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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from to

Commission file number: 001-39130

TELA Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-5320061**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1 Great Valley Parkway, Suite 24 Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	(Zip Code)

(484) 320-2930
(Registrant's telephone number, including area code)

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

Title of each class:	**Trading Symbol**	**Name of each exchange on which registered:**
Common Stock, $0.001 par value per share	TELA	The Nasdaq Global Market

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
	Smaller reporting company ☒
Non-accelerated filer ☒	Emerging growth company ☒

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

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

As of November 1, 2022, the registrant had 19,159,145 shares of Common Stock, $0.001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 ("Quarterly Report") that are not statements of historical or current facts, such as those under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that "we believe" or similar statements reflect our beliefs and opinions on the relevant subject. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- the full extent of the impact on our business from the pandemic resulting from the coronavirus and the disease it causes, including variants thereof ("COVID-19"), is highly uncertain and difficult to predict and it may continue to impact our business, results of operations and financial condition, including our revenue (resulting from deferrals of elective procedures using our products), expenses, manufacturing capability, supply chain integrity, research and development activities, and employee-related matters, including compensation;
- any future developments around COVID-19 and the uncertainty of COVID-19, including new information that may emerge, changes in the rate of COVID-19 transmission and infection, the emergence of new variants of COVID-19, the availability of vaccinations for COVID-19 and new variants thereof, changes in the level of restrictions imposed by governmental authorities (and the resulting impact on the frequency of surgical procedures using our products), access to hospitals, labor and hospital staffing shortages, and other actions taken to contain or treat COVID-19, as well as the economic impact on regional, national and international customers and markets;
- estimates regarding future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
- the commercial success and the degree of market acceptance of our products;
- our ability to expand, manage and maintain our direct sales and marketing organization and to market and sell our products in the United States, the European Union and the United Kingdom;
- the performance of Aroa Biosurgery Ltd. ("Aroa"), our exclusive contract manufacturer, in connection with the production of our OviTex portfolio products and the development of future products within these product lines;
- our ability to maintain our supply chain integrity and expand our supply chain to manage increased demand for our products;
- our ability to compete successfully with larger competitors in our highly competitive industry;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for our current products and any future products we may seek to commercialize;
- our ability to enhance our products, expand our indications and develop and commercialize additional products;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our business model and strategic plans for our products, technologies and business, including our implementation thereof;
- the size of the markets for our current and future products;
- our ability to attract and retain senior management and other highly qualified personnel;
- our ability to obtain additional capital to finance our planned operations;
- our ability to maintain regulatory approval for our products;
- our ability to commercialize or obtain regulatory approvals for our future products, or the effect of delays in commercializing or obtaining regulatory approvals;

- regulatory developments in the United States and internationally;
- the potential impact of healthcare reform in the United States, including the Inflation Reduction Act of 2022, and measures being taken worldwide designed to reduce healthcare costs;
- the volatility of capital markets and other adverse macroeconomic factors, including due to inflationary pressures, economic slowdown or recession, geopolitical tensions or the outbreak of hostilities or war;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our ability to establish and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others;
- our expectations regarding the use of proceeds from our public offering of common stock or future financings, if any;
- the occurrence of adverse safety events, restrictions on use with our products or product liability claims; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 (our “Annual Report”), our Quarterly Reports on Form 10-Q and the other documents we file with the Securities and Exchange Commission (the “SEC”).

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements may not be achieved or occur at all. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of any unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends on indications of future performance, unless expressed as such, and should only be viewed as historical data.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

TELA Bio, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 54,226	$ 43,931
Accounts receivable, net	5,688	4,234
Inventory	12,138	7,658
Prepaid expenses and other assets	1,903	3,232
Total current assets	73,955	59,055
Property and equipment, net	1,748	1,186
Intangible assets, net	2,594	2,303
Right-of-use assets	1,266	—
Total assets	$ 79,563	$ 62,544
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,856	$ 2,414
Accrued expenses and other current liabilities	10,358	8,161
Total current liabilities	15,214	10,575
Long-term debt	39,766	—
Long-term debt with related party	—	31,491
Other long-term liabilities	1,282	380
Total liabilities	56,262	42,446
Stockholders' equity:		
Preferred stock; $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock; $0.001 par value: 200,000,000 shares authorized; 19,159,145 and 14,529,606 shares issued and 19,159,145 and 14,529,577 shares outstanding at September 30, 2022 and December 31, 2021, respectively	19	15
Additional paid-in capital	287,266	250,064
Accumulated other comprehensive income (loss)	262	(52)
Accumulated deficit	(264,246)	(229,929)
Total stockholders' equity	23,301	20,098
Total liabilities and stockholders' equity	$ 79,563	$ 62,544

See accompanying notes to unaudited interim consolidated financial statements.

TELA Bio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenue	$ 11,159	$ 7,654	$ 29,796	$ 21,089
Cost of revenue (excluding amortization of intangible assets)	3,745	2,976	10,219	7,707
Amortization of intangible assets	95	76	709	228
Gross profit	7,319	4,602	18,868	13,154
Operating expenses:				
Sales and marketing	11,172	6,948	31,605	20,749
General and administrative	3,532	3,462	10,620	9,184
Research and development	2,102	1,409	6,211	5,018
Total operating expenses	16,806	11,819	48,436	34,951
Loss from operations	(9,487)	(7,217)	(29,568)	(21,797)
Other expense:				
Interest expense	(1,032)	(922)	(2,877)	(2,675)
Loss on extinguishment of debt	—	—	(1,228)	—
Other expense	(195)	(127)	(644)	(185)
Total other expense	(1,227)	(1,049)	(4,749)	(2,860)
Net loss	$ (10,714)	$ (8,266)	$ (34,317)	$ (24,657)
Net loss per common share, basic and diluted	$ (0.64)	$ (0.57)	$ (2.24)	$ (1.71)
Weighted average common shares outstanding, basic and diluted	16,758,573	14,485,688	15,293,094	14,461,174
Comprehensive loss:				
Net loss	$ (10,714)	$ (8,266)	$ (34,317)	$ (24,657)
Foreign currency translation adjustment	133	38	314	28
Comprehensive loss	$ (10,581)	$ (8,228)	$ (34,003)	$ (24,629)

See accompanying notes to unaudited interim consolidated financial statements.

TELA Bio, Inc.
Consolidated Statements of Stockholders' Equity
Three and Nine Months Ended September 30, 2022
(In thousands, except share amounts)
(Unaudited)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total
	Shares	Amount				
Balance at July 1, 2022	14,557,560	$ 15	$ 251,846	$ 129	$ (253,532)	$ (1,542)
Vesting of share-based awards and exercise of stock options	2,115	—	1	—	—	1
Shares withheld for employee taxes	(530)	—	(4)	—	—	(4)
Foreign currency translation adjustment	—	—	—	133	—	133
Stock-based compensation expense	—	—	1,027	—	—	1,027
Sale of common stock, net of underwriting discounts, commissions and offering costs	4,600,000	4	34,396	—	—	34,400
Net loss	—	—	—	—	(10,714)	(10,714)
Balance at September 30, 2022	19,159,145	$ 19	$ 287,266	$ 262	$ (264,246)	$ 23,301

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount				
Balance at January 1, 2022	14,529,577	$ 15	$ 250,064	$ (52)	$ (229,929)	$ 20,098
Vesting of common stock previously subject to repurchase	29	—	—	—	—	—
Vesting of share-based awards and exercise of stock options	42,987	—	13	—	—	13
Shares withheld for employee taxes	(13,448)	—	(157)	—	—	(157)
Foreign currency translation adjustment	—	—	—	314	—	314
Stock-based compensation expense	—	—	2,950	—	—	2,950
Sale of common stock, net of underwriting discounts, commissions and offering costs	4,600,000	4	34,396	—	—	34,400
Net loss	—	—	—	—	(34,317)	(34,317)
Balance at September 30, 2022	19,159,145	$ 19	$ 287,266	$ 262	$ (264,246)	$ 23,301

See accompanying notes to unaudited interim consolidated financial statements.

TELA Bio, Inc.
Consolidated Statements of Stockholders' Equity
Three and Nine Months Ended September 30, 2021
(In thousands, except share amounts)
(Unaudited)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount				
Balance at July 1, 2021	14,471,774	$ 14	$ 248,076	$ (81)	$ (213,044)	$ 34,965
Vesting of common stock previously subject to repurchase	36	—	—	—	—	—
Exercise of stock options	31,708	1	258	—	—	259
Foreign currency translation adjustment	—	—	—	38	—	38
Stock-based compensation expense	—	—	733	—	—	733
Net loss	—	—	—	—	(8,266)	(8,266)
Balance at September 30, 2021	14,503,518	$ 15	$ 249,067	$ (43)	$ (221,310)	$ 27,729

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount				
Balance at January 1, 2021	14,437,107	$ 14	$ 245,736	$ (71)	$ (196,653)	$ 49,026
Vesting of common stock previously subject to repurchase	118	—	—	—	—	—
Exercise of stock options	54,293	1	410	—	—	411
Foreign currency translation adjustment	—	—	—	28	—	28
Stock-based compensation expense	12,000	—	2,839	—	—	2,839
Reclassification of liability-classified stock-based compensation awards	—	—	82	—	—	82
Net loss	—	—	—	—	(24,657)	(24,657)
Balance at September 30, 2021	14,503,518	$ 15	$ 249,067	$ (43)	$ (221,310)	$ 27,729

See accompanying notes to unaudited interim consolidated financial statements.

TELA Bio, Inc.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (34,317)	$ (24,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	271	170
Noncash interest expense	507	488
Noncash loss on extinguishment of debt	1,228	—
Amortization of intangible assets	709	228
Net changes in operating lease ROU assets and liabilities	(26)	—
Inventory excess and obsolescence charge	1,809	1,334
Stock-based compensation expense	2,950	2,839
Change in operating assets and liabilities:		
Accounts receivable, net	(1,531)	(896)
Inventory	(6,540)	(3,701)
Prepaid expenses and other assets	1,322	180
Accounts payable	2,291	1,586
Accrued expenses and other current and long-term liabilities	799	1,561
Foreign currency remeasurement loss	763	24
Net cash used in operating activities	(29,765)	(20,844)
Cash flows from investing activities:		
Purchase of property and equipment	(826)	(338)
Net cash used in investing activities	(826)	(338)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of underwriting discounts, commissions and offering costs	34,675	—
Proceeds from issuance of long-term debt	40,000	—
Repayment of long-term debt	(30,000)	—
Payment of debt financing costs	(3,460)	—
Proceeds from exercise of stock options	13	411
Payment of withholding taxes related to stock-based compensation to employees	(157)	—
Net cash provided by financing activities	41,071	411
Effect of exchange rate on cash and cash equivalents	(185)	13
Net increase (decrease) in cash and cash equivalents	10,295	(20,758)
Cash and cash equivalents, beginning of period	43,931	74,394
Cash and cash equivalents, end of period	$ 54,226	$ 53,636
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 2,370	$ 2,187
Supplemental disclosures of noncash investing and financing activities:		
Property and equipment in accounts payable and accrued expenses and other current liabilities	$ 8	$ 97
Offering costs in accounts payable and accrued expenses and other current liabilities	$ 275	$ —
Reclassification of liability-classified stock-based compensation awards to equity-classified	$ —	$ 82
Intangible asset in accrued expenses and other liabilities	$ 1,000	$ —
Operating lease ROU asset exchanged for operating lease liabilities	$ 1,376	$ —
Tenant improvement and deferred rent reclassified to operating lease liabilities	$ 380	$ —
Operating lease liabilities assumed for operating lease ROU assets	$ 1,756	$ —

See accompanying notes to unaudited interim consolidated financial statements.

TELA Bio, Inc.

Notes to Unaudited Interim Consolidated Financial Statements

(1) Background

TELA Bio, Inc. (the "Company") was incorporated in the state of Delaware on April 17, 2012 and wholly owns TELA Bio Limited, a company incorporated in the United Kingdom. The Company is a commercial-stage medical technology company focused on providing innovative soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. OviTex Reinforced Tissue Matrix ("OviTex"), the Company's first portfolio of products, addresses unmet needs in hernia repair and abdominal wall reconstruction by combining the benefits of biologic matrices and polymer materials while minimizing their shortcomings, at a cost-effective price. OviTex PRS Reinforced Tissue Matrix ("OviTex PRS"), the Company's second portfolio of products, addresses unmet needs in plastic and reconstructive surgery. The Company's principal corporate office and research facility is located in Malvern, Pennsylvania.

The Company has been impacted by the pandemic resulting from the coronavirus and the disease it causes, including variants thereof ("COVID-19"). To date, among other impacts on the Company's business related to the pandemic, physicians and their patients have been required by state mandates, or have chosen or are still choosing to, defer elective surgery procedures in which the Company's products otherwise would be used. There remains uncertainty and lack of visibility regarding the Company's near-term revenue growth prospects and product development plans due to the rapidly evolving environment and continued uncertainties resulting from the COVID-19 pandemic and its effects on the frequency of surgical procedures using the Company's products, including through reduced patient access to hospitals, labor and hospital staffing shortages, and other similar actions taken to address COVID-19. Although the Company continues to monitor developments related to COVID-19, the full extent of the impact of the COVID-19 pandemic on the Company's business, results of operations and financial condition, including revenue, expenses, manufacturing capability, supply chain integrity, staffing availability, research and development costs and employee-related compensation, will depend on future developments that are highly uncertain. This includes new information that may emerge concerning COVID-19, the actions taken to mitigate the spread of or treat COVID-19, or to address challenges related to or arising from the COVID-19 pandemic, the emergence of new variants of COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

(2) Risks and Liquidity

The Company's operations to date have focused on commercializing products, developing and acquiring technology and assets, business planning, raising capital and organization and staffing. The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $264.2 million as of September 30, 2022. The Company anticipates incurring additional losses until such time, if ever, it can generate sufficient revenue from its products to cover its expenses.

In August 2022, the Company completed an underwritten public offering in which the Company issued and sold 4,600,000 shares of its common stock at a public offering price of $8.00 per share. The Company received net proceeds of $34.4 million after deducting underwriting discounts, commissions and other offering expenses.

The operations of the Company are subject to certain risks and uncertainties including, among others, the uncertainty of product development, the impact of COVID-19 and the emergence of any variants thereof on the business, ongoing economic uncertainty, including as a result of inflationary pressures and the measures undertaken by various governments to address them, geopolitical factors such as the conflict between Russia and Ukraine, technological uncertainty, commercial acceptance of any developed products, alternative competing technologies, dependence on collaborative partners, uncertainty regarding patents and proprietary rights, comprehensive government regulations, and dependence on key personnel.

(3) Summary of Significant Accounting Policies

The Company's complete summary of significant accounting policies can be found in "Note 3, Summary of Significant Accounting Policies" in the consolidated financial statements included in the Company's Annual Report on Form 10-K

for the year ended December 31, 2021. Any reference in these notes to applicable guidance is meant to refer to generally accepted accounting principles ("GAAP") in the United States as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

Interim Financial Statements

The accompanying unaudited interim consolidated financial statements have been prepared from the books and records of the Company in accordance with GAAP for interim financial information and Rule 10-01 of Regulation S-X promulgated by the SEC, which permits reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the accompanying consolidated balance sheets and statements of operations and comprehensive loss, stockholders' equity and cash flows have been made. Although these interim consolidated financial statements do not include all of the information and footnotes required for complete annual consolidated financial statements, management believes the disclosures are adequate to make the information presented not misleading. The unaudited interim results of operations and cash flows are not necessarily indicative of the results that may be expected for the full year. The unaudited interim consolidated financial statements and footnotes should be read in conjunction with the consolidated financial statements and footnotes included in the Annual Report on Form 10-K for the year ended December 31, 2021.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The most significant judgments are employed in estimates used to determine the fair value of stock-based awards issued and recoverability of the carrying value of the Company's inventory. As future events and their effects cannot be determined with precision, actual results may differ significantly from these estimates.

Revenue Recognition

Under ASC Topic 606, *Revenue from Contracts with Customers*, an entity recognizes revenue when its customer obtains control of the promised good, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods. The Company performs the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer.

A significant portion of the Company's revenue is generated from product shipped to a customer or from consigned inventory maintained at hospitals. Revenue from the sale of consigned products is recognized when control is transferred to the customer, which occurs at the time the product is used in a surgical procedure. For product that is not held on consignment, the Company recognizes revenue when control transfers to the customer, which occurs at the time the product is shipped or delivered. For all of the Company's customer contracts, the only identified performance obligation is providing the product to the customer.

Revenue is recognized at the estimated net sales price which includes estimates of variable consideration. The Company enters into contracts with certain third-party payors for the payment of rebates with respect to the utilization of its products. These rebates are based on contractual percentages. The Company estimates and records these rebates in the same period the related revenue is recognized, resulting in a reduction of product revenue.

TELA Bio, Inc.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

Payment terms with customers do not exceed one year and, therefore, the Company does not account for a financing component in these arrangements. There are no incremental costs of obtaining a contract that would rise to or enhance an asset other than product costs, which are a component of inventory. The Company expenses incremental costs of obtaining a contract with a customer (e.g., sales commissions) when incurred as the period of benefit is less than one year. Fees charged to customers for shipping are recognized as revenue.

The following table presents revenue disaggregated by our portfolio of products (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
OviTex	$ 7,839	$ 6,072	$ 20,528	$ 16,500
OviTex PRS	3,287	1,582	9,188	4,589
Other	33	—	80	—
Total revenue	$ 11,159	$ 7,654	$ 29,796	$ 21,089

Sales outside of the United States were immaterial for the three and nine months ended September 30, 2022 and 2021.

Fair value of financial instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction among market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments are made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, other assets, and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. Due to the related-party relationship of the credit facility (the "OrbiMed Credit Facility") with OrbiMed Royalty Opportunities II, LP ("OrbiMed") (Note 6), it was impractical to determine the fair value of the debt.

The Company follows the provisions of FASB ASC Topic 820, *Fair Value Measurement*, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- *Level 1:* Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- *Level 2:* Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.
- *Level 3:* Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair value measurement at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2022:			
Cash equivalents – money market fund	$ 50,677	$ —	$ —
December 31, 2021:			
Cash equivalents – money market fund	$ 41,396	$ —	$ —

Net loss per common share

Basic and diluted net loss per common share is determined by dividing net loss by the weighted-average shares of common stock outstanding during the reporting period. A net loss cannot be diluted, so when the Company is in a net loss position, basic and diluted net loss per common share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding for the periods presented, as they would be antidilutive.

	Three and nine months ended September 30,	
	2022	2021
Stock options (including shares subject to repurchase)	2,009,189	1,708,601
Unvested restricted stock units	306,722	163,978
Common stock warrants	88,556	88,556
Total	2,404,467	1,961,135

Recently Issued Accounting Pronouncements

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, ("ASU 2016-02") which requires a lessee to record a right-of-use ("ROU") asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the consolidated financial statements as its date of initial application. The Company adopted ASU 2016-02 on January 1, 2022 using the modified retrospective transition method and elected the transition practical expedients to not reassess lease identification, lease classification and initial indirect costs related to those leases entered into prior to the date of application.

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Notes to Unaudited Interim Consolidated Financial Statements (Continued)

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments*, which provides guidance for recognizing credit losses on financial instruments based on an estimate of current expected credit losses model. The standard is effective for the Company beginning January 1, 2023, and the adoption of this guidance is not expected to have a significant impact on the consolidated financial statements and related disclosures.

(4) Leases

The Company leases office and laboratory space in Malvern, Pennsylvania under a noncancelable lease (the "Malvern Lease"). The Malvern Lease, which was concluded to be an operating lease, was amended in December 2020 to extend the term of the lease from May 2021 to May 2028. The Malvern Lease has annual scheduled payment increases and provides the Company a renewal option for an additional term of 60 months at the end of the lease term. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. As the Company is not reasonably certain to exercise the renewal option, the additional 60-month term has been excluded.

On January 1, 2022 and upon adoption of ASU 2016-02, the Company recorded an operating lease liability of $1.8 million and an operating lease ROU asset of $1.4 million related to the Malvern Lease. The Company also eliminated approximately $0.4 million of deferred rent and tenant allowance liabilities as of January 1, 2022 as these components are reflected in the operating lease ROU asset.

Operating lease leasehold improvements are depreciated over the lesser of the useful lives of the leasehold improvements or the lease term. The tenant allowance was historically amortized over the initial, non-cancelable term of the Malvern Lease.

The Company's lease does not provide an implicit rate, and therefore, the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company used an incremental borrowing rate of 9.75% to discount the Malvern Lease payments included in the operating lease liabilities recognized upon adoption of ASU 2016-02.

The Company recognized $0.1 million and $0.2 million of lease cost during the three and nine months ended September 30, 2022. Cash paid for amounts included in the measurement of operating lease liabilities was $0.1 million and $0.3 million for the three and nine months ended September 30, 2022, and this amount is included in operating activities in the consolidated statements of cash flows. As of September 30, 2022, the remaining lease term for the Malvern Lease is 5.7 years.

The following table reconciles the undiscounted future minimum lease payments (displayed in aggregate by year) under non-cancelable operating leases with terms of more than one year to the total operating lease liabilities recognized on the consolidated balance sheets as of September 30, 2022 (in thousands):

Remainder of 2022	$	88
2023		358
2024		366
2025		375
2026		383
2027		392
Thereafter		165
Total undiscounted future minimum lease payments	$	2,127
Less imputed interest		(507)
Total operating lease liabilities	$	1,620

At December 31, 2021, the Company's future minimum lease payments under non-cancelable operating leases for the five years ending December 31, 2022 through 2026 and thereafter were as follows: $0.3 million, $0.4 million, $0.4 million, $0.4 million, $0.4 million and $0.5 million, respectively.

As of September 30, 2022, $0.3 million representing the current portion of operating lease liabilities is included in accrued expenses and other current liabilities in the consolidated balance sheets and $1.3 million representing the long-term portion of operating lease liabilities is included in other long-term liabilities in the consolidated balance sheets.

(5) Accrued Expenses and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Compensation and related benefits	$ 5,126	$ 4,976
Third-party and professional fees	2,431	2,233
Amounts due to contract manufacturer	2,248	842
Current portion of operating lease liabilities	338	—
Research and development expenses	90	31
Other	125	79
Total accrued expenses and other current liabilities	$ 10,358	$ 8,161

The Company has a License, Product Development, and Supplier Agreement with its contract manufacturer which requires payments upon the achievement of certain cumulative product sales. In June 2022, it became probable that the Company would achieve the sales milestones in the European territory, and as such, the Company recorded a liability of $1.0 million included in amounts due to contract manufacturer above and a corresponding developed technology right intangible asset.

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Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(6) Long-term Debt

Long-term debt consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
MidCap Term Loan	$ 40,000	$ —
OrbiMed Term Loan (related party)	—	30,000
End of term charge	2,000	3,000
Unamortized end of term charge and issuance costs	(2,234)	(1,509)
Long-term debt	$ 39,766	$ 31,491

MidCap Term Loan

On May 26, 2022, the Company entered into the Credit and Security Agreement (the "MidCap Credit Agreement") with MidCap Financial Trust, as agent (the "Agent"), and certain lender parties thereto. The MidCap Credit Agreement provides for up to $50.0 million in term loans (the "MidCap Term Loans"), consisting of a $40.0 million Tranche 1 ("Tranche 1") and a $10.0 million Tranche 2 ("Tranche 2"). Upon closing, the Company borrowed $40.0 million of Tranche 1 and used a portion of the proceeds to repay borrowings under the OrbiMed Credit Facility (described below) and intends to use the remaining proceeds to fund operations and other general corporate purposes. The Company will be eligible to borrow Tranche 2 at the Company's option upon meeting certain conditions, including, but not limited to, reaching $65.0 million of net product revenue over the preceding four quarters by fiscal year end 2023.

Pursuant to the MidCap Credit Agreement, the Company provided a first priority security interest in all existing and future acquired assets, including intellectual property, owned by the Company. The MidCap Credit Agreement contains certain covenants that limit the Company's ability to engage in certain transactions that may be in the Company's long-term best interests, including the incurrence of additional indebtedness, effecting certain corporate changes, making certain investments, acquisitions or dispositions and paying dividends.

The MidCap Credit Agreement also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (vi) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) termination of a pension plan, (xi) regulatory matters, (xii) material adverse effect and (xiii) breach of material contracts.

In addition, the Company must maintain minimum net revenue levels tested quarterly. In the event of default under the MidCap Credit Agreement, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 2%.

The MidCap Term Loans mature on May 1, 2027 and bear interest at a rate equal to 6.25% plus the greater of one-month Term SOFR (as defined in the MidCap Credit Agreement) or 1.0%. The Company is required to make 36 monthly interest payments beginning on June 1, 2022 (the "Interest-Only Period"). If the Company is in covenant compliance at the end of the Interest-Only Period, the Company will have the option to extend the Interest-Only Period by 12 months to 48 monthly interest payments, followed by 12 months of straight-line amortization, with the entire principal payment due at maturity. If the Company is not in covenant compliance at the end of the Interest-Only Period, the Company is required to make 24 months of straight-line amortization payments, with the entire principal amount due at maturity.

Subject to certain limitations, the MidCap Term Loans have a prepayment fee equal to 3.0% of the prepaid principal amount for the first year following the closing date of the MidCap Term Loans, 2.0% of the prepaid principal amount for the second year following the closing date and 1.0% of the prepaid principal amount for the third year following the closing date and thereafter. The Company is also required to pay an exit fee at the time of maturity or prepayment event equal to 5% of all principal borrowings (the "End of Term Charge") (or in the event of a prepayment event, the amount

of principal being prepaid). Interest expense associated with the MidCap Credit Facility recorded for the nine months ended September 30, 2022 was $1.4 million, of which $0.2 million was related to the amortization of debt issuance costs.

OrbiMed Term Loan (Related Party)

In November 2018, the Company entered into the OrbiMed Credit Facility with OrbiMed, a related party as the lender is affiliated with a stockholder of the Company, which consisted of up to $35.0 million in term loans (the "OrbiMed Term Loans"). The OrbiMed Term Loans consisted of two tranches, a $30.0 million Tranche 1 ("First Tranche") and a $5.0 million Tranche 2 ("Second Tranche"). In November 2018, the Company borrowed $30.0 million of the First Tranche. The Company elected not to borrow the Second Tranche prior to its expiration on December 31, 2019. On May 26, 2022, the Company entered into the MidCap Credit Agreement and upon closing used a portion of the proceeds to repay all borrowings under the OrbiMed Credit Facility.

The OrbiMed Term Loan bore interest at a rate equal to 7.75% plus the greater of one-month LIBOR or 2.0% until the aggregate principal, interest and End of Term Charge of $3.0 million were paid with part of the proceeds received from the MidCap Credit Agreement. As a result of these payments, a $1.2 million loss on extinguishment was recorded during the nine months ended September 30, 2022. Interest expense associated with the OrbiMed Credit Facility recorded for the nine months ended September 30, 2022, was $1.5 million, of which $0.3 million was related to the amortization of debt issuance costs. Interest expense associated with the OrbiMed Credit Facility recorded for the nine months ended September 30, 2021, was $2.7 million, of which $0.5 million was related to the amortization of debt issuance costs.

(7) Stockholders' Equity

In December 2020, the Company entered into an Equity Distribution Agreement (the "Equity Agreement") with Piper Sandler & Co (the "Sales Agent") in connection with the establishment of an at-the-market offering program under which it may sell up to an aggregate of $50.0 million of shares of the Company's common stock, from time to time through the Sales Agent. No sales were made under the Equity Agreement during the nine months ended September 30, 2022.

In August 2022, the Company completed an underwritten public offering in which the Company issued and sold 4,600,000 shares of its common stock at a public offering price of $8.00 per share. The Company received net proceeds of $34.4 million after deducting underwriting discounts, commissions and other offering expenses.

Warrants

The Company had the following warrants outstanding to purchase common stock at September 30, 2022:

	Outstanding	Exercise price	Expiration dates
Common stock warrants	8,379	$ 28.65	2028
Common stock warrants	80,177	28.65	2027
	88,556		

(8) Stock-Based Compensation

The Company has two equity incentive plans: the 2012 Stock Incentive Plan and the Amended and Restated 2019 Equity Incentive Plan. New awards can only be granted under the Amended and Restated 2019 Equity Incentive Plan (the "Plan"). At September 30, 2022, 989,491 shares of common stock were available for future issuances under the Plan. The Plan is subject to an annual increase, subject to prior approval by the Company's board of directors, equal to the lesser of (i) 432,442 shares, (ii) 4% of the shares outstanding on the last day of the immediately preceding fiscal year and (iii) such smaller number of shares as determined by the board of directors. The Plan provides for the grant of incentive

stock options, nonqualified stock options, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, directors, and other persons, as determined by the Company's board of directors. The Company estimates forfeitures that it expects will occur and adjusts expense for actual forfeitures in the periods they occur.

The Company measures employee and nonemployee stock-based awards at grant-date fair value and records compensation expense ratably over the vesting period of the award. The Company recorded stock-based compensation expense in the following expense categories of the accompanying consolidated statements of operations and comprehensive loss (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Sales and marketing	$ 353	$ 257	$ 1,000	$ 694
General and administrative	522	359	1,521	1,110
Research and development	152	117	429	1,035
Total stock-based compensation	$ 1,027	$ 733	$ 2,950	$ 2,839

Stock Options

The Company's stock options vest based on the terms in each award agreement and generally vest over four years and have a term of 10 years. The following table summarizes stock option activity:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2022	1,706,409	$ 11.88	
Granted	380,360	10.44	
Exercised	(2,204)	6.08	
Canceled/forfeited	(75,376)	13.30	
Outstanding at September 30, 2022	2,009,189	$ 11.57	7.32
Vested and expected to vest at September 30, 2022	1,956,285	$ 11.55	7.27
Exercisable at September 30, 2022	1,167,504	$ 10.99	6.32

Included in outstanding options at September 30, 2022, were 312,075 stock options granted outside of the Plan. These grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq listing rule 5635(c)(4). At September 30, 2022, the aggregate intrinsic value of both outstanding options and exercisable options was $1.2 million.

The 2012 Stock Incentive Plan provided the holders of stock options an election to early exercise prior to vesting. The Company had the right, but not the obligation, to repurchase early exercised options without transferring any appreciation to the employee if the employee terminates employment before the end of the original vesting period. The repurchase price was the lesser of the original exercise price or the then fair value of the common stock.

The following table summarizes activity relating to early exercise of stock options:

	Number of shares
Unvested balance at January 1, 2022	29
Vested	(29)
Unvested balance at September 30, 2022	—

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Notes to Unaudited Interim Consolidated Financial Statements (Continued)

The weighted average grant-date fair value per share of options granted was $6.61 during the nine months ended September 30, 2022. The aggregate intrinsic value of options exercised was $1,000 and $11,000 for the three and nine months ended September 30, 2022, respectively. At September 30, 2022, the total unrecognized compensation expense related to unvested employee and nonemployee stock option awards was $5.4 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.5 years.

Estimating Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Certain of these inputs are subjective and generally require judgment to determine.

Expected term – The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time to vesting and the contractual life of the options.

Expected volatility – Due to the Company's limited operating history and lack of sufficient company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers, including the Company, whose share prices are publicly available.

Risk-free interest rate – The risk-free rate assumption is based on U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

Expected dividend – The Company has not paid and does not intend to pay dividends.

The fair value of each option was estimated on the date of grant using the Black-Scholes option pricing model and the weighted average assumptions in the table below:

	Nine months ended September 30, 2022
Expected dividend yield	—
Expected volatility	68.9 %
Risk-free interest rate	2.28 %
Expected term (in years)	6.19

Restricted Stock Units

The Company's restricted stock units ("RSUs") vest based on the terms in each award agreement and generally vest over four years. The following table summarizes restricted stock units for the Plan:

	Number of shares
Outstanding at January 1, 2022	163,043
Granted	190,450
Vested	(40,783)
Canceled/forfeited	(5,988)
Outstanding at September 30, 2022	306,722

The weighted average grant-date fair value per RSU granted was $11.30 during the nine months ended September 30, 2022. The aggregate intrinsic value of RSUs outstanding was $2.6 million at September 30, 2022. The total unrecognized compensation expense at September 30, 2022 related to RSUs was $2.8 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.9 years.

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Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(9) Related-Party Transactions

On November 16, 2018, the Company entered into a senior secured term loan facility with OrbiMed, an entity affiliated with an owner of a material amount of the Company's outstanding voting securities. The terms of the debt and related components are described in more detail in Note 6. On May 26, 2022, the Company entered into the MidCap Credit Agreement and upon closing used a portion of the proceeds to repay all borrowings under the OrbiMed Credit Facility, and terminated the OrbiMed Credit Facility.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as other sections in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (the "Quarterly Report"), should be read in conjunction with our unaudited interim consolidated financial statements and related notes thereto included elsewhere herein and the consolidated financial statements and notes thereto for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operation, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report") filed with the Securities and Exchange Commission ("SEC") on March 23, 2022. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties, assumptions and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Overview

We are a commercial-stage medical technology company focused on providing innovative soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. Our growing product portfolio is purposefully designed to leverage the patient's natural healing response while minimizing long-term exposure to permanent synthetic materials. We are committed to delivering our advanced technologies with a strong economic value proposition to assist surgeons and institutions in providing next-generation soft-tissue repair solutions to more patients worldwide.

Our first portfolio of products, the OviTex Reinforced Tissue Matrix ("OviTex"), addresses unmet needs in hernia repair and abdominal wall reconstruction by combining the benefits of biologic matrices and polymer materials while minimizing their shortcomings, at a cost-effective price. Our OviTex products have received 510(k) clearance from the U.S. Food and Drug Administration ("FDA"), which clearance was obtained and is currently held by Aroa Biosurgery Ltd. ("Aroa"), our exclusive contract manufacturer of these products. In October 2022, the 24-month results of our single arm, multicenter post-market clinical study, which we refer to as our BRAVO study, were published in the *Annals of Medicine and Surgery*. The BRAVO study was designed to evaluate the clinical performance of OviTex for primary or recurrent ventral hernias using open, laparoscopic, or robotic techniques in 92 enrolled patients. The recurrence rate at the 24-month time point was 2.6%, and surgical site occurrences ("SSOs") were observed in 38% of the study population. 78% of all enrolled patients were characterized as high risk for experiencing an SSO based on at least one known risk factor, which included obesity, active smoking, COPD, diabetes mellitus, coronary artery disease, or advanced age (≥75 years). The results also indicated that BRAVO patients experienced clinically meaningful improvements in their quality of life and perceived health.

Our second portfolio of products, the OviTex PRS Reinforced Tissue Matrix ("OviTex PRS"), addresses unmet needs in plastic and reconstructive surgery. In April 2019, our OviTex PRS products received 510(k) clearance from the FDA, which clearance was obtained by Aroa and is currently held by us.

We began commercialization of our OviTex products in the United States in July 2016. Our OviTex portfolio consists of multiple products for hernia repair and abdominal wall reconstruction, inguinal hernia repair and hiatal hernia repair. In addition, to address the significant increase in the number of robotic-assisted hernia repairs over the last several years, we have designed an OviTex product line for use in laparoscopic and robotic-assisted surgery ("OviTex LPR"), which we began commercializing in November 2018.

OviTex PRS is indicated for use in implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. We commenced a limited launch in May 2019 and gathered clinical feedback from our initial surgeon users. Based on this feedback, we expanded our commercial launch in June 2020 and expect to continue to expand our surgeon network. We have also engaged in discussions with the FDA regarding an Investigational Device Exemption protocol to study the safety and effectiveness of our OviTex PRS product for an indication in breast reconstruction surgery. The FDA has stated that a premarket approval, rather than a 510(k) clearance, will be required for such an indication.

We market our products through a single direct sales force, predominantly in the United States, as augmented by a smaller number of sales representatives and distributors in certain European countries. We have invested in our direct sales and marketing infrastructure to expand our presence and to promote awareness and adoption of our products. As of September 30, 2022, we had 64 sales territories in the United States. As part of our commercial strategy, we plan to continue to invest in our commercial organization by hiring additional account managers, clinical development specialists and administrative support staff to support and service new accounts for soft tissue reconstruction procedures. Additionally, we believe we can enhance the productivity of our sales force by improving customer segmentation and targeting, leveraging digital channels to engage customers and utilizing engagement analytics to support development.

We announced, in November 2021, that we entered into a distribution agreement with Next Science Technologies Pty Limited (“Next Science”), a medical technology company, granting us the exclusive rights to sell and market Next Science’s proprietary antimicrobial surgical wash with XBIO® technology across the U.S. plastic reconstructive market. We commenced private label marketing of the solution for plastic surgery in early 2022. Next Science’s XBIO Technology delivers an advanced option for surgical infection control. We believe that an infection control solution will expand our service offerings and diversify our supplier base as we continue to create a soft-tissue restoration portfolio.

We are currently devoting research and development resources to develop additional versions of our OviTex hernia product lines, including self-adhering technology to further enhance product compatibility in robotic procedures, as well as additional versions of our OviTex PRS product lines. We are also working to develop new product features and designs for both our existing OviTex and OviTex PRS products. Additionally, we are exploring new packaging technology to increase the shelf life of our OviTex and OviTex PRS products. We are also exploring additional technologies that may complement our existing products, or expand the number of our product lines, in each case within the hernia, plastic and reconstruction, and broader soft-tissue reconstruction and preservation market. We intend to continue to make investments in research and development efforts to develop improvements and enhancements. We are also assessing strategic partnerships with medical device companies whereby we may enter into distribution, product development and/or licensing agreements for products complimentary to, or related to, existing and future products in our distribution channel, which could result in the payment of single digit royalties or other product acquisition costs.

Our OviTex products are manufactured by Aroa at their FDA registered and ISO 13485 compliant facility in Auckland, New Zealand. We maintain our Aroa License for the exclusive supply of ovine rumen and manufacture of our reinforced tissue matrices under which we purchase product from Aroa at a fixed cost equal to 27% of our net sales of licensed products. This revenue sharing arrangement allows us to competitively price our products and pass along cost savings to our customers.

The vast majority of our revenue to date has been generated by the sale of our OviTex products. Our revenue increased by $3.5 million, or 46%, from $7.7 million for the three months ended September 30, 2021 to $11.2 million for the three months ended September 30, 2022 and by $8.7 million, or 41%, from $21.1 million for the nine months ended September 30, 2021 to $29.8 million for the nine months ended September 30, 2022. Our net loss increased by $2.4 million, or 30%, from $8.3 million for the three months ended September 30, 2021 to $10.7 million for the three months ended September 30, 2022 and by $9.7 million, or 39%, from $24.7 million for the nine months ended September 30, 2021 to $34.3 million for the nine months ended September 30, 2022. We have not been profitable since inception and as of September 30, 2022, we had an accumulated deficit of $264.2 million. We expect to incur losses for the foreseeable future.

Business Update Regarding COVID-19

Our business, results of operations and commercial operations have been impacted by the COVID-19 pandemic and the emergence of variants of COVID-19, and their broader effects on hospitals and other surgical settings in which we sell our products. We continue to closely monitor developments related to the COVID-19 pandemic and our decisions will continue to be driven by the health and well-being of our employees, our customers, and their patients while maintaining operations to support our customers and their patients in the near-term. These developments include:

- *Surgery Deferrals*: We believe our revenue was impacted during the nine months ended September 30, 2022 due to the impact of COVID-19 resurgences and lower surgical procedural volumes. The extent of future elective surgery deferrals and the timing and extent of the economic impact of the pandemic on us, and the pace at which the economy recovers therefrom, cannot be determined at this time, particularly in light of recent trends relating to the impact of COVID-19 and its effects on labor and hospital staffing. Further, the allocation of hospital resources to treat COVID-19, to address staffing shortages, and to prioritize non-elective procedures, and other labor and financial strain on healthcare systems may continue to reduce procedural volumes. We continue to work closely with our hospital and physician customers and suppliers to navigate through this uncertainty while maintaining flexible operations to respond to the changing environment.

- *Operations*: Our sales, marketing and research and development efforts have continued since the outbreak of the COVID-19 pandemic. As access to hospitals continues to evolve throughout this pandemic and vary from hospital to hospital and state to state, our sales team has continued to adapt to changing conditions within their regions. Most of our sales professionals have used a virtual selling program, which includes virtual sales calls with physicians, peer-to-peer discussions with key opinion leaders, physician webinars and sales professional training to supplement our in-person sales and marketing programs. We expect to continue to adapt our sales and marketing strategies as we continue to gain better visibility into the effects of the COVID-19 pandemic on our business. Since our contract manufacturer is located and headquartered in Auckland, New Zealand, where COVID-19 mitigation efforts have to date been effective, our manufacturing and supply chain has largely been uninterrupted. However, it could be disrupted in the future due to staffing shortages, production slowdowns or stoppages, travel and shipping restrictions or disruptions in delivery systems related to COVID-19 or other geopolitical events.

- *Product Development*: We continue to evaluate the timing and scope of planned next generation product development and commercialization initiatives in light of the COVID-19 pandemic, and we plan to continue to prioritize and invest in our critical R&D and clinical programs.

- *2022 Results*. During January and February, we experienced increased volatility in demand for our products as COVID-19 cases and hospitalizations increased. We saw improvement in our business during the second quarter of 2022 but then saw some softening in June that continued into the third quarter of 2022. We continue to monitor the potential impact from the emergence of the Omicron BA.4 and BA.5 variants and labor and hospital staffing levels on procedural volumes and ultimately on our results. The timing, extent and continuation of any increase in procedures, any corresponding increase in sales of our products, and whether there could be a future decrease in the current level of procedures being performed, remain uncertain and are subject to a variety of factors, including:

    - A significant increase in COVID-19 cases in one or more locations, including as a result of the emergence of new variants of COVID-19, may result in an increase in COVID-19 hospitalizations and a corresponding decrease in elective procedures in such impacted locations.

    - The perceived safety of COVID-19 vaccines and boosters, the speed of COVID-19 vaccine distribution and administration, the timing and extent to which the vaccination process will affect the progression of the virus, and the efficacy of such vaccines against the new variants of the virus.

    - Government vaccine mandates could affect our ability to retain or hire employees.

- Government restrictions on elective procedures may change over time and may vary in different geographic locations due to localized increases or decreases in the number of COVID-19 cases.
- Patients electing to defer or avoid treatment for elective procedures due to concerns about being exposed to COVID-19, loss of employer-sponsored health insurance related to unemployment or other reasons.
- Hospitals may reserve increased space, personal protective equipment and staff for potential COVID-19 patients, especially if the number of COVID-19 cases in a particular region spike or a new variant of COVID-19 emerges in such region, limiting the space and resources allocated to inpatient and outpatient elective procedures.
- Hospitals may experience staffing shortages due to normal turnover and due to COVID-19 and its effects, which could reduce the number of elective procedures that can be performed at hospitals with staffing shortages.
- Hospitals may continue to preserve cash and may not immediately replenish their inventories of our products, which would impact our future sales and revenues and make it difficult to accurately predict our inventory requirements.

We continue to closely monitor local, regional and global COVID-19 surges as well as new variants of the virus for an impact on procedures during the fourth quarter of 2022 and beyond.

- *Outlook*. There remains uncertainty and lack of visibility regarding our near-term revenue growth prospects and product development plans due to the rapidly evolving environment and continued uncertainties resulting from the COVID-19 pandemic and its effects on the frequency of surgical procedures using our products, including through reduced patient access to hospitals, labor and hospital staffing shortages, and other similar actions taken to address COVID-19. While the Company continues to monitor the effects of COVID-19, the full extent of the impact of the COVID-19 pandemic on our business, financial condition and results of operations is uncertain and cannot be predicted with reasonable accuracy and will depend on future developments that are also uncertain, such as the potential development of new variants of COVID-19, the efficacy of existing vaccines against new variants of COVID-19, the future geographic scope of COVID-19, and the actions of governments and hospital systems to address the continuing challenges that arose in light of the COVID-19 pandemic.

Components of Our Results of Operations

Revenue

Substantially all of our revenue consists of direct sales of our products to hospital accounts in the United States. Depending on the terms of our agreements with our customers, we recognize revenue related to product sales when control transfers, which generally occurs when the product is shipped to the customer, or when the product is utilized in a surgical procedure in the case of consignment agreements. Fees charged to customers for shipping are recognized as revenue. Recent revenue growth has been driven by increasing revenue from product sales due to our expanding customer base, although it is unclear at this point what long-term effect the COVID-19 pandemic will have on our ability to continue to generate revenue and expand our customer base.

Cost of Revenue (excluding amortization of intangible assets)

Cost of revenue primarily consists of the costs of licensed products, charges related to excess and obsolete inventory adjustments, current royalties and costs related to shipping. We purchase product from our contract manufacturer, Aroa, at a fixed cost equal to 27% of our net sales of licensed products. The initial term of our Aroa License terminates on the expiration of the last patent covering bovine and ovine products, with an option to extend for an additional ten-year period. We expect our cost of revenue to increase in absolute dollars as, and to the extent, our sales volume grows, although it is unclear at this point what long-term effect, if any, the COVID-19 pandemic will have on product demand which could lead to additional charges to excess and obsolete inventory.

Amortization of Intangible Assets

Amortization of intangible assets relates to the amortization of capitalized milestone amounts paid or probable to be paid to Aroa related to license fees or commercialization rights after future economic benefit has been established for a product. These capitalized milestone amounts relate to regulatory clearances, the receipt of certain supply quantities of product, and amounts based upon aggregate net sales thresholds within a specified territory and are amortized over the remaining useful life of the intellectual property.

Gross Profit and Gross Margin

Our gross profit is calculated by subtracting our cost of revenue and amortization of intangible assets from our revenue. We calculate our gross margin percentage as our gross profit divided by our revenue. Our gross profit has been, and we expect it will continue to be, affected by a variety of factors, including sales volume, current and potential royalties and excess and inventory obsolescence costs. Our gross profit may increase to the extent our revenue grows.

Sales and Marketing Expenses

Sales and marketing expenses consist of market research and commercial activities related to the sale of our products, along with the salaries and related benefits, including sales commissions and stock-based compensation for employees focused on these efforts. Other significant sales and marketing expenses include costs incurred with post-market clinical studies, conferences and trade shows, promotional and marketing activities, as well as travel and training expenses.

Over time we expect our sales and marketing expenses to increase in absolute dollars as we continue to expand our commercial organization to both drive and support our planned growth in revenue. It is unclear at this point, however, what long-term effect, if any, the COVID-19 pandemic will have on these expansion plans. We expect our sales and marketing expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, for personnel in executive, finance, information technology and administrative functions. General and administrative expenses also include professional service fees for legal, accounting, consulting, investor and public relations, insurance costs and direct and allocated facility-related costs.

We expect that our general and administrative expenses will increase in absolute dollars as we execute our growth initiatives and expand our business and headcount to support these initiatives. It is unclear at this point, however, what long-term effect, if any, the COVID-19 pandemic will have on these expansion plans. We expect our general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Research and Development Expenses

Research and development expenses consist primarily of product research, engineering, product development, regulatory compliance and clinical development. These expenses include salaries and related benefits, including stock-based compensation, for employees focused on these efforts, consulting services, costs associated with our preclinical studies, costs incurred with our manufacturing partner under development agreements related to technology transfer, laboratory materials and supplies and an allocation of related facilities costs. We expense research and development costs as they are incurred.

We expect that our research and development expenses in absolute dollars will increase in the future as we develop new products and enhance existing products although it is unclear at this point what long-term effect, if any, the COVID-19 pandemic will have on these development plans. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of new product development initiatives.

Interest Expense

Interest expense consists of cash interest related to our credit facilities, non-cash interest attributable to the amortization of final payment fees and the amortization of deferred financing costs related to our indebtedness.

Loss on Extinguishment of Debt

Loss on extinguishment of debt consists of the excess consideration paid over the net carrying value of our debt at the time of extinguishment.

Other Expense

Other expense consists primarily of miscellaneous tax expenses and foreign currency exchange gains and losses offset by income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

	Three months ended September 30,		Change	
	2022	2021	Dollar	Percentage
	(in thousands, except percentages)			
Revenue	$ 11,159	$ 7,654	$ 3,505	46 %
Cost of revenue (excluding amortization of intangible assets)	3,745	2,976	769	26
Amortization of intangible assets	95	76	19	25
Gross profit	7,319	4,602	2,717	59
Gross margin	66 %	60 %		
Operating expenses:				
Sales and marketing	11,172	6,948	4,224	61
General and administrative	3,532	3,462	70	2
Research and development	2,102	1,409	693	49
Total operating expenses	16,806	11,819	4,987	42
Loss from operations	(9,487)	(7,217)	(2,270)	31
Other expense:				
Interest expense	(1,032)	(922)	(110)	12
Other expense	(195)	(127)	(68)	54
Total other expense	(1,227)	(1,049)	(178)	17
Net loss	$ (10,714)	$ (8,266)	$ (2,448)	30 %

Revenue

Revenue increased by $3.5 million, or 46%, to $11.2 million for the three months ended September 30, 2022 from $7.7 million for the three months ended September 30, 2021. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization, increased penetration within existing customer accounts and stronger international sales. During the three months ended September 30, 2022, we sold 2,631 units of OviTex as compared to 1,991 units of OviTex during the three months ended September 30, 2021, a 32% increase in unit sales volume. Additionally, we sold 618 units of OviTex PRS during the three months ended September 30, 2022 as compared to 302 units during the three months ended September 30, 2021, a 105% increase in unit sales volume.

Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by $0.8 million, or 26%, to $3.7 million for the three months ended September 30, 2022 from $3.0 million for the three months ended September 30, 2021. The increase in cost of revenue for the three months ended September 30, 2022 was primarily the result of an increase in products purchased from our contract manufacturer to support our higher unit sales volume.

Amortization of Intangible Assets

Amortization of intangible assets increased by $19,000, or 25% to $95,000 for the three months ended September 30, 2022 from $76,000 for the three months ended September 30, 2021. In June 2022, we determined that our final milestone target under our licensing agreement with Aroa was probable of being met and recorded the payment obligation as an intangible asset, resulting in the increase in amortization.

Gross Margin

Gross margin increased to 66% for the three months ended September 30, 2022 from 60% for the three months ended September 30, 2021. The increase was primarily due to a lower provision for excess and obsolete inventory.

Sales and Marketing

Sales and marketing expenses increased by $4.2 million, or 61%, to $11.2 million for the three months ended September 30, 2022 from $6.9 million for the three months ended September 30, 2021. The increase was primarily due to higher salaries, benefits and commission costs as a result of an expansion of our commercialization activities, higher travel and consulting expenses and additional employee-related costs due to an increase in headcount.

General and Administrative

General and administrative expenses remained at $3.5 million for both the three months ended September 30, 2022 and 2021.

Research and Development

Research and development expenses increased by $0.7 million, or 49%, to $2.1 million for the three months ended September 30, 2022 from $1.4 million for the three months ended September 30, 2021. The increase was primarily due to higher salaries and benefits due to an increase in headcount and consulting and study costs.

Interest Expense

Interest expense increased by $0.1 million, or 12%, to $1.0 million for the three months ended September 30, 2022 from $0.9 million for the three months ended September 30, 2021 as the term loan amount outstanding increased under the MidCap Credit Agreement, which offset the lower interest rate also from the MidCap Credit Agreement.

Other Expense

Other expense increased $68,000, or 54%, to $0.2 million for the three months ended September 30, 2022 from $0.1 million for the three months ended September 30, 2021. The increase was primarily due to foreign currency translation adjustments, which offset an increase in interest income.

Comparison of the Nine months Ended September 30, 2022 and 2021

	Nine Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
	(in thousands, except percentages)			
Revenue	$ 29,796	$ 21,089	$ 8,707	41 %
Cost of revenue (excluding amortization of intangible assets)	10,219	7,707	2,512	33
Amortization of intangible assets	709	228	481	211
Gross profit	18,868	13,154	5,714	43
Gross margin	63 %	62 %		
Operating expenses:				
Sales and marketing	31,605	20,749	10,856	52
General and administrative	10,620	9,184	1,436	16
Research and development	6,211	5,018	1,193	24
Total operating expenses	48,436	34,951	13,485	39
Loss from operations	(29,568)	(21,797)	(7,771)	36
Other expense:				
Interest expense	(2,877)	(2,675)	(202)	8
Loss on extinguishment of debt	(1,228)	—	(1,228)	—
Other expense	(644)	(185)	(459)	248
Total other expense	(4,749)	(2,860)	(1,889)	66
Net loss	$ (34,317)	$ (24,657)	$ (9,660)	39 %

Revenue

Revenue increased by $8.7 million, or 41%, to $29.8 million for the nine months ended September 30, 2022 from $21.1 million for the nine months ended September 30, 2021. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization, increased penetration within existing customer accounts and stronger international sales. During the nine months ended September 30, 2022, we sold 7,096 units of OviTex as compared to 5,341 units of OviTex during the nine months ended September 30, 2021, a 33% increase in unit sales volume. Additionally, we sold 1,733 units of OviTex PRS during the nine months ended September 30, 2022 as compared to 909 units during the nine months ended September 30, 2021, a 91% increase in unit sales volume.

Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by $2.5 million, or 33%, to $10.2 million for the nine months ended September 30, 2022 from $7.7 million for the nine months ended September 30, 2021. The increase in cost of revenue for the nine months ended September 30, 2022 was primarily the result of an increase in products purchased from our contract manufacturer to support our higher unit sales volume.

Amortization of Intangible Assets

Amortization of intangible assets increased by $0.5 million, or 211%, to $0.7 million for the nine months ended September 30, 2022 from $0.2 million for the nine months ended September 30, 2021. In June 2022, we determined that our final milestone target under our licensing agreement with Aroa was probable of being met and recorded the payment obligation as an intangible asset, resulting in a cumulative amortization charge of $0.5 million.

Gross Margin

Gross margin increased to 63% for the nine months ended September 30, 2022 from 62% for the nine months ended September 30, 2021. The increase was primarily due to a to a lower provision for excess and obsolete inventory as a percentage of revenue.

Sales and Marketing

Sales and marketing expenses increased by $10.9 million, or 52%, to $31.6 million for the nine months ended September 30, 2022 from $20.7 million for the nine months ended September 30, 2021. The increase was primarily due to higher salaries, benefits and commission costs as a result of an expansion of our commercialization activities, higher travel and consulting expenses and additional employee-related costs due to an increase in headcount.

General and Administrative

General and administrative expenses increased by $1.4 million, or 16%, to $10.6 million for the nine months ended September 30, 2022 from $9.2 million for the nine months ended September 30, 2021. The increase was primarily due to higher salaries and benefits due to an increase in headcount and increased professional, consulting and legal expenses.

Research and Development

Research and development expenses increased by $1.2 million, or 24%, to $6.2 million for the nine months ended September 30, 2022 from $5.0 million for the nine months ended September 30, 2021. The increase was primarily due to higher salaries and benefits due to an increase in headcount and consulting and study costs which offset a decrease in stock based compensation expense.

Interest Expense

Interest expense increased by $0.2 million, or 8%, to $2.9 million for the nine months ended September 30, 2022 from $2.7 million for the nine months ended September 30, 2021 as the term loan amount borrowed increased under our MidCap Credit Agreement which offset the lower interest rate also from the MidCap Credit Agreement.

Loss on Extinguishment of Debt

We recorded a loss on the extinguishment of debt of $1.2 million during the nine months ended September 30, 2022 related to the repayment of borrowings of our credit facilities with OrbiMed in May. The losses were primarily comprised of the write-off of unamortized debt discounts and prepayment penalties at the time of extinguishment.

Other Expense

Other expense increased $0.5 million, or 248%, to $0.6 million for the nine months ended September 30, 2022 from $0.2 million for the nine months ended September 30, 2021. The increase was primarily due to foreign currency translation adjustments, which offset an increase in interest income.

Liquidity and Capital Resources

Overview

As of September 30, 2022, we had cash and cash equivalents of $54.2 million, working capital of $58.7 million and an accumulated deficit of $264.2 million. As of December 31, 2021, we had cash and cash equivalents of $43.9 million, working capital of $48.5 million and an accumulated deficit of $229.9 million.

In August 2022, the Company completed an underwritten public offering in which the Company issued and sold 4,600,000 shares of its common stock at a public offering price of $8.00 per share. The Company received net proceeds of $34.4 million after deducting underwriting discounts, commissions and other offering expenses.

We have incurred operating losses since our inception, and we anticipate that our operating losses will continue in the near term as we seek to invest in our sales and marketing initiatives to support our growth in existing and new markets and in additional research and development activities. As of September 30, 2022, we had $40.0 million of borrowings

outstanding under our Credit and Security Agreement (the "MidCap Credit Agreement") with MidCap Financial Trust, as agent and certain lender parties thereto. The MidCap Credit Agreement matures in May 2027 and provides for up to $50.0 million in term loans (the "MidCap Term Loans"), consisting of a $40.0 million Tranche 1 ("Tranche 1") and a $10.0 million Tranche 2 ("Tranche 2"). Upon closing, we borrowed $40.0 million of Tranche 1 and used a portion of the proceeds to repay borrowings under the OrbiMed Credit Facility and intends to use the remaining proceeds to fund operations and other general corporate purposes. We will be eligible to borrow Tranche 2 at our option upon meeting certain conditions, including, but not limited to, reaching $65.0 million of net product revenue over the preceding four quarters by fiscal year end 2023.

Based on our current business plan, we believe that our existing cash resources will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months from the issuance of this Quarterly Report. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell common or preferred equity or debt securities or enter into a new credit facility. In December 2020, we entered into an Equity Distribution Agreement (the "Equity Agreement") with Piper Sandler & Co (the "Agent") in connection with the establishment of an at-the-market offering program under which it may sell up to an aggregate of $50.0 million of shares of our common stock, from time to time through the Agent as sales agent. No sales were made under the Equity Agreement during the nine months ended September 30, 2022. If we raise additional funds by issuing equity or equity-linked securities, our stockholders would experience dilution and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We cannot be assured that additional equity, equity-linked or debt financing will be available on terms favorable to us or our stockholders, or at all, including as a result of market volatility following the COVID-19 pandemic or other factors. If we are unable to obtain adequate financing, we may be required to delay or reduce the current development, commercialization and marketing plans for our products.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**
Cash used in operating activities	$ (29,765)	$ (20,844)
Cash used in investing activities	(826)	(338)
Cash provided by financing activities	41,071	411
Effect of exchange rate on cash	(185)	13
Net increase (decrease) in cash and cash equivalents	$ 10,295	$ (20,758)

Operating Activities

During the nine months ended September 30, 2022, we used $29.8 million of cash in operating activities, resulting from our net loss of $34.3 million and the change in operating assets and liabilities of $2.9 million, offset by non-cash charges of $7.4 million. Our non-cash charges were comprised of stock-based compensation expense of $3.0 million, our excess and obsolete inventory charge of $1.8 million, a loss on debt extinguishment of $1.2 million, depreciation and amortization expense of $1.0 million and noncash interest expense of $0.5 million. The change in our operating assets and liabilities was primarily related to an increase in our inventory and accounts receivable offset by increases in accounts payable and accrued expenses and other current and long-term liabilities.

During the nine months ended September 30, 2021, we used $20.8 million of cash in operating activities, resulting from our net loss of $24.7 million and the change in operating assets and liabilities of $1.2 million, offset by non-cash charges of $5.1 million. Our non-cash charges were comprised of stock-based compensation expense of $2.8 million, our excess and obsolete inventory charge of $1.3 million, noncash interest expense of $0.5 million and depreciation and amortization expense of $0.4 million. The change in our operating assets was primarily related to increases in our inventory and accounts receivable partially offset by increases in accounts payable and accrued expenses and other current and long-term liabilities.

Investing Activities

During the nine months ended September 30, 2022, cash used in investing activities was $0.8 million consisting of purchases of property and equipment.

During the nine months ended September 30, 2021, cash used in investing activities was $0.3 million, consisting of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2022, cash provided by financing activities was $41.1 million, consisting primarily of $34.7 million in proceeds from an underwritten public offering, $40.0 million in proceeds received from the issuance of long-term debt offset by $30.0 million in repayments of long-term debt and $3.5 million in payments of issuance costs.

During the nine months ended September 30, 2021, cash provided by financing activities was $0.4 million, consisting of proceeds received from the exercise of stock options.

Indebtedness

On May 26, 2022, we entered into the MidCap Credit Agreement with MidCap Financial Trust, as agent and certain lender parties thereto. The MidCap Credit Agreement provides for up to $50.0 million in MidCap Term Loans, consisting of a $40.0 million Tranche 1 and a $10.0 million Tranche 2. Upon closing, we borrowed $40.0 million of Tranche 1 and used a portion of the proceeds to repay borrowings under the OrbiMed Credit Facility and intend to use the remaining proceeds to fund operations and other general corporate purposes. We will be eligible to borrow Tranche 2 at our option upon meeting certain conditions, including, but not limited to, reaching $65.0 million of net product revenue over the preceding four quarters by fiscal year end 2023.

Pursuant to the MidCap Credit Agreement, we provided a first priority security interest in all existing and future acquired assets, including intellectual property, owned by us. The MidCap Credit Agreement contains certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests, including the incurrence of additional indebtedness, effecting certain corporate changes, making certain investments, acquisitions or dispositions and paying dividends.

The MidCap Credit Agreement also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (vi) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) termination of a pension plan, (xi) regulatory matters, (xii) material adverse effect and (xiii) breach of material contracts.

In addition, we must maintain minimum net revenue levels tested quarterly. In the event of default under the MidCap Credit Agreement, we would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 2%.

The MidCap Term Loans mature on May 1, 2027 and bear interest at a rate equal to 6.25% plus the greater of one-month Term SOFR (as defined in the MidCap Credit Agreement) or 1.0%. We are required to make 36 monthly interest payments beginning on June 1, 2022 (the “Interest-Only Period”). If we are in covenant compliance at the end of the Interest-Only Period, we will have the option to extend the Interest-Only Period by 12 months to 48 monthly interest payments, followed by 12 months of straight-line amortization, with the entire principal payment due at maturity. If we are not in covenant compliance at the end of the Interest-Only Period, we are required to make 24 months of straight-line amortization payments, with the entire principal amount due at maturity.

Subject to certain limitations, the MidCap Term Loans have a prepayment fee equal to 3.0% of the prepaid principal amount for the first year following the closing date of the MidCap Term Loans, 2.0% of the prepaid principal amount for

the second year following the closing date and 1.0% of the prepaid principal amount for the third year following the closing date and thereafter. We are also required to pay an exit fee at the time of maturity or prepayment event equal to 5% of all principal borrowings (or in the event of a prepayment event, the amount of principal being prepaid).

Contractual Obligations and Commitments

As of September 30, 2022, there were no significant changes to our commitments and future minimum contractual obligations as set forth in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

Critical Accounting Policies and Significant Judgments and Estimates

The Critical Accounting Policies and Significant Judgements and Estimates included in our 2021 Annual Report have not materially changed.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our cash is held on deposit in demand accounts at high credit quality financial institutions in amounts in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the consolidated financial statements of these institutions and believe they have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

Financial instruments that potentially subject us to concentrations of credit risk principally consist of cash equivalents and accounts receivable. We limit our credit risk associated with cash equivalents by placing investments in highly-rated money market funds and agency securities. We limit our credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but we do not require collateral to secure amounts owed to us by our customers.

As discussed above in the section entitled "Liquidity and Capital Resources — Indebtedness," the MidCap Credit Facility bears interest at a floating rate of interest, which resets monthly and is equal to 6.25% plus the greater of one-month Term SOFR or 1.0%. As a result, we are exposed to risks from changes in interest rates. A 1% increase in interest rates would have resulted in a $0.1 million increase to our interest expense for the nine months ended September 30, 2022.

Inflationary factors, such as increases in our cost of revenue and operating expenses, may adversely affect our operating results. Although we do not believe inflation has had a material impact on our financial condition, results of operations or cash flows to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin or decrease our operating expenses as a percentage of our revenue if our selling prices of our products do not increase as much or more than our costs increase.

We do not currently have any material exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and

15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risk factors described in our 2021 Annual Report, under the caption "Item 1A. Risk Factors." There have been no material changes in our risk factors disclosed in our 2021 Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

None.

Purchase of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

The following exhibits are being filed herewith:

EXHIBIT INDEX

Exhibit No.	Exhibit
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101 INS	Inline XBRL Instance Document (filed herewith).
101 SCH	Inline XBRL Taxonomy Extension Schema Document (filed herewith).
101 CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
101 LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
101 PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

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.

TELA BIO, INC.

Date: November 10, 2022

By: /s/ ANTONY KOBLISH
Antony Koblish
President and Chief Executive Officer
(Principal executive officer)

Date: November 10, 2022

By: /s/ ROBERTO CUCA
Roberto Cuca
Chief Operating Officer and Chief Financial Officer
(Principal financial officer)

Date: November 10, 2022

By: /s/ MEGAN SMEYKAL
Megan Smeykal
Chief Accounting Officer and Controller
(Principal accounting officer)

EXHIBIT 31.1

CERTIFICATION

Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934,
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Antony Koblish, certify that:

1. I have reviewed this Form 10-Q of TELA Bio, 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.

Date: November 10, 2022

/s/ Antony Koblish
Antony Koblish
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934,
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Roberto Cuca, certify that:

1. I have reviewed this Form 10-Q of TELA Bio, 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.

Date: November 10, 2022

/s/ Roberto Cuca
Roberto Cuca
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to 18 U.S.C. Section 1350,
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that: Antony Koblish, Chief Executive Officer of TELA Bio, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2022

/s/ Antony Koblish
Antony Koblish
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION

Pursuant to 18 U.S.C. Section 1350,
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that: Roberto Cuca, Chief Operating Officer and Chief Financial Officer of TELA Bio, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2022

/s/ Roberto Cuca
Roberto Cuca
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)