------------------------------|-------------------|------------------------|-------------------------|-------------------|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| U.S. Treasury securities | \$ 81,184 | \$ — | \$ (52) | \$ 81,132 |
| Government-sponsored enterprises | 7,739 | — | (5) | 7,734 |
| Corporate debt securities | 31,285 | — | (4) | 31,281 |
| Total | <u>\$ 120,208</u> | <u>\$ —</u> | <u>\$ (61)</u> | <u>\$ 120,147</u> |

All available-for-sale marketable debt securities held as of September 30, 2022 and December 31, 2021 had contractual maturities of less than one year. All of the Company's available-for-sale marketable debt securities in an unrealized loss position as of September 30, 2022 and December 31, 2021 were in a loss position for less than twelve months. Unrealized losses on available-for-sale debt securities as of September 30, 2022 and December 31, 2021 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, no allowance for credit losses related to the Company's available-for-sale debt securities was

recorded for any periods presented. The Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

5. Inventory, Net

All of the Company's inventory relates to the manufacturing of MARGENZA. The following table sets forth the Company's net inventory (in thousands):

| | September 30, 2022 | December 31, 2021 |
|----------------------|--------------------|-------------------|
| Work in process | \$ 209 | \$ 3,929 |
| Finished goods | 877 | 459 |
| Total inventory, net | <u>\$ 1,086</u> | <u>\$ 4,388</u> |

Prior to U.S. Food and Drug Administration (FDA) approval of MARGENZA in December 2020, the cost of materials and expenses associated with the manufacturing of MARGENZA were recorded as research and development expense. Subsequent to FDA approval, the Company began capitalizing inventory costs related to the manufacture of MARGENZA. The inventory balance as of September 30, 2022 and December 31, 2021 is net of a reserve of \$4.9 million and \$2.0 million, respectively, for unsaleable inventory. These reserves are reflected in cost of product sales during the period they are recorded.

6. Stockholders' Equity

In November 2020, the Company entered into a sales agreement (Sales Agreement) with an agent to sell, from time to time, shares of its common stock having an aggregate sales price of up to \$100.0 million through an "at the market offering" (ATM Offering) as defined in Rule 415 under the Securities Act of 1933, as amended. The shares that were sold under the Sales Agreement were issued and sold pursuant to the Company's shelf registration statement on Form S-3 that was filed with the SEC on November 4, 2020. During the nine months ended September 30, 2021, the Company sold 3,622,186 shares of common stock at a weighted average price per share of \$27.60, resulting in net proceeds of approximately \$98.2 million, net of underwriting discounts and commissions and other offering expenses.

In April 2021, the Company entered into Amendment No. 1 to the Sales Agreement which increased the amount of the Company's common stock that can be sold by the Company through its agent under the ATM Offering, from an aggregate offering price of up to \$100.0 million to an aggregate offering price of up to \$300.0 million. The Company has not sold any shares of common stock related to Amendment No. 1 to the Sales Agreement as of September 30, 2022.

As part of the consideration for the rights granted to Zai Lab US LLC under the collaboration and license agreement described more fully in Note 7, Revenue, the Company and Zai Lab US LLC entered into a separate stock purchase agreement (Stock Purchase Agreement) in June 2021. Under this Stock Purchase Agreement, Zai Lab US LLC paid the Company approximately \$30.0 million to purchase 958,467 newly issued shares of the Company's common stock, par value \$0.01, at a fixed price of \$31.30 which represented a \$10.4 million premium over the share price on the Stock Purchase Agreement date.

7. Revenue

Collaborative and Other Agreements

Incyte Corporation

Incyte License Agreement

In 2017, the Company entered into an exclusive global collaboration and license agreement with Incyte Corporation (Incyte), which was amended in March 2018, April 2022 and July 2022, for retifanlimab, an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1) (Incyte License Agreement). Incyte has obtained exclusive worldwide rights for the development and commercialization of retifanlimab in all indications, while the Company retains the right to develop its pipeline assets in combination with retifanlimab. Under the terms of the Incyte License Agreement, Incyte paid the Company an upfront payment of \$150.0 million in 2017. In July 2021, Incyte announced that the FDA had issued a Complete Response Letter (CRL) regarding its Biologics License Application (BLA) for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal. Incyte's announcement indicated that the FDA determined that additional data are needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte was reviewing the CRL and would discuss next steps with the FDA. Incyte subsequently

withdrew its European application for marketing authorization of retifanlimab for the treatment of squamous carcinoma of the anal canal. Incyte has stated it is pursuing development of retifanlimab in potentially registration-enabling studies beyond squamous cell carcinoma of the anal canal, including in patients with MSI-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer. Incyte is also pursuing development of retifanlimab in combination with multiple product candidates from its pipeline. In April 2022, the Company and Incyte executed an amendment to the Incyte License Agreement to add a milestone for U.S. approval of retifanlimab in a specific indication and to exclude certain other regulatory and development achievements with retifanlimab in this same indication from the milestone events of the Incyte License Agreement. In July 2022, the Company and Incyte further amended the Incyte License Agreement to reflect changes related to the payment of certain milestones and Incyte paid the Company \$30.0 million in milestone payments, which the Company recognized as revenue during the three months ended September 30, 2022.

Under the terms of the Incyte License Agreement, as amended, Incyte will lead global development of retifanlimab. Assuming successful development and commercialization by Incyte, the Company could receive up to \$435.0 million in development and regulatory milestones and up to \$330.0 million in commercial milestones. From the inception of the Incyte License Agreement through September 30, 2022, the Company has recognized \$100.0 million in development milestones under the Incyte License Agreement. If retifanlimab is approved and commercialized, the Company would be eligible to receive tiered royalties of 15% to 24% on any global net sales. The Company retains the right to develop its pipeline assets in combination with retifanlimab, with Incyte commercializing retifanlimab and the Company commercializing its asset(s), if any such potential combinations are approved. In addition, the Company retains the right to manufacture a portion of both companies' global commercial supply needs of retifanlimab, subject to the separate commercial supply agreement.

The Company evaluated the Incyte License Agreement under the provisions of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606) at inception and identified the following two performance obligations under the agreement: (i) the license of retifanlimab and (ii) the performance of certain clinical activities through a brief technology transfer period. The Company determined that the license and clinical activities are separate performance obligations because they are capable of being distinct and are distinct in the context of the contract. The license has standalone functionality as it is sublicensable, Incyte has significant capabilities in performing clinical trials, and Incyte is capable of performing these activities without the Company's involvement; the Company performed the activities during the transfer period as a matter of convenience. The Company determined that the transaction price of the Incyte License Agreement at inception was \$154.0 million, consisting of the consideration to which the Company was entitled in exchange for the license and an estimate of the consideration for clinical activities to be performed. The transaction price was allocated to each performance obligation based on their relative standalone selling price. The standalone selling price of the license was determined using the adjusted market assessment approach considering similar collaboration and license agreements. The standalone selling price for the agreed-upon clinical activities to be performed was determined using the expected cost approach based on similar arrangements the Company has with other parties. The potential development and regulatory milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, as they were determined to relate predominantly to the license granted to Incyte and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur. From 2018 through September 30, 2022, it became probable that a significant reversal of cumulative revenue would not occur for development milestones totaling \$100.0 million related to clinical and regulatory activities related to the further advancement of retifanlimab, including Incyte's initiation of a Phase 3 clinical trial. Therefore, the associated consideration was added to the estimated transaction price and was recognized as revenue.

The Company recognized the \$150.0 million allocated to the license when it satisfied its performance obligation and transferred the license to Incyte in 2017. The \$4.0 million allocated to the clinical activities was recognized ratably as services were performed during 2017 and 2018. The Company recognized \$30.0 million in revenue under the Incyte License Agreement during the three and nine months ended September 30, 2022. No revenue was recognized under the Incyte License Agreement during the three months ended September 30, 2021. During the nine months ended September 30, 2021, \$15.0 million in milestone revenue was recognized under the Incyte License Agreement.

Incyte Clinical Supply Agreement

In 2018, the Company entered into an agreement with Incyte, under which the Company is to perform development and manufacturing services for Incyte's clinical needs of retifanlimab (Incyte Clinical Supply Agreement). The Company evaluated the Incyte Clinical Supply Agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to the development and manufacturing of the clinical supply of retifanlimab. The

transaction price is based on the costs incurred to develop and manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price is being recognized using the input method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing services. During the three months ended September 30, 2022 and 2021, the Company recognized revenue of \$0.1 million and \$0.2 million, respectively, for services performed under the Incyte Clinical Supply Agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized revenue of \$0.6 million and \$1.0 million, respectively, for services performed under the Incyte Clinical Supply Agreement.

Incyte Commercial Supply Agreement

In 2020, the Company entered into an agreement with Incyte pursuant to which the Company is entitled to manufacture a portion of the global commercial supply needs for retifanlimab (Incyte Commercial Supply Agreement). Unless terminated earlier, the term of the Incyte Commercial Supply Agreement will expire upon the expiration of Incyte's obligation to pay royalties under the Incyte License Agreement. The Company evaluated the Incyte Commercial Supply Agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to manufacturing the commercial supply of retifanlimab. The transaction price is based on a fixed price per batch of bulk drug substance to be manufactured and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price is being recognized using the input method reflecting the costs incurred (including resources consumed and labor costs incurred) related to the manufacturing services. During the three months ended September 30, 2022 and 2021, the Company recognized de minimis revenue and \$1.4 million, respectively, for services performed under the Incyte Commercial Supply Agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized \$0.3 million and \$7.4 million, respectively, for services performed under the Incyte Commercial Supply Agreement.

Zai Lab Limited

2018 Zai Lab Agreement

In 2018, the Company entered into a collaboration and license agreement with Zai Lab Limited (Zai Lab) under which Zai Lab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (Zai Lab's territory) for (i) margetuximab, an immune-optimized anti-HER2 monoclonal antibody, (ii) tebotelimab, a bispecific DART® molecule designed to provide coordinate blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies, and (iii) an undisclosed multi-specific TRIDENT molecule in preclinical development (2018 Zai Lab Agreement). Zai Lab will lead clinical development of these molecules in its territory. Zai Lab has informed the Company that they have decided to discontinue development of tebotelimab for indications they were enrolling in their territory and is evaluating future development plans in other indications.

Under the terms of the 2018 Zai Lab Agreement, Zai Lab paid the Company an upfront payment of \$25.0 million (\$22.5 million after netting value-added tax withholdings of \$2.5 million). Assuming successful development and commercialization of margetuximab, tebotelimab and the TRIDENT molecule, the Company could receive up to \$140.0 million in development and regulatory milestones, of which the Company has earned \$9.0 million through September 30, 2022. In addition, Zai Lab would pay the Company tiered royalties at percentage rates of mid-teens to 20% for net sales of margetuximab in Zai Lab's territory, mid-teens for net sales of tebotelimab in Zai Lab's territory and 10% for net sales of the TRIDENT molecule in Zai Lab's territory, which may be subject to adjustment in specified circumstances.

The Company evaluated the 2018 Zai Lab Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement for each of the two product candidates, margetuximab and tebotelimab: (i) an exclusive license to develop and commercialize the product candidate in Zai Lab's territory and (ii) certain research and development activities. The Company determined that each license and the related research and development activities were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that these promises should be combined into a single performance obligation for each product candidate. Activities related to margetuximab and tebotelimab are separate performance obligations from each other because they are capable of being distinct, and are distinct in the context of the contract. The Company evaluated the promises related to the TRIDENT molecule and determined they were immaterial in context of the contract, therefore there is no performance obligation related to that molecule. The Company determined that the net \$22.5 million upfront payment from Zai Lab constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, and the transaction price was allocated to the two performance obligations based on their relative standalone selling price. The standalone selling price of the performance obligations was determined using the adjusted market assessment approach considering similar collaboration and license agreements. The potential development and regulatory milestone payments are

fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Zai Lab and, therefore, have also been excluded from the transaction price.

The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur. From 2020 through September 30, 2022, it became probable that a significant reversal of cumulative revenue would not occur for development and regulatory milestones totaling \$9.0 million. Therefore, the associated consideration, \$8.1 million net of value-added tax withholdings, was added to the estimated transaction price and was recognized as revenue. During the three months ended September 30, 2022, no revenue was recognized, and during the nine months ended September 30, 2022, the Company recognized \$4.9 million under the 2018 Zai Lab Agreement. No revenue was recognized during the three and nine months ended September 30, 2021 under the 2018 Zai Lab Agreement.

Zai Lab Clinical Supply Agreements

During 2019, the Company entered into two agreements under which the Company is to perform manufacturing services for Zai Lab's clinical needs of margetuximab and tebotelimab (Zai Lab Clinical Supply Agreements). The Company evaluated the agreements under ASC 606 and determined that they should be accounted for as a single contract and identified two performance obligations within that contract: to perform services related to manufacturing the clinical supply of each of margetuximab and tebotelimab. The transaction price is based on the costs incurred to manufacture drug product and drug substance and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price is being recognized using the input method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing service. No revenue was recognized during the three months ended September 30, 2022, and \$0.6 million was recognized related to the Zai Lab Clinical Supply Agreements during the three months ended September 30, 2021. During the nine months ended September 30, 2022 and 2021, the Company recognized revenue of \$0.3 million and \$2.3 million, respectively, related to the Zai Lab Clinical Supply Agreements.

2021 Zai Lab Agreement

In June 2021, the Company entered into a collaboration and license agreement with Zai Lab US LLC (collectively with Zai Lab Limited referred herein as Zai Lab) involving collaboration programs and license-only programs (collectively, the Programs) encompassing four separate immuno-oncology molecules (2021 Zai Lab Agreement). The first program covers a lead research molecule that incorporates the Company's DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors (Lead Program). The second program covers a target to be designated by the Company. For these programs, Zai Lab receives commercial rights in Greater China, Japan, and Korea while the Company receives commercial rights in all other territories. Zai Lab also obtained exclusive, global licenses from the Company to develop, manufacture and commercialize two additional molecules. Zai Lab granted the Company a worldwide, royalty-free, co-exclusive license to conduct the development activities allocated to the Company. In August 2022, the Company and Zai Lab agreed to discontinue research and development of the Lead Program.

Under the terms of the 2021 Zai Lab Agreement, the Lead Program included joint research and development services by both the Company and Zai Lab. For the other programs, Zai Lab can separately negotiate and agree with the Company to perform research and development services in the future.

In connection with the execution of the 2021 Zai Lab Agreement, Zai Lab paid the Company an upfront payment of \$25.0 million. Additionally, as part of the consideration for the rights granted to Zai Lab under the 2021 Zai Lab Agreement, the Company and Zai Lab entered into the Stock Purchase Agreement whereby Zai Lab paid the Company approximately \$30.0 million to purchase shares of the Company's common stock, par value \$0.01, at a fixed price of \$31.30 which represented a \$10.4 million premium over the share price on the Stock Purchase Agreement date.

Assuming successful development and commercialization of the remaining Programs, the Company could receive up to approximately \$680.0 million in development and regulatory milestones and \$600.0 million in commercial milestones. In addition, Zai Lab would pay the Company tiered royalties at percentage rates of mid-single digits to low double digit teens on annual net sales of products in Zai Lab's territory, which may be subject to specified royalty reduction pursuant to the 2021 Zai Lab Agreement. Per the terms of the 2021 Zai Lab Agreement, the Company may also receive reimbursements from Zai Lab for certain research and development costs incurred by the Company.

The Company evaluated the 2021 Zai Lab Agreement under the provisions of ASC 606 and identified the following material promises: (i) exclusive licenses to develop, manufacture and commercialize the products in Zai Lab's territory for each Program and (ii) certain research and development activities for the Lead Program. The Company determined that for the Lead Program, the license is not distinct from the related research and development activities, considering the early stage of development of the molecule and the Company's significant expertise in this area and as such, the research and development services are expected to significantly modify and customize the license. Therefore, for the Lead Program, the license and the services were combined into a single performance obligation. Since the other programs each represent distinct intellectual property and there are no other services included in the 2021 Zai Lab Agreement related to these licenses, each license is considered to be a distinct performance obligation. As such, there are four performance obligations included in the 2021 Zai Lab Agreement.

The Company concluded that the estimated transaction price is \$40.4 million, consisting of the \$25.0 million upfront payment, the \$10.4 million premium related to the purchase of the Company's common stock, and the \$5.0 million estimated reimbursement by Zai Lab for research and development activities for the Lead Program. The potential milestone payments were deemed to be fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Zai Lab and, therefore, have also been excluded from the transaction price. The Company will re-assess the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

The transaction price of \$40.4 million was then allocated to the four performance obligations based on their relative standalone selling price. The standalone selling price of the performance obligations was not directly observable; therefore, the Company estimated the standalone selling price using an adjusted market assessment approach, representing the amount that the Company believes a market participant is willing to pay for the product or service. The estimate was based on consideration of observable inputs, such as values of other preclinical collaboration arrangements adjusted for the Company's estimate of the probability of success for each Program.

Revenue related to the Lead Program license and related research and development services performance obligation was recognized over time as the research and development activities were performed. The Company utilized a cost-based input method according to costs incurred to date compared to estimated total costs. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligations. The Company recognized revenue allocated to the other programs at a point in time upon transfer of the licenses to Zai Lab in June 2021. During the three months ended September 30, 2022 and 2021, the Company recognized revenue of \$1.8 million and \$3.7 million, respectively, under the 2021 Zai Lab Agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized revenue of \$16.8 million and \$18.1 million, respectively, under the 2021 Zai Lab Agreement. As of December 31, 2021, \$16.1 million in revenue was deferred, all of which was current. As of September 30, 2022 there is no revenue deferred under the 2021 Zai Lab Agreement.

Janssen Biotech, Inc.

In December 2020, the Company entered into a research collaboration and license agreement with Janssen Biotech, Inc. (Janssen) to develop a novel DART molecule (Janssen Agreement). The research collaboration will incorporate the Company's proprietary DART platform to enable simultaneous targeting of two undisclosed targets in a therapeutic area outside oncology. Under the terms of the Janssen Agreement, Janssen paid the Company an upfront payment of \$20.0 million and will be responsible for funding all research and development expenses. The Company will also be eligible to receive up to \$312.0 million in potential milestone payments and tiered royalties of up to 10% on worldwide product sales.

Subject to the terms of this agreement, the Company granted Janssen an exclusive, royalty-bearing license to develop, manufacture and commercialize the preclinical bispecific molecule and the Company will perform certain research and development activities during a specified research term. The Company evaluated the Janssen Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement: (i) a license to develop the preclinical bispecific molecule and (ii) performing certain research and development activities during the research term. The Company determined that the license and research and development activities are separate performance obligations because they are capable of being distinct, and are distinct in the context of the contract. The license has standalone functionality as Janssen could benefit from the license on its own without the Company's involvement during the research term. The Company determined that the transaction price of the Janssen Agreement at inception was \$22.2 million, consisting of the consideration to which the Company was entitled in exchange for the license and an estimate of the consideration for research and development activities to be performed. The transaction price was allocated to each performance obligation based on their relative standalone selling price. The standalone selling price of the license was determined using the adjusted market assessment approach

considering similar collaboration and license agreements as well as current market conditions. The standalone selling price for agreed-upon research and development activities to be performed was determined using the expected cost approach based on similar arrangements the Company has with other parties. This variable consideration is fully constrained until the Company begins its work under the performance obligation. The potential milestone payments are fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur, as they were determined to relate predominantly to the license granted to Janssen and, therefore, have also been excluded from the transaction price. The Company re-assesses the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

The Company recognized the \$20.0 million allocated to the license when it satisfied its performance obligation and transferred the license to Janssen in December 2020. The \$2.2 million allocated to the research and development activities is being recognized over the Company's involvement in the research term, which is estimated to be less than two years. During the three months ended September 30, 2022 and 2021, the Company recognized revenue of \$0.1 million and \$0.2 million, respectively, for research and development activities performed under the Janssen Agreement. During the nine months ended September 30, 2022, and 2021 the Company recognized revenue of \$0.7 million and \$1.1 million, respectively, for research and development activities performed under the Janssen Agreement.

I-Mab Biopharma

I-Mab License Agreement

In 2019, the Company entered into a collaboration and license agreement with I-Mab Biopharma (I-Mab) to develop and commercialize enoblituzumab, an immune-optimized, anti-B7-H3 monoclonal antibody that incorporates the Company's proprietary Fc Optimization technology platform (I-Mab License Agreement). I-Mab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (I-Mab's territory), will lead clinical development of enoblituzumab in its territories, and will participate in global studies conducted by the Company. In August 2022, I-Mab notified the Company of its intention to terminate the I-Mab License Agreement effective February 25, 2023.

Under the terms of the I-Mab License Agreement, I-Mab paid the Company an upfront payment of \$15.0 million, and \$5.0 million of milestone revenue has been earned from the inception of the I-Mab License Agreement through September 30, 2022.

The Company evaluated the I-Mab License Agreement under the provisions of ASC 606 and identified the following material promises under the arrangement: (i) an exclusive license to develop and commercialize enoblituzumab in I-Mab's territories, (ii) perform certain research and development activities and (iii) conduct a chronic toxicology study. The Company determined that the license and the related research and development activities were not distinct from one another, as the license has limited value without the performance of the research and development activities. As such, the Company determined that the license and related research and development activities should be combined into a single performance obligation. The Company determined that the \$15.0 million upfront payment from I-Mab constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement for the license and related research and development activities. The Company has also determined that the chronic toxicology study is distinct from the other promises and has estimated the variable consideration of that performance obligation to be approximately \$1.0 million. I-Mab paid the Company for the cost of this study as the costs were incurred and I-Mab received a one-time credit of eighty percent of the total amount of such costs against the milestone achieved during 2021. The Company reassessed the transaction price as it became probable that a significant reversal of cumulative revenue would not occur for a \$5.0 million milestone (\$4.5 million after netting a one-time credit as described above) related to development progress of enoblituzumab, therefore the associated consideration was added to the estimated transaction price and was recognized as revenue during 2021.

Revenue under the I-Mab License Agreement was recognized using a cost-based input method according to costs incurred to date compared to estimated total costs. The transfer of control occurs over this time period and, in management's judgment, was the best measure of progress towards satisfying the performance obligations. During the three months ended September 30, 2022 and 2021, the Company recognized revenue of \$3.8 million and \$5.5 million, respectively, under the I-Mab License Agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized revenue of \$4.5 million and \$7.9 million, respectively, under the I-Mab License Agreement. As of December 31, 2021, \$4.5 million in revenue was deferred under the I-Mab License Agreement, all of which was current. As of September 30, 2022 there is no revenue deferred under the I-Mab Agreement.

I-Mab Clinical Supply Agreement

In October 2021, the Company entered into an agreement under which the Company is to perform development and manufacturing services for I-Mab's clinical needs of enoblituzumab (I-Mab Clinical Supply Agreement). The Company evaluated this agreement under ASC 606 and identified one performance obligation under the agreement: to perform services related to the development and manufacturing of the clinical supply of enoblituzumab. The transaction price is based on the costs incurred to develop and manufacture drug product and drug substance, and is recognized over time as the services are provided, as the performance by the Company does not create an asset with an alternative use and the Company has an enforceable right to payment for the performance completed to date. The transaction price will be recognized using the input method reflecting the costs incurred (including resources consumed and labor hours expended) related to the manufacturing services. During the three and nine months ended September 30, 2022, the Company recognized revenue of \$0.3 million and \$1.5 million, respectively, for research and development activities performed under the I-Mab Clinical Supply Agreement.

Manufacturing Services Agreement

Incyte

In January 2022, the Company entered into a Manufacturing and Clinical Supply Agreement with Incyte (Incyte Manufacturing and Clinical Supply Agreement) to provide manufacturing services to produce certain Incyte bulk drug substance over a three-year period at one of the Company's manufacturing facilities. Under the terms of the Incyte Manufacturing and Clinical Supply Agreement, the Company received an upfront payment of \$10.0 million and is eligible to receive annual fixed payments paid quarterly over the term of the contract totaling \$14.4 million. The Company will also be reimbursed for materials used to manufacture product as well as other costs incurred to provide manufacturing services. In July 2022, the Company and Incyte executed an amendment to the Incyte Manufacturing and Clinical Supply Agreement which extended the term for one year and provided for an additional annual fixed payment of \$5.1 million (July 2022 Incyte Amendment).

The Company evaluated the Incyte Manufacturing and Clinical Supply Agreement and the July 2022 Incyte Amendment under the provisions of ASC 606 and identified one performance obligation to provide manufacturing runs to Incyte, as and when requested by Incyte, over the term of the contract that is part of a series of goods and services. The Company determined that the transaction price consists of the upfront payment received of \$10.0 million and the annual fixed payments totaling \$19.5 million. The Company will recognize revenue over time on a straight-line basis as the manufacturing services are provided to Incyte, as the Company determined that its efforts in providing the manufacturing services will be incurred evenly throughout the performance period and therefore straight-line revenue recognition closely approximates the level of effort for the manufacturing services. Variable consideration relating to the reimbursed materials and other reimbursed costs incurred to manufacture product for Incyte will be allocated to the related manufacturing activities and will be recognized as revenue as those activities occur. Materials purchased by the Company to manufacture the product for Incyte are considered costs to fulfill a contract and will be capitalized and expensed as the materials are used to provide the manufacturing services.

The Company recognized revenue of \$1.1 million and \$5.1 million under the Incyte Manufacturing and Clinical Supply Agreement during the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, \$9.5 million in revenue was deferred under this agreement, \$4.4 million of which was current and \$5.1 million of which was non-current.

Government Agreement

NIAID Contract

The Company entered into a contract with National Institute of Allergy and Infectious Diseases (NIAID), effective as of September 15, 2015, to perform product development and to advance up to two DART molecules, MGD014 and MGD020 (NIAID Contract). Under the NIAID Contract, the Company will develop these product candidates for Phase 1/2 clinical trials as therapeutic agents, in combination with latency reversing treatments, to deplete cells infected with human immunodeficiency virus (HIV) infection. NIAID does not receive goods or services from the Company under this contract, therefore the Company does not consider NIAID to be a customer and concluded this contract is outside the scope of ASC 606.

Since the inception of the NIAID Contract, NIAID has exercised the two options contemplated in the original contract and executed modifications such that the total funded contract value as of September 30, 2022 is \$25.1 million. In addition, the most recent modification changed the period of performance under the NIAID Contract to end in July 2023. During the three months ended September 30, 2022 and 2021, the Company recognized revenue under the NIAID Contract of \$0.5 million and \$0.1 million, respectively. During the nine months ended September 30, 2022 and 2021, the Company recognized revenue under the NIAID Contract of \$1.5 million and \$1.3 million, respectively.

8. Stock-Based Compensation

Employee Stock Purchase Plan

In May 2017, the Company's stockholders approved the 2016 Employee Stock Purchase Plan (the 2016 ESPP). The 2016 ESPP is structured as a qualified employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended (IRC), and is not subject to the provisions of the Employee Retirement Income Security Act of 1974. The Company reserved 800,000 shares of common stock for issuance under the 2016 ESPP. The 2016 ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 10% of their eligible compensation, subject to any plan limitations. The 2016 ESPP provides for six-month offering periods ending on May 31 and November 30 of each year. At the end of each offering period, employees are able to purchase shares at 85% of the fair market value of the Company's common stock on the last day of the offering period. During the nine months ended September 30, 2022, 65,125 shares of common stock were purchased under the 2016 ESPP.

Employee Stock Option Plans

Effective February 2003, the Company implemented the 2003 Equity Incentive Plan (2003 Plan), and it was amended and approved by the Company's stockholders in 2005. Stock options granted under the 2003 Plan may be either incentive stock options as defined by the IRC, or non-qualified stock options. In 2013, the 2003 Plan was terminated, and no further awards may be issued under the plan. Any shares of common stock subject to awards under the 2003 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised, or resulting in any common stock being issued, will become available for issuance under the 2013 Stock Incentive Plan (2013 Plan), up to a specified number of shares. As of September 30, 2022, under the 2003 Plan, there were options to purchase an aggregate of 103,040 shares of common stock outstanding.

In October 2013, the Company implemented the 2013 Plan. The 2013 Plan provides for the grant of stock options and other stock-based awards, as well as cash-based performance awards. The number of shares of common stock reserved for issuance under the 2013 Plan will automatically increase on January 1 of each year from January 1, 2014 through and including January 1, 2023, by the lesser of (a) 1,960,168 shares, (b) 4.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (c) the number of shares of common stock determined by the Company's Board of Directors. During the nine months ended September 30, 2022, the maximum number of shares of common stock authorized to be issued by the Company under the 2013 Plan was increased to 15,816,949. If an option expires or terminates for any reason without having been fully exercised, if any shares of restricted stock are forfeited, or if any award terminates, expires or is settled without all or a portion of the shares of common stock covered by the award being issued, such shares are available for the grant of additional awards. However, any shares that are withheld (or delivered) to pay withholding taxes or to pay the exercise price of an option are not available for the grant of additional awards. As of September 30, 2022, there were options to purchase an aggregate of 10,224,203 shares of common stock outstanding.

The following stock-based compensation expense was recognized for the periods indicated (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|-----------------|---------------------------------|------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | \$ 2,571 | \$ 3,109 | \$ 7,621 | \$ 8,894 |
| Selling, general and administrative | 2,552 | 3,249 | 8,076 | 8,820 |
| Total stock-based compensation expense | <u>\$ 5,123</u> | <u>\$ 6,358</u> | <u>\$ 15,697</u> | <u>\$ 17,714</u> |

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions in the following table for options issued during the period indicated:

| | Nine Months Ended September 30, | |
|-------------------------|---------------------------------|---------------|
| | 2022 | 2021 |
| Expected dividend yield | 0% | 0% |
| Expected volatility | 87.8% - 90.8% | 86.2% - 87.4% |
| Risk-free interest rate | 1.4% - 3.6% | 0.6% - 1.4% |
| Expected term | 5.95 years | 6.25 years |

The following table summarizes stock option activity during the nine months ended September 30, 2022:

| | Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (in thousands) |
|---------------------------------|------------|---------------------------------|---|--|
| Outstanding, December 31, 2021 | 8,373,921 | \$ 21.47 | 6.6 | |
| Granted | 2,730,597 | 9.40 | | |
| Exercised | (82,963) | 1.46 | | |
| Forfeited | (427,074) | 16.05 | | |
| Expired | (267,238) | 22.76 | | |
| Outstanding, September 30, 2022 | 10,327,243 | \$ 18.63 | 6.7 | \$ 124 |
| As of September 30, 2022: | | | | |
| Exercisable | 6,455,853 | \$ 21.77 | 5.5 | 96 |
| Vested and expected to vest | 9,622,594 | \$ 18.96 | 6.6 | 120 |

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2022 and 2021 was \$6.89 and \$15.21, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2022 and 2021 was approximately \$0.5 million and \$3.2 million, respectively. The total cash received for options exercised during the nine months ended September 30, 2022 and 2021 was \$0.3 million and \$5.4 million, respectively. The total fair value of shares vested in the nine months ended September 30, 2022 and 2021 was approximately \$15.1 million and \$14.8 million, respectively. As of September 30, 2022, the total unrecognized compensation expense related to unvested stock options, net of related forfeiture estimates, was approximately \$28.6 million, which the Company expects to recognize over a weighted-average period of approximately 1.4 years.

Restricted Stock Units

The Company grants restricted stock units (RSUs) under the 2013 Plan to employees from time to time as a component of their compensation. During the nine months ended September 30, 2022, the Company awarded RSUs to employees in conjunction with the annual performance review process. Each RSU vests over a two-year period and entitles the holder to receive one share of the Company's common stock when the RSU vests. Compensation expense is recognized on a straight-line basis over the vesting period.

The following table summarizes RSU activity during the nine months ended September 30, 2022:

| | Shares | Weighted-Average Grant Date Fair Value |
|---------------------------------|----------|--|
| Outstanding, December 31, 2021 | 21,500 | \$ 25.97 |
| Granted | 476,772 | 8.42 |
| Exercised | (10,445) | 25.65 |
| Forfeited | (41,000) | 10.15 |
| Outstanding, September 30, 2022 | 446,827 | 8.70 |

At September 30, 2022, there was \$2.6 million of total unrecognized compensation cost related to unvested RSUs, which the Company expects to recognize over a remaining weighted-average period of approximately 1.2 years.

9. Commitments and Contingencies

On September 13, 2019, a securities class action complaint was filed in the U.S. District Court for the District of Maryland (District Court) by Todd Hill naming the Company, its Chief Executive Officer, Dr. Koenig, and its Chief Financial Officer, Mr. Karrels, as defendants for allegedly making false and materially misleading statements regarding the Company's SOPHIA trial. On August 17, 2020, the Employees' Retirement System of the City of Baton Rouge and Parish of East Baton Rouge was appointed as Lead Plaintiff, and on October 16, 2020, the Lead Plaintiff filed an amended complaint. The amended complaint asserts a putative class period stemming from February 6, 2019 to June 4, 2019. The Company filed a Motion to Dismiss on November 30, 2020. On September 29, 2021, the District Court issued an Order dismissing the case, with prejudice. On October 28, 2021 the Lead Plaintiff filed a Notice of Appeal. The appeal is now pending in the Fourth Circuit. The

Company intends to vigorously defend against this action. However, the outcome of this legal proceeding is uncertain at this time and the Company cannot reasonably estimate a range of loss, if any. Accordingly, the Company has not accrued any liability associated with this action.

10 . Subsequent Events

On October 14, 2022, the Company and Gilead Sciences, Inc. (Gilead) entered into an exclusive option and collaboration agreement (Gilead Agreement) to develop MGD024, an investigational, bispecific antibody that binds CD123 and CD3 using the Company's DART platform, and up to two additional bispecific research programs. The agreement grants Gilead the option to license MGD024, a potential treatment for certain blood cancers, including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

As part of the Gilead Agreement, Gilead paid the Company an upfront payment of \$60.0 million and the Company will be eligible to receive up to \$1.7 billion in target nomination, option fees, and development, regulatory and commercial milestones. The Company will also be eligible to receive tiered, low double-digit royalties on worldwide net sales of MGD024 and a flat royalty on worldwide net sales of products resulting from two research programs.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations is based upon our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared by us in accordance with U.S. generally accepted accounting principles (GAAP), for interim periods and with Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended. This discussion and analysis should be read in conjunction with these unaudited consolidated financial statements and the notes thereto as well as in conjunction with our audited consolidated financial statements and related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics for the treatment of cancer. We have a pipeline of product candidates being evaluated in clinical trials sponsored by us or our collaborators. These product candidates include multiple immuno-oncology programs, some of which were created primarily using our proprietary, antibody-based technology platforms. We believe our product candidates have the potential, if approved for marketing by regulatory authorities, to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents. In March 2021, we and our commercialization partner commenced U.S. marketing of MARGENZA (margetuximab-cmkb), a human epidermal growth factor receptor 2 (HER2) receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

We commenced active operations in 2000, and have since devoted substantially all of our resources to staffing our company, developing our technology platforms, identifying potential product candidates, undertaking preclinical studies, conducting clinical trials, developing collaborations, business planning and raising capital. We only began generating revenues from the sale of products in 2021. We have financed our operations primarily through the public and private offerings of our securities, collaborations with other biopharmaceutical companies, and government grants and contracts. Although it is difficult to predict our funding requirements, we anticipate that our cash, cash equivalents and marketable securities as of September 30, 2022, combined with the \$60.0 million received from Gilead Sciences, Inc. (Gilead) under the option and collaboration agreement executed in October 2022, anticipated and potential collaboration payments, product revenues and savings from the execution of our corporate restructuring plan announced in August 2022, should enable us to fund our operations into mid-2024. Our expected funding requirements reflect anticipated expenditures related to the planned Phase 2 portion of the MGC018 clinical trial in metastatic castration-resistant prostate cancer (TAMARACK study), as well as our other clinical and preclinical studies currently ongoing.

Through September 30, 2022, we had an accumulated deficit of \$1.1 billion. We expect that over the next several years this deficit will increase as we continue to incur research and development expense in connection with our ongoing preclinical and clinical studies.

COVID-19 Pandemic

The COVID-19 pandemic, including the resulting adverse macroeconomic conditions, has negatively impacted the global economy, created significant financial market volatility, disrupted global supply chains, and resulted in a significant number of infections and deaths worldwide. In addition, several national, state and local governments have placed restrictions on people from gathering in groups or interacting within a certain physical distance.

To date, although there has been some negative impact on our business and operations, including, for example, slowed clinical trial enrollment, we have been able to mitigate against more severe impacts of the COVID-19 pandemic on our business and operations. However, the COVID-19 pandemic could have a more significant negative impact on our business in the future depending on the depth of the effects and the duration of the crisis. In response to the COVID-19 pandemic, we have been focused on keeping our employees safe, continuing patients on trials, and maintaining our manufacturing capabilities and research efforts. The COVID-19 pandemic and its variants continue to evolve and we continue to monitor our business very closely to try and mitigate any potential impacts. We expect the pandemic to continue to have some near-term impact on the initiation of new studies and on clinical trial enrollment. Significant delays in the timing of our clinical trials and in regulatory reviews could adversely affect our ability to commercialize the product candidates in our pipeline. We are classified as a government contractor and were required to comply with Executive Order 14042, which the federal government has indicated it is not currently enforcing. Should the federal government reinstate a vaccination requirement for contractors, we may be

required to implement an additional company-wide vaccination requirement for all employees, with certain exceptions. To date, we do not believe our 2021 vaccination requirement resulted in other than minimal workforce attrition nor did it result in material difficulty securing labor needs. If we reinstitute a vaccination or vaccination booster requirement, and associated attrition is significant, our business could be adversely affected.

Notwithstanding the foregoing, we cannot precisely predict the impact that the COVID-19 pandemic will have in the future due to numerous uncertainties, including the severity, duration and resurgences of the disease and new variants, actions that may be taken by governmental authorities, the impact to the business of potential variations or disruptions in our supply chain, and other factors identified in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021. Given these uncertainties, the COVID-19 pandemic could disrupt the business of certain of our collaborators and impact our business operations and our ability to execute on our associated business strategies and initiatives, and adversely impact our consolidated results of operations and/or our financial condition in the future. We will continue to closely monitor and evaluate the nature and extent of the impact of the COVID-19 pandemic to our business, consolidated results of operations, and financial condition.

Collaborations

Our approach is to develop product candidates either by ourselves or in collaboration with partners. Under our strategic collaborations to date, we have received significant non-dilutive funding and continue to have rights to additional funding upon completion of certain research, achievement of key product development milestones and royalties and other payments upon the commercial sale of products. Our current collaborations include the following:

- *Incyte*. In 2017, we entered into an exclusive global collaboration and license agreement with Incyte Corporation (Incyte) for retifanlimab, an investigational monoclonal antibody that inhibits programmed cell death protein 1 (PD-1) (Incyte License Agreement). Incyte has obtained exclusive worldwide rights for the development and commercialization of retifanlimab in all indications, while we retain the right to develop our pipeline assets in combination with retifanlimab. Incyte paid us an upfront payment of \$150.0 million under the terms of the agreement. In July 2021, Incyte announced that the U.S. Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL) regarding its Biologics License Application (BLA) for retifanlimab as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal. Incyte's announcement indicated that the FDA determined that additional data were needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte was reviewing the CRL and would discuss next steps with the FDA. Incyte subsequently withdrew its European application for marketing authorization of retifanlimab for the treatment of squamous carcinoma of the anal canal. Incyte has stated it is pursuing development of retifanlimab in potentially registration-enabling studies beyond squamous cell carcinoma of the anal canal, including in patients with MSI-high endometrial cancer, Merkel cell carcinoma and non-small cell lung cancer. Incyte is also pursuing development of retifanlimab in combination with multiple product candidates from its pipeline. In April 2022, we and Incyte executed an amendment to the Incyte License Agreement to add a milestone for U.S. approval of retifanlimab in a specific indication and to exclude certain other regulatory and development achievements with retifanlimab in this same indication from the milestone events of the Incyte License Agreement. In July 2022, we and Incyte further amended the Incyte License Agreement to reflect changes related to the payment of certain milestones and we received \$30.0 million in milestone payments from Incyte.

Under the terms of the Incyte License Agreement, as amended, Incyte leads global development of retifanlimab. Assuming successful development and commercialization of retifanlimab by Incyte, we could receive total development and regulatory milestones of up to approximately \$435.0 million and up to \$330.0 million in commercial milestones. We received \$100.0 million of the total development milestones through September 30, 2022. If retifanlimab is approved and commercialized, we would be eligible to receive tiered royalties of 15% to 24% on any global net sales and we have the option to co-promote retifanlimab with Incyte. We retain the right to develop our pipeline assets in combination with retifanlimab, with Incyte commercializing retifanlimab and us commercializing our asset(s), if any such potential combinations are approved. We also have an agreement with Incyte under which we are to perform development and manufacturing services for Incyte's clinical needs of retifanlimab (Incyte Clinical Supply Agreement) and another agreement under which we are entitled to manufacture a portion of Incyte's global commercial supply of retifanlimab (Incyte Commercial Supply Agreement).

In January 2022, we entered into a Manufacturing and Clinical Supply Agreement with Incyte (Incyte Manufacturing and Clinical Supply Agreement) to provide manufacturing services to produce certain Incyte bulk drug substance over a three-year period at one of our manufacturing facilities. Under the terms of the Incyte Manufacturing and Clinical Supply Agreement, we received an upfront payment of \$10.0 million and are eligible to receive annual fixed payments paid quarterly over the term of the contract totaling \$14.4 million. We will also be reimbursed for materials used to manufacture product as well as other costs incurred to provide manufacturing services. In July 2022, we and Incyte executed an amendment to the Incyte Manufacturing and Clinical Supply Agreement which extended the term for one year and provided for an additional annual fixed payment of \$5.1 million.

- *Zai Lab.* In 2018, we entered into a collaboration and license agreement with Zai Lab Limited (Zai Lab) under which Zai Lab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (Zai Lab's territory) for (i) margetuximab, an immune-optimized anti-HER2 monoclonal antibody, (ii) tebotelimab, a bispecific DART molecule designed to provide coordinate blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies, and (iii) an undisclosed multi-specific TRIDENT molecule in preclinical development (2018 Zai Lab Agreement). Zai Lab will lead clinical development in its territory. Zai Lab has informed us that they have decided to discontinue development of tebotelimab for indications they were enrolling in their territory and is evaluating future development plans in other indications.

Under the terms of the 2018 Zai Lab Agreement, Zai Lab paid us an upfront payment of \$25.0 million less foreign withholding tax of \$2.5 million. Assuming successful development and commercialization of margetuximab, tebotelimab and the TRIDENT molecule, we could receive up to \$140.0 million in development and regulatory milestones, of which we have already earned \$9.0 million. In addition, Zai Lab would pay us tiered royalties at percentage rates of mid-teens to 20% for net sales of margetuximab in Zai Lab's territory, mid-teens for net sales of tebotelimab in Zai Lab's territory and 10% for net sales of the TRIDENT molecule in Zai Lab's territory, which may be subject to adjustment in specified circumstances.

In 2019, we entered into two agreements under which we are to perform manufacturing services for Zai Lab's clinical needs of margetuximab and tebotelimab (Zai Lab Clinical Supply Agreements).

In June 2021, we entered into a collaboration and license agreement with Zai Lab US LLC (collectively with Zai Lab Limited referred herein as Zai Lab) involving collaboration programs and license-only programs (collectively, the Programs) encompassing four separate immunoncology molecules (2021 Zai Lab Agreement). The first program covers a lead research molecule that incorporates our DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors (Lead Program). The second program covers a target to be designated by us. For these programs, Zai Lab receives commercial rights in Greater China, Japan, and Korea while we receive commercial rights in all other territories. Zai Lab also obtained exclusive, global licenses from us to develop, manufacture and commercialize two additional molecules (license-only programs). Zai Lab granted us a worldwide, royalty-free, co-exclusive license to conduct the development activities allocated to us. In August 2022, we and Zai Lab agreed to discontinue research and development of the Lead Program.

Under the terms of the 2021 Zai Lab Agreement, the Lead Program included joint research and development services by both us and Zai Lab. For the other programs, Zai Lab can separately negotiate and agree with us to perform research and development services in the future.

In connection with the execution of the 2021 Zai Lab Agreement, Zai Lab paid us an upfront payment of \$25.0 million. Additionally, as part of the consideration for the rights granted to Zai Lab under the 2021 Zai Lab Agreement, we and Zai Lab entered into a separate stock purchase agreement (Stock Purchase Agreement) whereby Zai Lab paid us approximately \$30.0 million to purchase 958,467 newly issued shares of our common stock, par value \$0.01, at a fixed price of \$31.30 which represented a \$10.4 million premium over the share price on the Stock Purchase Agreement date.

Assuming successful development and commercialization of the remaining Programs under the 2021 Zai Lab Agreement, we could receive up to \$1.3 billion in development, regulatory and commercial milestones. In addition, Zai Lab would pay us tiered royalties at percentage rates of mid-single digits to low double digit teens on annual net sales of products in Zai Lab's territory, subject to specified royalty reduction pursuant to the 2021 Zai Lab Agreement. Per the terms of the 2021 Zai Lab Agreement, we may also receive reimbursements from Zai Lab for certain research and development costs incurred by us.

- *I-Mab Biopharma*. In 2019, we entered into a collaboration and license agreement with I-Mab Biopharma (I-Mab) to develop and commercialize enoblituzumab, an immune-optimized, anti-B7-H3 monoclonal antibody that incorporates our proprietary Fc Optimization technology platform (I-Mab License Agreement). I-Mab obtained regional development and commercialization rights in mainland China, Hong Kong, Macau and Taiwan (I-Mab's territory), will lead clinical development of enoblituzumab in its territories, and will participate in global studies conducted by us. In August 2022, I-Mab notified us of its intention to terminate the I-Mab License Agreement effective February 25, 2023.

Under the terms of the agreement, I-Mab paid us an upfront payment of \$15.0 million and \$5.0 million in milestone revenue has been earned from the inception of the I-Mab License Agreement through September 30, 2022.

In October 2021, we entered into an agreement under which we are to perform development and manufacturing services for I-Mab's clinical needs of enoblituzumab.

- *Janssen*. In December 2020, we entered into a research collaboration and global license agreement to develop a preclinical bispecific molecule with Janssen Biotech, Inc. (Janssen). The research collaboration will incorporate our proprietary DART platform to enable simultaneous targeting of two undisclosed targets in a therapeutic area outside oncology. Under the terms of the agreement, Janssen paid us an upfront payment of \$20.0 million and will be responsible for funding all expenses. We will also be eligible to receive up to \$312.0 million in potential milestone payments and tiered royalties of up to 10% on worldwide product sales.
- *Gilead*. On October 14, 2022, we and Gilead Sciences, Inc. (Gilead) entered into an exclusive option and collaboration agreement (Gilead Agreement) to develop MGD024, an investigational, bispecific antibody that binds CD123 and CD3 using our DART platform, and up to two additional bispecific research programs. The agreement grants Gilead the option to license MGD024, a potential treatment for certain blood cancers, including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). As part of the Gilead Agreement, Gilead paid us an upfront payment of \$60.0 million and we will be eligible to receive up to \$1.7 billion in target nomination, option fees, and development, regulatory and commercial milestones. We will also be eligible to receive tiered, low double-digit royalties on worldwide net sales of MGD024 and a flat royalty on worldwide net sales of products resulting from two research programs.

Critical Accounting Estimates

Our critical accounting estimates are policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. A summary of our critical accounting estimates is presented in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes with respect to our critical accounting estimates during the nine months ended September 30, 2022.

Results of Operations

Revenue

The following represents a comparison of our revenue for the three and nine months ended September 30, 2022 and 2021 (dollars in millions):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|------------------------------------|----------------------------------|---------|---------|-------|---------------------------------|---------|---------|------|
| | 2022 | 2021 | Change | % | 2022 | 2021 | Change | % |
| Collaborative and other agreements | \$ 35.7 | \$ 12.0 | \$ 23.7 | 198 % | \$ 59.6 | \$ 54.3 | \$ 5.3 | 10 % |
| Product sales, net | 4.4 | 3.6 | 0.8 | 22 % | 12.6 | 7.7 | 4.9 | 64 % |
| Contract manufacturing | 1.1 | — | 1.1 | N/A | 5.1 | — | 5.1 | N/A |
| Government agreements | 0.5 | 0.1 | 0.4 | 400 % | 1.5 | 1.3 | 0.2 | 15 % |
| Total revenue | \$ 41.7 | \$ 15.7 | \$ 26.0 | 166 % | \$ 78.8 | \$ 63.3 | \$ 15.5 | 24 % |

The increase in revenue of \$26.0 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was primarily due to:

- recognition of \$30.0 million in milestone payments under the Incyte License Agreement during the three months ended September 30, 2022; and
- \$1.1 million recognized under the Incyte Manufacturing and Clinical Supply Agreement.

These increases were partially offset by:

- a decrease of \$1.6 million in revenue recognized under the I-Mab License Agreement;
- a decrease of \$1.4 million in revenue recognized under the Incyte Commercial Supply Agreement due to timing of manufacturing activities; and
- a decrease of \$1.9 million in revenue recognized under the 2021 Zai Lab Agreement.

The increase in revenue of \$15.5 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was primarily due to:

- an increase of \$15.0 million in development milestones recognized under the Incyte License Agreement during the nine months ended September 30, 2022;
- recognition of a \$4.5 million milestone (after netting value-added tax withholding) under the 2018 Zai Lab Agreement during the nine months ended September 30, 2022;
- an increase of \$4.9 million in net product revenue from sales of MARGENZA; and
- \$5.1 million recognized under the Incyte Manufacturing and Clinical Supply Agreement.

These increases were partially offset by:

- a decrease of \$7.0 million in revenue recognized under the Incyte Commercial Supply Agreement due to timing of manufacturing activities;
- a decrease of \$3.4 million in revenue recognized under the I-Mab License Agreement;
- a decrease of \$1.9 million in revenue recognized under the Zai Lab Clinical Supply Agreements; and
- a decrease of \$1.3 million in revenue recognized under the 2021 Zai Lab Agreement.

Revenue from collaborative and other agreements may vary substantially from period to period depending on the progress made by our collaborators with their product candidates and the timing of milestones achieved under current agreements, and whether we enter into additional collaboration agreements.

Cost of Product Sales

Cost of product sales for all periods presented consists primarily of reserves for unsaleable externally-manufactured inventory, as well as product royalties and fill finish costs. Product sold during these periods consisted of drug product that was previously charged to research and development expense prior to FDA approval of MARGENZA, which favorably impacted our gross margin. We expect cost of product sales to continue to be positively impacted as we sell through this drug product.

Cost of Manufacturing Services

Cost of manufacturing services consists of the costs to provide manufacturing services to produce certain Incyte bulk drug substance under the Incyte Manufacturing and Clinical Supply Agreement. We entered into this agreement in January 2022, therefore there are no such costs during the three and nine months ended September 30, 2021.

Research and Development Expense

The following represents a comparison of our research and development expense for the three and nine months ended September 30, 2022 and 2021 (dollars in millions):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|--|----------------------------------|----------------|-----------------|-------------|---------------------------------|-----------------|---------------|------------|
| | 2022 | 2021 | Change | % | 2022 | 2021 | Change | % |
| MGC018 | \$ 10.1 | \$ 6.7 | \$ 3.4 | 51 % | \$ 37.6 | \$ 21.4 | \$ 16.2 | 76 % |
| Margetuximab | 6.9 | 7.1 | (0.2) | (3)% | 22.6 | 29.2 | (6.6) | (23)% |
| Lorigerlimab | 4.9 | 2.7 | 2.2 | 81 % | 14.6 | 8.5 | 6.1 | 72 % |
| Enoblituzumab | 3.7 | 4.3 | (0.6) | (14)% | 12.5 | 12.5 | — | — % |
| MGD024 | 2.1 | — | 2.1 | N/A | 6.1 | 2.4 | 3.7 | 154 % |
| Tebotelimab | 1.9 | 4.7 | (2.8) | (60)% | 9.3 | 15.4 | (6.1) | (40)% |
| DART molecules under HIV government contract | 1.8 | 0.8 | 1.0 | 125 % | 3.6 | 3.5 | 0.1 | 3 % |
| Flotetuzumab | 1.5 | 5.9 | (4.4) | (75)% | 10.8 | 23.6 | (12.8) | (54)% |
| IMGC936 | 1.4 | 2.4 | (1.0) | (42)% | 6.2 | 4.5 | 1.7 | 38 % |
| Retifanlimab | 0.2 | 5.2 | (5.0) | (96)% | 1.9 | 14.1 | (12.2) | (87)% |
| Other programs (a) | 13.7 | 10.0 | 3.7 | 37 % | 36.2 | 23.6 | 12.6 | 53 % |
| Total research and development expense | <u>\$ 48.2</u> | <u>\$ 49.8</u> | <u>\$ (1.6)</u> | <u>(3)%</u> | <u>\$ 161.4</u> | <u>\$ 158.7</u> | <u>\$ 2.7</u> | <u>2 %</u> |

(a) Includes research and discovery projects, as well as early preclinical and terminated molecules.

Our research and development expense for the three months ended September 30, 2022 decreased by \$1.6 million compared to the three months ended September 30, 2021 primarily due to:

- decreased retifanlimab manufacturing costs related to the Incyte Commercial Supply Agreement;
- decreased development, manufacturing and clinical trial costs related to flotetuzumab (due to discontinuance of our company-sponsored trial); and
- decreased development, manufacturing and clinical trial costs related to tebotelimab.

These decreases were partially offset by:

- increased development, manufacturing and clinical trial costs related to MGC018;
- increased expenses related to discovery projects and preclinical molecules;
- increased clinical trial enrollment costs related to lorigerlimab; and
- clinical trial costs related to initiation of a Phase 1 trial of MGD024 during the three months ended September 30, 2022.

Our research and development expense for the nine months ended September 30, 2022 increased by \$2.7 million compared to the nine months ended September 30, 2021 primarily due to:

- increased development, manufacturing and clinical trial costs related to MGC018;
- increased development of discovery projects and preclinical molecules;
- increased clinical trial enrollment costs related to lorigerlimab; and
- clinical trial costs related to initiation of a Phase 1 trial of MGD024.

These increases were partially offset by:

- decreased development, manufacturing and clinical trial costs related to flotetuzumab (due to discontinuance of our company-sponsored trial);
- decreased retifanlimab manufacturing costs related to the Incyte Commercial Supply Agreement;
- decreased development, manufacturing and clinical trial costs related to tebotelimab; and
- decreased margetuximab manufacturing costs related to the Zai Lab Clinical Supply Agreement.

There are uncertainties associated with our research and development expenses for future quarters which are impacted by multiple variables, including timing of wind down activities for recently closed studies and current and expected expenditures associated with our Phase 2/3 MGC018 TAMARACK study.

Selling, General and Administrative Expense

Selling, general and administrative expenses decreased by \$1.8 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 and by \$2.2 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 primarily due to decreased selling costs for MARGENZA, which launched in March 2021, as well as decreased consulting expenses.

Liquidity and Capital Resources

Our multiple product candidates currently under development will require significant additional research and development efforts that include extensive preclinical studies and clinical testing, and regulatory approval prior to commercial use. Our future success is dependent on our ability to identify and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

As a biotechnology company, we have primarily funded our operations with proceeds from the sale of our common stock in equity offerings, revenue from our multiple collaboration agreements, and contracts and grants from the National Institute of Allergy and Infectious Diseases. Management regularly reviews our available liquidity relative to our operating budget and forecast to monitor the sufficiency of our working capital, and anticipates continuing to draw upon available sources of capital, including equity and debt instruments, to support our product development activities. There can be no assurances that new sources of capital will be available to us on commercially acceptable terms, if at all. Also, any future collaborations, strategic alliances and marketing, distribution or licensing arrangements may require us to give up some or all rights to a product or technology at less than its full potential value. If we are unable to enter into new arrangements or to perform under current or future agreements or obtain additional capital, we will assess our capital resources and may be required to delay, reduce the scope of, or eliminate one or more of our product research and development programs or clinical studies, and/or downsize our organization. Although it is difficult to predict our funding requirements, we anticipate that our cash, cash equivalents and marketable securities as of September 30, 2022, combined with \$60.0 million subsequently received from Gilead, anticipated and potential collaboration payments, product revenues and savings from the execution of our corporate restructuring plan, should enable us to fund our operations into mid-2024. Our expected funding requirements reflect anticipated expenditures related to the planned Phase 2 portion of the MGC018 TAMARACK study, as well as our other clinical and nonclinical studies currently ongoing.

Material Cash Requirements

During the nine months ended September 30, 2022, there were no significant changes to our material cash requirements, including contractual and other obligations, as presented in 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 fiscal year ended December 31, 2021.

Cash Flows

The following table represents a summary of our cash flows for the nine months ended September 30, 2022 and 2021:

| | Nine Months Ended September 30, | |
|--|---------------------------------|---------------|
| | 2022 | 2021 |
| | (dollars in millions) | |
| Net cash provided by (used in): | | |
| Operating activities | \$ (116.3) | \$ (89.5) |
| Investing activities | 76.5 | (23.1) |
| Financing activities | 0.3 | 122.0 |
| Net change in cash and cash equivalents | \$ (39.5) | \$ 9.4 |

Operating Activities

Net cash used in operating activities consists of our net loss adjusted for non-cash items such as depreciation and amortization expense and stock-based compensation and changes in working capital. Net cash used in operating activities for the nine months ended September 30, 2022 benefited from the \$30.0 million in milestones received from Incyte under the Incyte License Agreement and \$4.5 million (after netting value-added tax withholding) in milestones received under the 2018 Zai Lab Agreement. Net cash used in operating activities for the nine months ended September 30, 2021 benefited from the \$25.0 million upfront payment under the 2021 Zai Lab Agreement, the \$10.4 million premium over the share price under the Stock Purchase Agreement with Zai Lab, and the \$15.0 million milestone payments received under the Incyte License Agreement.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2022 is primarily due to maturities of marketable securities, partially offset by purchases of marketable securities. Net cash used in investing activities during the nine months ended September 30, 2021 is primarily due to purchases of marketable securities, partially offset by maturities of marketable securities.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 includes net cash proceeds from our securities offerings of approximately \$117.8 million.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide the information required by this item in this Quarterly Report on Form 10-Q.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in our periodic reports filed with the SEC (such as this Quarterly Report on Form 10-Q) has been appropriately recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Based on their evaluation of our disclosure controls and procedures as of September 30, 2022, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Changes in Internal Control

There were no changes in our internal control over financial reporting during the three months ended September 30, 2022 that materially affected, or are reasonably likely to materially effect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are or may be involved in various legal or regulatory proceedings, claims or class actions related to alleged patent infringements and other intellectual property rights, or alleged violation of commercial, corporate, securities, labor and employment, and other matters incidental to our business. We do not currently, however, expect such legal proceedings to have a material adverse effect on our business, financial condition or results of operations. However, depending on the nature and timing of a given dispute, an eventual unfavorable resolution could materially affect our current or future results of operations or cash flows.

See Note 9, Commitments and Contingencies, to the consolidated financial statements of this Quarterly Report on Form 10-Q for more information.

Item 1A. Risk Factors

There have been no material changes in the risk factors described in “Item 1A. Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021, aside from the risk factors included below:

Risks Related to Our Business and the Development and Commercialization of Our Products and Product Candidates

Clinical drug development involves a lengthy and expensive process, with a highly uncertain outcome. We expect to incur significant additional costs related to the development of MGC018 and our other product candidates and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our other products and product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a Biologics License Application (BLA) from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. For example, in November 2021, we announced the discontinuation of Cohort A of the MAHOGANY trial for margetuximab in gastric cancer, based on a number of factors, including the prioritization of our other product candidates given the competition in this indication, and the FDA’s approval of competing combination therapy with pembrolizumab. Also in July 2022, we announced the discontinuation of the Phase 2 trial of enoblituzumab in combination with either retifanlimab or tebotelimab in the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN), based on an internal review of safety data. In addition, our collaborator Incyte submitted a BLA for retifanlimab in January 2021 and in July 2021, received a Complete Response Letter (CRL) from the FDA regarding its BLA. Incyte’s announcement indicated that the FDA determined that additional data are needed to demonstrate the clinical benefit of retifanlimab for the submitted indication, and that Incyte is reviewing the CRL and will discuss next steps with the FDA. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. Further, in October 2021, Incyte withdrew its European application for marketing authorization of retifanlimab for the treatment of squamous carcinoma of the anal canal. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, subject our company or our collaborators to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers, manufacturing facilities or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;

- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs or analogous marketing approvals outside the United States.

The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number of nonclinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- the results may not confirm the positive results from earlier nonclinical studies or clinical trials;
- regulatory agencies may not find the data from nonclinical studies and clinical trials sufficient or meaningful;
- regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; or
- regulatory agencies may change their approval policies or adopt new regulations.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the potential market for a product candidate, if approved.

If clinical trials for our product candidates are prolonged, delayed or stopped, for any reason, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.

We, or our collaborators, are either currently enrolling patients in clinical trials or anticipate initiating, continuing, designing or supporting clinical trials for molecules that include MGC018, lorigerlimab, retifanlimab, IMG0936 and MGD024 as monotherapies or in combination with other product candidates. In addition, Incyte is currently enrolling patients in clinical trials for retifanlimab, and other collaborators outside the United States are developing our product candidates. We anticipate in the future collaborators will initiate or continue clinical trials of one or more our product candidates. The continuation, modification, or commencement of existing or new clinical trials could be substantially delayed or prevented by several factors, including:

- further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure in patient recruitment or enrollment in our or our collaborators' trials for any reason, including as a result of public health crises such as the evolving COVID-19 pandemic;
- any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial terms or clinical trial protocols with prospective sites or CROs the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain institutional review board (IRB) approval to conduct a clinical trial at a prospective site;
- significant competition of product candidates that are expected to be more effective or have a more favorable safety profile; and
- approval of potential therapies by competitors.

The progress or completion of our, or our collaborators', clinical trials have been and could also be substantially delayed or prevented by many factors, including:

- unforeseen safety issues, including severe or unexpected adverse effects experienced by patients, including actual and possible deaths;
- delays in expected site initiation, patient recruitment and enrollment, for any reason, including as a result of public health crises such as the evolving COVID-19 pandemic;
- failure of patients to complete the clinical trial;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- economic and political instability in countries where our trial sites are located, including terrorist attacks, civil unrest and actual or threatened armed conflict;
- inability to monitor patients adequately during or after treatment by us, our collaboration partners and/or our CROs; and
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

Clinical trials of our product candidates are subject to partial or full clinical holds from time to time. A clinical hold received in the midst of conducting a trial may delay the progress of a clinical trial, or may require us to modify or discontinue such trial. Any failure or significant delay in completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

The results of previous clinical trials may not be predictive of future results, and interim or top line data may be subject to change or qualification, based on several factors, including a complete analysis of data, or in the case of interim analysis, the continued or ongoing accrual of data. In addition, the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities for product approval.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or nonclinical testing. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

We may publicly disclose top line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial or continued progress of the study or trial. The top line or interim results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top line and interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously

published. In addition, the achievement of one primary endpoint for a trial does not guarantee that additional co-primary endpoints or secondary endpoints will be achieved, which may have an adverse effect on our ability to obtain or retain additional regulatory approval of MARGENZA and our product candidates in the U.S. or in other jurisdictions.

Our product candidates may have undesirable side effects which may delay or prevent further clinical development or marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Although all of our product candidates have undergone or will undergo safety testing, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or after the approved product has been marketed. Ongoing or future trials of our product candidates may not support the conclusion that one or more of these product candidates have acceptable safety profiles. The results of future clinical or nonclinical trials may show undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings, risk-management measures, or potential product liability claims. For example, in July 2022 we announced the discontinuation of our Phase 2 trial of enoblituzumab in combination with either retifanlimab or tebotelimab in the treatment of patients with recurrent or metastatic SCCHN, based on an internal review of safety data.

If we or others later identify undesirable or unacceptable side effects potentially caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, impose other risk-management measures, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

For example, the prescribing information for MARGENZA include warnings and precautions for infusion-related reactions, as well as a boxed warning related to left ventricular dysfunction and embryo-fetal toxicity. Further, based on the identification of future adverse events, we may be required to further revise the prescribing information, including MARGENZA's boxed warning, which could negatively impact sales of MARGENZA or adversely affect MARGENZA's acceptance in the market.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

Risks Related to Our Financial Position and Need for Additional Capital

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate,

including as a result of political unrest or war, it may make any necessary debt or equity financing more costly or more dilutive or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Risks Relating to Employee Matters and Managing Growth

Our restructuring and the associated workforce reduction announced in August 2022 may not result in anticipated cost savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In August 2022, we announced a reduction in workforce by approximately 15% in connection with the restructuring of our business to prioritize and focus on our lead assets. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our results of operation and financial condition would be adversely affected. We expect to incur additional costs as we recognize one-time employee termination-related charges. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our strategic restructuring plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support at unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

Item 6. Exhibits

| | |
|---------|---|
| 10.1+ | <u>Amendment No. 3 to the Global Collaboration and License Agreement by and between the Company and Incyte Corporation, dated July 14, 2022</u> |
| 31.1* | <u>Rule 13a-14(a) Certification of Principal Executive Officer</u> |
| 31.2* | <u>Rule 13a-14(a) Certification of Principal Financial Officer</u> |
| 32.1** | <u>Section 1350 Certification of Principal Executive Officer</u> |
| 32.2** | <u>Section 1350 Certification of Principal Financial Officer</u> |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Schema Document |
| 101.CAL | XBRL Calculation Linkbase Document |
| 101.DEF | XBRL Definition Linkbase Document |
| 101.LAB | XBRL Labels Linkbase Document |
| 101.PRE | XBRL Presentation Linkbase Document |
| 104 | Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101 filed herewith) |

+ Portions of this document (indicated by “[***]”) have been omitted because they are not material and are the type that MacroGenics, Inc. treats as private and confidential.

* Filed herewith

** Furnished herewith

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.

MACROGENICS, INC.

BY: /s/ Scott Koenig

Scott Koenig, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

BY: /s/ James Karrels

James Karrels
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Dated: November 3, 2022

CERTAIN PORTIONS OF THIS EXHIBIT (INDICATED BY []) HAVE BEEN EXCLUDED PURSUANT TO ITEM 601(B)(10) OF REGULATION S-K BECAUSE THEY ARE BOTH NOT MATERIAL AND ARE THE TYPE THAT THE COMPANY TREATS AS PRIVATE AND CONFIDENTIAL.**

AMENDMENT NO. 3 TO GLOBAL COLLABORATION AND LICENSE AGREEMENT

This Amendment No. 3 to Global Collaboration and License Agreement (this “Amendment No. 3”) is dated as of July 14, 2022, by and between **INCYTE CORPORATION**, a Delaware corporation, having its principal place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803 (hereinafter “Incyte”), and **MACROGENICS, INC.**, a Delaware corporation, having its principal place of business at 9704 Medical Center Drive, Rockville, MD 20850 (“MacroGenics”, together with Incyte, the “Parties” and each separately, a “Party”), and is meant to amend that certain Global Collaboration and License Agreement, dated as of October 24, 2017, between Incyte and MacroGenics and amended on March 15, 2018 (“Amendment No. 1”) and April 7, 2022 (“Amendment No. 2”). The Global Collaboration and License Agreement, Amendment No. 1, and Amendment No. 2 are referred to herein collectively as the “Agreement”. Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, the Parties wish to modify the Agreement to reflect changes agreed to between the Parties with respect to (a) the acceleration of payment for certain Milestones with respect to [**] and (b) the [**] of certain Milestones with respect to [**];

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained herein, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1. Acceleration of First Development Milestones with respect to [**] Indications. The Parties agree that the first Development Milestone set forth in Section 8.2(b) of the Agreement, [**] (including Incyte Monotherapy Studies and Incyte Combination Studies) [**] Milestone”) shall be deemed to have been achieved with respect to the Indications [**]. Incyte shall pay MacroGenics within [**] Business Days of the date hereof the amount of [**], representing payment for the achievement of such [**] Milestones. The Parties agree that only [**] remains unachieved and potentially payable by Incyte in the future.
2. Removal of Certain Milestones and Payments for [**]. The Parties agree that:
 - a. The [**] shall not apply with respect to the Indication [**], and [**] for the [**] shall [**] with respect to the Indication of [**], whether by reason of (i) actually [**] in the Indication [**] or (ii) the occurrence of any of the events set forth in the final sentence in the first paragraph of Section 8.2 stating, “In addition, except with respect to the Breakthrough Designation Milestone, if for any reason any other Development Milestone corresponding to a Milestone payment does not occur prior to the occurrence of Regulatory Approval, then such prior non-occurring Development Milestone shall be deemed to occur concurrently with Regulatory Approval, and the applicable Milestone payments for the applicable Development Milestones shall become due and payable in accordance with this Section 8.2.” For clarity, [**] by Incyte, its Affiliates, or sublicensees for a Monotherapy Regimen or Incyte Combination Regimen in the [**] any such Milestone payment.

- b. The Regulatory Filing Milestone [***] set forth in Section 8.2(c) of the Agreement [***] respect to the Indication [***], and [***] of such Milestone [***] with respect to the [***].
 - c. The Approval Milestone [***] set forth in Section 8.2(d) of the Agreement [***] with respect to the Indication of [***], and [***] for the [***] Milestone shall [***] with respect to the Indication [***].
3. Entire Agreement; Remaining Provisions of the Agreement. The Agreement, as supplemented and modified by this Amendment No. 3, contains the entire understanding of the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into the Agreement. Upon the effectiveness of this Amendment No. 3, on and after the date hereof, each reference in the Agreement to “this Agreement,” “hereunder,” “hereof,” “herein” or words of like import shall mean and be a reference to the Agreement, as amended hereby. Except as provided herein, each of the other provisions of the Agreement shall remain in full force and effect.
4. Governing Law. This Amendment No. 3 shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.
5. Execution in Counterparts. This Amendment No. 3 may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment No. 3 may be executed by .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were the original signatures.

[remainder of page intentionally blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment No. 3 to Global Collaboration and License Agreement to be duly executed by their respective authorized signatories effective as of the date first indicated above.

MACROGENICS, INC.

By: _____
Name: [***]
Title: [***]

INCYTE CORPORATION

By: _____
Name: [***]
Title: [***]

I, Scott Koenig, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of MacroGenics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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.

/s/ Scott Koenig
Scott Koenig, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 3, 2022

I, James Karrels, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of MacroGenics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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.

/s/ James Karrels

James Karrels
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Dated: November 3, 2022

**Certification of Principal Executive Officer
Pursuant to 18 U.S.C. 1350
(Section 906 of the Sarbanes-Oxley Act of 2002)**

I, Scott Koenig, President and Chief Executive Officer (principal executive officer) of MacroGenics, Inc. (the Registrant), certify, to the best of my knowledge, based upon a review of the Quarterly Report on Form 10-Q for the period ended September 30, 2022 of the Registrant (the Report), that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Scott Koenig

Name: Scott Koenig, M.D., Ph.D.

Date: November 3, 2022

**Certification of Principal Financial Officer
Pursuant to 18 U.S.C. 1350
(Section 906 of the Sarbanes-Oxley Act of 2002)**

I, James Karrels, Senior Vice President and Chief Financial Officer (principal financial officer) of MacroGenics, Inc. (the Registrant), certify, to the best of my knowledge, based upon a review of the Quarterly Report on Form 10-Q for the period ended September 30, 2022 of the Registrant (the Report), that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ James Karrels

Name: James Karrels

Date: November 3, 2022