#### 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, 2024 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE **ACT OF 1934** For the transition period from \_\_\_\_ to \_ Commission File Number: 001-39130 TELA Bio, Inc. (Exact name of registrant as specified in its charter) **Delaware** (State or other jurisdiction of 45-5320061 (I.R.S. Employer incorporation or organization) Identification No.) 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) Not applicable (Former name, former address and former fiscal year, if changed since last report) Securities registered pursuant to Section 12(b) of the Act: Trading Symbol Title of each class Name of each exchange on which registered Common Stock, \$0.001 par value per share 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). \( \times \text{Y by No.} \) 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 ⊠ 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.  $\Box$ 

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\square$  No  $\boxtimes$ As of November 1, 2024, the registrant had 39,388,443 shares of Common Stock, \$0.001 par value per share, outstanding

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") and the documents incorporated by reference herein contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, we may, through our officers and other authorized representatives, make certain forward-looking statements in publicly released materials, both written and oral, including statements contained in filings with the Securities and Exchange Commission, press releases, and our communications with our stockholders.

Forward-looking statements are neither statements of historical facts nor assurances of future performance, but instead discuss the future of our business, operations, future financial performance, future financial condition, plans, anticipated growth strategies, anticipated or perceived trends in our business, the industry in which we operate or the broader economy, and other objectives of management. 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," the negative of such terms, and other similar expressions although not all forward-looking statements contain these identifying words.

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:

- estimates regarding future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
- the commercial success and degree of market acceptance of our products;
- the introduction of new products or product enhancements by us or others in our industry, including new products which may be perceived to negatively impact the demand for our products now or in the future;
- our ability to expand, manage and maintain our direct sales and marketing organization and to market and sell our products in the U.S. and Europe;
- the performance of our exclusive contract manufacturer for our OviTex and OviTex PRS products, Aroa Biosurgery Ltd. ("Aroa"), in connection with the supply of product and in the development of additional products and product configurations 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 recruit 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;
- decreasing selling prices and pricing pressures;
- regulatory developments in the U.S. and European markets;
- the potential impact of healthcare reform in the U.S., including the Inflation Reduction Act of 2022, and measures being taken worldwide designed to reduce healthcare costs;
- the possible effects arising from pandemics, epidemics or outbreaks of a contagious illness, including coronavirus disease, influenza, or respiratory syncytial virus among others and associated economic disruptions, including the frequency of surgical procedures using our products, labor and hospital staffing shortages, supply

- chain integrity, and adverse healthcare economic factors affecting our products or the procedures in which they are used:
- the impact of external cybersecurity events, including ransomware attacks, infiltration and hacking and other system outages, affecting hospitals, third-party payors and other vendors within the healthcare industry may result in a decrease in surgical procedures that would utilize our products;
- the potential impact of supply delays of critical surgical and hospital supplies, including as a result of labor or
  work stoppages or extreme weather events, which may result in the deferral or reduction of surgical procedures
  that would utilize our products;
- the volatility of capital markets and other adverse macroeconomic factors, including due to inflationary pressures, interest rate and currency rate fluctuations, economic slowdown or recession, banking instability, monetary policy changes, geopolitical tensions or the outbreak of hostilities or war, including from the ongoing Russia-Ukraine conflict, the current conflicts in the Middle East (including any escalation or expansion) and increasing tensions between China and Taiwan;
- 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 recent and any 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, 2023 (our "Annual Report"), our subsequent 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.

You should refer to the section titled "Risk Factors" in our Annual Report, this Quarterly Report and any subsequent Quarterly Reports for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. 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.

#### PART I — FINANCIAL INFORMATION

#### **Item 1. Financial Statements**

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

	Sej	ptember 30, 2024	Dec	cember 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	\$	17,301	\$	46,729
Accounts receivable, net of allowances of \$230 and \$416		11,222		9,737
Inventory		13,600		13,162
Prepaid expenses and other current assets		2,009		2,098
Total current assets		44,132		71,726
Property and equipment, net		2,423		1,984
Intangible assets, net		1,834		2,119
Right-of-use assets		1,796		1,954
Other long-term assets		2,566		_
Restricted cash		265		265
Total assets	\$	53,016	\$	78,048
Liabilities and stockholders' (deficit) equity				
Current liabilities:				
Accounts payable	\$	2,479	\$	1,667
Accrued expenses and other current liabilities		14,379		15,300
Total current liabilities		16,858		16,967
Long-term debt		40,970		40,515
Other long-term liabilities		1,460		1,685
Total liabilities		59,288		59,167
Sec. 11, 11,				
Stockholders' (deficit) 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; 24,717,193 and				
24,494,675 shares issued and outstanding at September 30, 2024 and December 31, 2023,				
respectively		25		24
Additional paid-in capital		343,076		339,655
Accumulated other comprehensive income		149		91
Accumulated deficit		(349,522)	(	(320,889)
Total stockholders' (deficit) equity		(6,272)		18,881
Total liabilities and stockholders' (deficit) equity	\$	53,016	\$	78,048

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

	Th	ree months end	led S	eptember 30, 2023	Nine months ended Sept			eptember 30, 2023
Revenue	\$	18,957	\$	15,052	\$	51,651	\$	41,455
Cost of revenue (excluding amortization of intangible		- ,	•	- ,	•	- ,	•	,
assets)		6,004		4,568		16,099		12,682
Amortization of intangible assets		95		95		285		285
Gross profit		12,858		10,389		35,267		28,488
Operating expenses:								
Sales and marketing		16,472		14,474		50,691		42,517
General and administrative		3,683		3,728		11,133		10,834
Research and development		2,068		2,368		6,784		6,934
Total operating expenses		22,223		20,570		68,608		60,285
Other operating income:								
Gain on sale of product line		_		_		7,580		
Loss from operations		(9,365)		(10,181)		(25,761)		(31,797)
Other expense:								
Interest expense		(1,344)		(1,334)		(4,007)		(3,878)
Other income		337		558		1,135		1,901
Total other expense, net		(1,007)		(776)		(2,872)		(1,977)
Net loss	\$	(10,372)	\$	(10,957)	\$	(28,633)	\$	(33,774)
Net loss per common share, basic and diluted	\$	(0.42)	\$	(0.45)	\$	(1.16)	\$	(1.51)
Weighted average common shares outstanding, basic	_		_		_			
and diluted	2	24,703,578		24,483,664	2	4,648,933	2	22,322,256
Comprehensive loss:								
Net loss	\$	(10,372)	\$	(10,957)	\$	(28,633)	\$	(33,774)
Foreign currency translation adjustment		51		51		58		(15)
Comprehensive loss	\$	(10,321)	\$	(10,906)	\$	(28,575)	\$	(33,789)

# TELA Bio, Inc. Consolidated Statements of Stockholders' (Deficit) Equity Three and Nine Months Ended September 30, 2024 (In thousands, except share amounts) (Unaudited)

	Commo	n stoc	k	A	dditional paid-in	ccumulated other mprehensive	A	ccumulated	
	Shares	Am	ount		capital	income		deficit	Total
Balance at July 1, 2024	24,675,832	\$	25	\$	341,897	\$ 98	\$	(339,150)	\$ 2,870
Vesting of restricted stock units and exercise of stock options	14,702		_		_	_			_
Issuance of common stock under the employee stock purchase									
plan	31,025		_		117	_		_	117
Shares withheld for employee taxes	(4,366)		_		(19)	_		_	(19)
Foreign currency translation adjustment	_		_			51		_	51
Stock-based compensation expense	_				1,081	_		_	1,081
Net loss	_		_		_	_		(10,372)	(10,372)
Balance at September 30, 2024	24,717,193	\$	25	\$	343,076	\$ 149	\$	(349,522)	\$ (6,272)

				A	dditional	A	ccumulated other			
	Commo	n sto	ck		paid-in	col	mprehensive	Ac	cumulated	
	Shares Amo		Amount		capital		l income		deficit	Total
Balance at January 1, 2024	24,494,675	\$	24	\$	339,655	\$	91	\$	(320,889)	\$ 18,881
Vesting of restricted stock units and exercise of stock options	217,267		1		225		_			226
Issuance of common stock under the employee stock purchase										
plan	58,994		_		281		_		_	281
Shares withheld for employee taxes	(53,743)		_		(358)		_			(358)
Foreign currency translation adjustment	_		_		_		58		_	58
Stock-based compensation expense	_		_		3,273		_		_	3,273
Net loss	_		_				_		(28,633)	(28,633)
Balance at September 30, 2024	24,717,193	\$	25	\$	343,076	\$	149	\$	(349,522)	\$ (6,272)

# TELA Bio, Inc. Consolidated Statements of Stockholders' Equity Three and Nine Months Ended September 30, 2023 (In thousands, except share amounts) (Unaudited)

				A	dditional	A	ccumulated other		
	Commo	n stock		paid-in comprehensive Accumulate				cumulated	
	Shares	Amou	ınt		capital income def			deficit	Total
Balance at July 1, 2023	24,475,504	\$	24	\$	336,939	\$	84 \$	(297,042)	\$ 40,005
Vesting of share-based awards and exercise of stock options	2,002		_		1		_	_	1
Issuance of common stock under the employee stock purchase									
plan	10,602		—		88		_	_	88
Shares withheld for employee taxes	(530)		—		(5)		_	_	(5)
Foreign currency translation adjustment	_		—		_		51	_	51
Stock-based compensation expense	_		_		1,369		_	_	1,369
Net loss	_		_		· —		_	(10,957)	(10,957)
Balance at September 30, 2023	24,487,578	\$	24	\$	338,392	\$	135 \$	(307,999)	\$ 30,552

			Additional	Accumulated other		
	Commo	n stock	paid-in	comprehensive A	Accumulated	
	Shares Amount		capital	income	deficit	Total
Balance at January 1, 2023	19,165,027	\$ 19	\$ 288,361	\$ 150 \$	(274,225)	\$ 14,305
Vesting of share-based awards and exercise of stock options	119,240	_	101	_	_	101
Issuance of common stock under the employee stock purchase						
plan	10,602	_	88	_	_	88
Shares withheld for employee taxes	(26,481)		(285)	_	_	(285)
Foreign currency translation adjustment	_	_	_	(15)	_	(15)
Stock-based compensation expense			3,791	_		3,791
Sale of common stock, net of underwriting discounts,						
commissions and offering costs	5,219,190	5	46,336	_	_	46,341
Net loss	_	_	_	_	(33,774)	(33,774)
Balance at September 30, 2023	24,487,578	\$ 24	\$ 338,392	\$ 135 \$	(307,999)	\$ 30,552

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

(*,	Ni	ne months end	ed Sep	tember 30,
		2024		2023
Cash flows from operating activities:				
Net loss	\$	(28,633)	\$	(33,774)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation expense		461		362
Noncash interest expense		455		447
Amortization of intangible assets		285		285
Net changes in operating lease ROU assets and liabilities		(73)		(33)
Inventory excess and obsolescence charge		1,563		992
Stock-based compensation expense		3,273		3,791
Gain on sale of product line		(7,580)		_
Change in operating assets and liabilities:				
Accounts receivable, net		(1,745)		(1,456)
Inventory		(2,356)		(3,503)
Prepaid expenses and other current assets		524		361
Accounts payable		636		1,535
Accrued expenses and other current and long-term liabilities		(967)		1,373
Foreign currency transaction gain (loss)		93		(186)
Net cash used in operating activities		(34,064)		(29,806)
Cash flows from investing activities:				
Purchase of property and equipment		(725)		(406)
Proceeds from the sale of product line		5,366		
Net cash provided by (used in) investing activities		4,641		(406)
Cash flows from financing activities:				
Proceeds from sale of common stock, net				46,341
Proceeds from exercise of stock options		226		101
Payment of withholding taxes related to stock-based compensation to employees		(358)		(285)
Proceeds from issuance of common stock under the employee stock purchase plan		281		88
Net cash provided by financing activities		149		46,245
Effect of exchange rate on cash and cash equivalents		(154)		150
Net (decrease) increase in cash and cash equivalents and restricted cash		(29,428)		16,183
Cash and cash equivalents and restricted cash, beginning of period		46,994		42,019
Cash and cash equivalents and restricted cash, end of period	\$	17,566	\$	58,202
Supplemental disclosure of cash flow information:				
Cash paid during the period for interest	\$	3,552	\$	3,431
Supplemental disclosures of noncash investing and financing activities:	_	7		,
Property and equipment in accounts payable and accrued expenses and other current liabilities	\$	175	\$	23

#### **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 and TELA Bio GmbH, a company incorporated in Germany. 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.

#### (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 \$349.5 million as of September 30, 2024. The Company anticipates incurring additional losses until such time, if ever, it can generate sufficient revenue from its products to cover its expenses.

In March 2024, the Company sold its distribution rights for NIVIS Fibrillar Collagen Pack to MiMedx Group, Inc. in exchange for an initial \$5.0 million payment and additional future payments aggregating between a minimum of \$3.0 million and a maximum of \$7.0 million based on net sales of NIVIS during the first two years following its launch by MiMedx Group, Inc.

Subsequent to September 30, 2024, the Company completed an underwritten public offering which is described in Note 9, Subsequent Event.

The operations of the Company are subject to certain risks and uncertainties including, among others, the uncertainty of product development, the impact of macroeconomic conditions, including any lingering effects of the COVID-19 pandemic or other public health crises, general economic uncertainty, including as a result of inflationary pressures and the measures undertaken by various governments to address them, banking instability, monetary policy changes, geopolitical factors such as the ongoing Russia-Ukraine conflict, the current conflicts in the Middle East (including any escalation or expansion) and increasing tensions between China and Taiwan, cybersecurity events affecting or disrupting normal hospital operations, constraints on the supply of critical surgical and hospital supplies necessary to facilitate the surgical procedures in which our products are utilized, 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, 2023. Any reference in these notes to applicable guidance is meant to refer to generally accepted accounting principles ("GAAP") in the U.S. 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 Securities and Exchange Commission ("SEC"), which permits reduced disclosures for interim

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

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, 2023.

#### 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 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*, ("ASC 606"), 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 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 or other surgical facilities. 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.

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.

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

The following table presents revenue disaggregated by the Company's portfolio of products (in thousands):

	T	hree months en	ded Sept	tember 30,	I	Nine months end	led Sept	tember 30,
		2024		2023		2024		2023
OviTex	\$	12,463	\$	10,159	\$	34,122	\$	28,240
OviTex PRS		6,313		4,812		17,054		13,063
Other		181		81		475		152
Total revenue	\$	18,957	\$	15,052	\$	51,651	\$	41,455

Sales outside of the U.S. were \$2.8 million and \$1.7 million, respectively, for the three months ended September 30, 2024 and 2023 and \$7.5 million and \$4.2 million, respectively, for the nine months ended September 30, 2024 and 2023.

#### 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. The carrying amounts of the Company's Credit and Security Agreement approximates fair value due to its variable interest rate.

The Company follows the provisions of 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					
	activ for	Quoted prices in active markets for identical assets (Level 1)		Significant other observable inputs (Level 2)		ificant ervable puts vel 3)
September 30, 2024:						
Cash equivalents – money market fund	\$	13,786	\$	_	\$	_
December 31, 2023:						
,						
Cash equivalents – money market fund	\$	41,561	\$	_	\$	_

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

#### 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. In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share since dilutive shares are not assumed to have been issued if their effect is antidilutive. Therefore, the weighted-average shares used to calculate both basic and diluted net loss per 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.

	Nine months ende	d September 30,
	2024	2023
Stock options	2,128,862	2,202,264
Unvested restricted stock units	971,439	864,427
Common stock warrants	88,556	88,556
Total	3,188,857	3,155,247

#### 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 August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options and Derivatives and Hedging - Contracts in Entity's Own Equity ("ASU 2020-06")*. ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. The new guidance also modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those annual periods. The adoption of this guidance did not have a significant impact on the consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures*, which expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. This guidance is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024, with early adoption permitted, including adoption in any interim period. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, requiring entities to provide additional information in the income tax rate reconciliation and additional disclosures about income taxes paid. The new accounting guidance requires entities to disclose in their rate reconciliation table additional categories of information about federal, state and foreign income taxes and to provide more details about the reconciling items in

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

some categories if the items meet a quantitative threshold. This guidance is effective for annual periods beginning after December 15, 2024, and should be applied prospectively, but entities have the option to apply it retrospectively for each period presented. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

#### (4) Accrued Expenses and Other Current Liabilities

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

	<u>September 30, 2024</u>		December 31, 2023	
Compensation and related benefits	\$	7,854	\$	9,216
Third-party and professional fees		2,828		2,828
Amounts due to contract manufacturer		2,314		2,024
Current portion of operating lease liabilities		559		565
Research and development expenses		16		140
Other		808		527
Total accrued expenses and other current liabilities	\$	14,379	\$	15,300

#### (5) Long-term Debt

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

	Sep	September 30,		ember 31,
		2024		2023
MidCap term loan	\$	40,000	\$	40,000
End of term charge		2,000		2,000
Unamortized end of term charge and issuance costs		(1,030)		(1,485)
Long-term debt	\$	40,970	\$	40,515

#### 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, and certain lender parties thereto. The MidCap Credit Agreement consists of \$40.0 million in a term loan. Upon closing, the Company used a portion of the proceeds to repay borrowings under a previous credit facility and intends to use the remaining proceeds to fund operations and other general corporate purposes.

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.

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

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 loan matures on May 1, 2027 and bears 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 loan has a prepayment fee equal to 3.0% of the prepaid principal amount for the first year following the closing date of the MidCap term loan, 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 three and nine months ended September 30, 2024 was \$1.3 million and \$4.0 million, respectively, of which \$0.2 million and \$0.5 million, respectively, was related to the amortization of debt issuance costs. Interest expense associated with the MidCap Credit Facility recorded for the three and nine months ended September 30, 2023 was \$1.3 million and \$3.9 million, respectively, of which \$0.2 million and \$0.4 million, respectively, was related to the amortization of debt issuance costs.

#### (6) Stockholders' Equity

In November 2023, the Company entered into an Equity Distribution Agreement (the "2023 Equity Agreement") with Piper Sandler & Co, ("Piper") in connection with the establishment of an at-the-market offering program under which the Company may sell shares of its common stock, from time to time through Piper as sales agent, in an initial amount of up to \$50.0 million. The 2023 Equity Agreement superseded and replaced the Company's previous Equity Distribution Agreement with Piper dated December 18, 2020 (the "2020 Equity Agreement"), which is no longer effective. No sales were made under the 2023 Equity Agreement or the 2020 Equity Agreement during the nine months ended September 30, 2024 or 2023.

#### Warrants

The Company had the following warrants outstanding to purchase common stock at September 30, 2024:

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

There have been no grants, exercises or cancellations of warrants during the nine months ended September 30, 2024.

#### (7) Sale of Product Line

In March 2024, the Company entered into an Asset Purchase Agreement ("APA") with MiMedx Group, Inc. ("MDXG") to sell certain assets (the "Transaction") related to NIVIS Fibrillar Collagen Pack Device ("NIVIS"). These assets mainly

#### **Notes to Unaudited Interim Consolidated Financial Statements (Continued)**

included the Company's existing inventory of NIVIS, with a net carrying value of \$0.8 million, and certain intellectual property rights to sell NIVIS, with no carrying value. MDXG assumed the Company's existing supply agreements, including the minimum obligations for NIVIS that the Company entered into in 2022 ahead of the initial sales of NIVIS. In exchange for entering into the Transaction, the Company received an initial \$5.0 million upfront payment and is entitled to receive future revenue-sharing payments based on the net sales of NIVIS during the first two years following its launch by MDXG, which revenue-sharing payments would range from a minimum of \$3.0 million to a maximum of \$7.0 million in the aggregate. Any consideration in excess of \$3.0 million up to \$7.0 million is considered variable consideration that is fully constrained.

The Company accounted for the Transaction as a sale of a nonfinancial asset group in accordance with ASC 610-20 and followed the principals of ASC 606 to determine the consideration of \$8.4 million related to the Transaction. The Company transferred control of the nonfinancial asset group in March 2024 and recognized a gain of \$7.6 million on the consolidated statement of operations and comprehensive loss during the three months ended March 31, 2024. Additionally, the Company recorded the minimum revenue-share payment of \$3.0 million as a receivable at September 30, 2024, with \$0.4 million representing the current portion in prepaid expenses and other assets in the consolidated balance sheet and \$2.6 million representing the long-term portion in other long-term assets in the consolidated balance sheet. At each reporting date, the Company assesses the constraint of variable consideration and records increases in the transaction price in the period that the estimate of variable consideration changes. For the three and nine months ended September 30, 2024, no changes were made to the variable consideration.

#### (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, 2024, 907,293 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,			Nin	e months end	ded September 30,		
		2024		2023		2024		2023
Sales and marketing	\$	318	\$	507	\$	993	\$	1,375
General and administrative		607		670		1,804		1,861
Research and development		156		192		476		555
Total stock-based compensation	\$	1,081	\$	1,369	\$	3,273	\$	3,791

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.

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

The following table summarizes stock option activity:

	Number of shares	avei	Weighted rage exercise ce per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2024	2,162,453	\$	11.48	
Granted	259,900		6.86	
Exercised	(38,431)		5.88	
Canceled/forfeited	(255,060)		12.35	
Outstanding at September 30, 2024	2,128,862	\$	10.91	6.12
Vested and expected to vest at September 30, 2024	2,099,563	\$	10.94	6.08
Exercisable at September 30, 2024	1,612,281	\$	11.45	5.35

Included in outstanding options at September 30, 2024 were 319,684 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, 2024, the aggregate intrinsic value of both outstanding options and exercisable options was immaterial.

The weighted average grant-date fair value per share of options granted was \$4.67 during the nine months ended September 30, 2024. The aggregate intrinsic value of options exercised was immaterial and \$41,000 for the three and nine months ended September 30, 2024, respectively. At September 30, 2024, the total unrecognized compensation expense related to unvested employee and nonemployee stock option awards was \$2.8 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.2 years.

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, 2024
Expected dividend yield	_
Expected volatility	73.2 %
Risk-free interest rate	4.29 %
Expected term (in years)	6.14

#### Restricted Stock Units

The Company has issued service-based and performance-based restricted stock units ("RSUs"). Vesting of the service-based RSUs is based on the terms in each award agreement and is generally over four years. Vesting of the performance-based RSUs is subject to continued service through 2026 and the achievement of certain performance milestones for fiscal year 2026. The amount of performance-based RSUs that will vest can range from 0% to 110% of the original number of RSUs granted. Expense for the performance-based RSUs is not recognized until the performance conditions are deemed probable of achievement. The Company has not recorded any expense related to the performance-based RSUs.

#### Notes to Unaudited Interim Consolidated Financial Statements (Continued)

The following table summarizes the service-based RSUs for the Plan:

	Number of shares
Outstanding at January 1, 2024	657,054
Granted	411,825
Vested	(178,836)
Canceled/forfeited	(135,104)
Outstanding at September 30, 2024	754,939

The following table summarizes the performance-based RSUs for the Plan:

	Number of shares
Outstanding at January 1, 2024	250,149
Granted	_
Vested	_
Canceled/forfeited	(33,649)
Outstanding at September 30, 2024	216,500

Included in outstanding RSUs at September 30, 2024 were 115,210 RSUs 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). The weighted average grant-date fair value per RSU granted was \$6.63 during the nine months ended September 30, 2024. The aggregate intrinsic value of RSUs outstanding was \$2.5 million at September 30, 2024. The total unrecognized compensation expense at September 30, 2024 related to RSUs was \$4.6 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.6 years.

#### (9) Subsequent Event

On October 24, 2024, the Company completed an underwritten public offering of 14,670,000 shares of its common stock, including the exercise in full of the underwriters' option to purchase additional shares of common stock, at a price to the public of \$2.25 per share and, in lieu of common stock to investors who so chose, pre-funded warrants to purchase 5,800,000 shares of common stock at a public offering price of \$2.2499 per pre-funded warrant, which represents the per share public offering price for the shares of common stock less the \$0.0001 per share exercise price for each pre-funded warrant. The offering resulted in gross proceeds of \$46.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses and assuming no subsequent exercise of the pre-funded warrants. The exercise of the pre-funded warrants, if any, is not expected to provide significant additional funding to the Company.

### 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, 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, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report filed with the SEC on March 22, 2024. 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 (the "Exchange Act"). 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.

We are dedicated to building true partnerships with surgeons and healthcare providers to deliver solutions that provide both clinical and economic improvements. We believe that genuine collaboration with surgeons and healthcare providers results in the development of new solutions that empower patient care.

Our first portfolio of products, the OviTex Reinforced Tissue Matrix ("OviTex") which we first commercialized in the U.S. in July 2016 and in Europe in February 2019, 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.

Hernia repair is one of the most common surgeries performed in the U.S., representing approximately 1.1 million procedures annually. Based on the volume weighted average selling price of our OviTex products, we estimate the annual U.S. total addressable market opportunity for our OviTex products to be approximately \$1.5 billion.

Our OviTex portfolio consists of multiple product configurations intended to address various surgical procedures within hernia repair and abdominal wall reconstruction, including ventral, inguinal, and hiatal hernia repair. In addition, we have also designed an OviTex product specifically for use in laparoscopic and robotic-assisted hernia repair, which we market as OviTex LPR and began commercializing this product in November 2018. In February 2023, we launched two larger configurations of OviTex LPR, designed for ventral and incisional hernias. In April 2024, we launched OviTex IHR Reinforced Tissue Matrix, a new OviTex configuration specifically designed to address inguinal hernia procedures performed robotically and laparoscopically.

We have also focused on evaluating and publishing clinical data on the effectiveness and safety of our OviTex products. To date, there have been over thirty published or presented works relating to these clinical findings, either by us or a third-party evaluating the OviTex product. 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, or SSOs, were observed in 38% of the study population. Of the enrolled patients, 78% 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 statistically significant and clinically meaningful improvements in their quality of life and perceived health based on patient responses to the EuroQol-5 Dimension (EQ-5D) health assessment and the validated 12-question Hernia-Related Quality of Life survey (HerQLes). In addition to the BRAVO study and other current clinical initiatives, we also commenced enrollment in May 2021 for our BRAVO II study, a prospective study evaluating the use of OviTex in robot-assisted ventral and inguinal hernia repairs.

Our second portfolio of products, the OviTex PRS Reinforced Tissue Matrix, ("OviTex PRS") which we first commercialized in the U.S. in May 2019, addresses unmet needs in plastic and reconstructive surgery. 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. Our OviTex PRS portfolio consists of three product configurations with two or three layers of high-quality tissue derived from ovine rumen, which is reinforced with either permanent or resorbable polymer for added strength, stabilization, and controlled stretch. These products are designed to improve outcomes by facilitating functional tissue remodeling while controlling the degree and direction of stretch. In August 2023, we announced the launch of our OviTex PRS Long-Term Resorbable product configuration, which was designed to enhance the OviTex PRS portfolio with specific design features including bi-directional stretch and a fully resorbable, long-term polymer for reinforcement.

Our OviTex PRS portfolio is supported by non-human primate data that demonstrated more rapid tissue integration and tissue remodeling compared to the market leading biologic matrix used in this indication. Based on the current sales of biologic matrices in the U.S., we estimate the annual U.S. current addressable market opportunity for our OviTex PRS products to be approximately \$700 million.

Our OviTex products have received 510(k) clearances from the U.S. Food and Drug Administration, ("FDA") which clearances were obtained and are currently held by our exclusive contract manufacturer of these products, Aroa. In April 2019, our first OviTex PRS products received 510(k) clearance from the FDA, which clearance was initially obtained by Aroa and is currently held by us. In March 2023, we received an additional 510(k) clearance for our OviTex PRS Long-Term Resorbable device, which is currently held by us. In May 2024, we received clearance of a Special 510(k) related to minor changes to our OviTex PRS Permanent and Short-Term Resorbable devices. In October 2024, we received approval from the FDA for our investigational device exemption application relating to the study of the safety and effectiveness of our OviTex PRS product in implant-based breast reconstruction. We continue to evaluate and finalize the clinical study protocol and anticipate additional FDA interactions related to such to support a pre-market application to obtain an indication for OviTex PRS for use in breast reconstruction.

We also continue to expand our service offerings and diversify our supplier base as we continue to create a soft tissue preservation and restoration portfolio, including through the development of complimentary solutions in our indications such as atraumatic mesh fixation devices or surgical wound management and infection control. In September 2023, we entered into a distribution agreement with Advanced Medical Solutions Limited, a company registered in England, to distribute their LiquiFix Hernia Mesh Fixation Devices (LiquiFix FIX8<sup>TM</sup> and LiquiFix Precision<sup>TM</sup>). In March 2024, we announced the full commercial launch of LiquiFix in the U.S. We previously co-developed and commercialized our NIVIS Fibrillar Collagen Pack, ("NIVIS") an absorbent matrix of Type I and Type III bovine collagen designed to manage moderately to heavily exudating wounds and to control minor bleeding, in partnership with Regenity Biosciences. In March 2024, we sold our distribution rights to MiMedx Group, Inc. in exchange for an initial \$5.0 million payment and additional future payments aggregating between a minimum of \$3.0 million and a maximum of \$7.0 million based on net sales of NIVIS during the first two years following its launch by MiMedx Group, Inc. We continue to assess additional strategic partnerships with medical device companies whereby we may enter into distribution, product development and/or licensing agreements for new products complimentary to, or related to, existing and future products in our distribution channel.

We have a broad portfolio of intellectual property protecting our products that we believe, when combined with the proprietary manufacturing processes associated with our products and our know-how, provides significant barriers to entry. Our intellectual property applies to our differentiated product construction and materials. In addition, we believe our exclusive manufacturing and long-term supply and license agreement with Aroa creates a competitive advantage by allowing us to secure an exclusive supply of ovine rumen at a low cost. Ovine rumen, the forestomach of a sheep, is the source of the biologic material used in our OviTex and OviTex PRS products. We use biologic material from ovine rumen because of its plentiful supply, optimal biomechanical profile and open collagen architecture that allows for rapid cellular infiltration. Our OviTex products are manufactured by Aroa at their FDA registered and ISO 13485 compliant facility in Auckland, New Zealand. We purchase product from Aroa at a fixed transfer cost as a percentage of Aroa's cost of goods sold, and, with the exception of our recent IHR-dedicated products, equals 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.

We market our products through a single direct sales force, predominantly in the U.S., 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, 2024, we had 75 sales territories in the U.S. We believe we can enhance the productivity of our sales force by improving customer segmentation and targeting, implementing and further refining our proprietary training programs, leveraging support from our medical education and medical affairs functions to drive physician awareness, education and clinical understanding of our products, and utilizing engagement analytics to support further product development and enhancement opportunities. Additionally, we have contracted with three national group purchasing organizations, ("GPOs") covering our OviTex and OviTex PRS products and plan to continue to contract with additional GPOs and other integrated delivery networks ("IDNs") to increase access to and penetration of hospital accounts.

We are currently devoting research and development resources to develop additional variations of our OviTex and OviTex PRS product lines, including larger versions of our current product configurations, the development of configurations with longer-acting resorbable polymers and other potential product and packaging enhancements to extend the shelf life of our products. In addition, we also continue to explore the development of lower-cost, higher-margin resorbable polymer-based devices targeting our current indications. 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 markets. We intend to continue to make investments in research and development efforts to develop improvements and enhancements to our product portfolio. 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 by us of single digit percentage royalties or other product acquisition costs.

The vast majority of our revenue to date has been generated by the sale of our OviTex products. Our revenue increased by \$3.9 million, or 26%, from \$15.1 million for the three months ended September 30, 2023 to \$19.0 million for the three months ended September 30, 2024 and by \$10.2 million, or 25%, from \$41.5 million for the nine months ended September 30, 2023 to \$51.7 million for the nine months ended September 30, 2024. Our net loss decreased by \$0.6 million, or 5%, from \$11.0 million for the three months ended September 30, 2023 to \$10.4 million for the three months ended September 30, 2024. Our net loss decreased by \$5.1 million, or 15%, from \$33.8 million to \$28.6 million for the nine months ended September 30, 2024 due to the gain on sale of NIVIS. We have not been profitable since inception and as of September 30, 2024, we had an accumulated deficit of \$349.5 million. Starting in the third quarter of 2024, we implemented certain cost-cutting measures which are expected to result in reduced operating expenses in future periods. However, we expect to incur losses for the foreseeable future.

#### Business Update Regarding Macroeconomic Conditions and COVID-19

Our business, results of operations and commercial operations have been impacted by macroeconomic conditions, including the COVID-19 pandemic, as well as, to a lesser extent, inflationary pressures, fluctuations in foreign currency

in the jurisdictions in which we operate, banking instability, monetary policy changes and geopolitical conflicts. These factors have and may continue to impact us in the following ways:

COVID-19: Our business was directly impacted by the COVID-19 pandemic, including due to government restrictions on elective procedures and surgical staffing challenges that lead to the deferral of elective surgeries and lower surgical procedural volumes overall. We believe that surgical procedures have started to normalize to pre-pandemic levels and that hospital systems have begun to address any remaining backlog of procedures previously delayed due to the COVID-19 pandemic. However, the true economic effects of the COVID-19 pandemic may have created other labor and financial strains on healthcare systems that continue to reduce procedural volumes.

General Economic Uncertainty: Continued concerns about the systemic impact of a potential economic downturn or recession, increasing interest rates, further economic downturn or banking instability, monetary policy changes and geopolitical issues, including the ongoing Russia-Ukraine conflict, the current conflict in Israel and Gaza (including any escalation or expansion) and increasing tensions between China and Taiwan, have contributed to increased market volatility and diminished expectations for economic growth in the world. Due to this uncertainty and other factors, we have experienced high volatility in our stock price over the prior year. Continued uncertainty, perception of worsening market conditions and the introduction of new products which may, or may be perceived to, negatively impact the demand for our products now or in the future could result in a decline in our stock price, high inflation, an increase in our cost of capital and an adverse effect on our ability to access the capital markets in the future on terms acceptable to us or at all.

External Cybersecurity Events: The sale of our medical products is correlated to the frequency of surgical procedural volumes at current and prospective hospital accounts. During the second quarter of 2024, we became aware of multiple cybersecurity events, including ransomware attacks and other similar system disruptions and outages, in the U.S. and Europe that adversely impacted the procedural volumes at current customer accounts, including those affiliated across one of our GPOs. To the extent current or future cybersecurity events continue to impact the hospital systems we serve, or otherwise affect third-party payors or other vendors within the healthcare industry critical to the patient care, we may experience additional reductions in procedural volumes that lead to lower sales volume for our products.

External Supply Constraints for Critical Surgical Supplies: Any disruptions to the supply of critical surgical supplies, including, for example, IV fluids, could lead to deferrals of elective surgical procedures, including those utilizing our products. To the extent that our current and prospective hospital customers experience significant shortages of these critical supplies, whether due to extreme weather events, labor or work stoppages, or other supply chain disruptions, we may experience reductions in procedural volumes that lead to lower sales volume for our products.

Financial Strain: Market acceptance of our medical products in the U.S. and other countries is dependent upon the procurement practices of our customers, patient need for our products and procedures and the reimbursement of patients' medical expenses by government healthcare programs and third-party payors. The continuing uncertainty surrounding macroeconomic conditions and financial markets, including the financial strain suffered by hospital customers during the COVID-19 pandemic, may adversely affect demand for our products and procedures and result in lower reimbursement rates or coverage for our products, resulting in lower sales volume and downward pricing pressure on our products and slower adoption of new products.

#### **Components of Our Results of Operations**

#### Revenue

The majority of our revenue consists of direct sales of our products to hospital accounts in the U.S. 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 macroeconomic pressures described in this Quarterly Report may impair our ability to continue to generate revenue and expand our customer base at historic rates.

#### Cost of Revenue

Cost of revenue primarily consists of the costs of licensed products, charges related to excess and obsolete inventory adjustments, royalties and costs related to shipping. We purchase product from Aroa at a fixed transfer cost as a percentage of Aroa's cost of goods, which, with the exception of our recent IHR-dedicated products, equals 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. Any delay in volume growth, whether due to macroeconomic pressures or otherwise, 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 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 margin has been, and we expect it will continue to be, affected by a variety of factors, including sales volume, royalties and inventory excess and obsolescence costs. Our gross profit may increase to the extent our revenue grows.

#### Sales and Marketing Expenses

Sales and marketing expenses consist of 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, market research, as well as travel and training expenses.

We expect future sales and marketing expenses will primarily depend on our ability to drive operational leverage and efficiencies from our expanded commercial organization. We expect our sales and marketing expenses to continue to decrease as a percentage of revenue, 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 future general and administrative expenses will primarily depend on our ability to efficiently execute on our growth initiatives. 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, costs incurred from license agreements with no alternative future uses, laboratory materials and supplies and an allocation of related facilities costs. We expense research and development costs as they are incurred.

We expect future research and development expenses will primarily depend on our ability to efficiently develop new products, enhance existing products and conduct research to generate clinical data in support of new or expanded indications for our products. 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 and clinical trial initiatives.

#### Gain on Sale of Product Line

In March 2024, we entered into an asset purchase agreement with MiMedx Group, Inc. to sell certain assets related to NIVIS. These assets mainly included our existing inventory of NIVIS, with a net carrying value of \$0.8 million, and certain intellectual property rights to sell NIVIS, with no carrying value. We transferred control of the nonfinancial asset group in March 2024 and recognized a gain of \$7.6 million on the consolidated statement of operations and comprehensive loss during the nine months ended September 30, 2024. At each reporting date, we assess the constraint of variable consideration and record increases in the transaction price in the period that the estimate of variable consideration changes.

#### Interest Expense

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

#### Other Income

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

#### **Results of Operations**

#### Comparison of the Three Months Ended September 30, 2024 and 2023

	Three months ended September 30,				Change		
	2024			ands, except pe	<u>Dollar</u>	Percentage	
		(III	mous	ands, except pe	icemages)		
Revenue	\$	18,957	\$	15,052	\$ 3,905	26 %	
Cost of revenue (excluding amortization of intangible assets)		6,004		4,568	1,436	31	
Amortization of intangible assets		95		95		_	
Gross profit		12,858		10,389	2,469	24	
Gross margin		68 %		69 %			
Operating expenses:							
Sales and marketing		16,472		14,474	1,998	14	
General and administrative		3,683		3,728	(45)	(1)	
Research and development		2,068		2,368	(300)	(13)	
Tatal an anatin a samanasa		22 222		20.570	1 (52	0	
Total operating expenses	_	22,223	_	20,570	1,653	8	
Loss from operations		(9,365)		(10,181)	816	(8)	
Other expense:							
Interest expense		(1,344)		(1,334)	(10)	1	
Other income		337		558	(221)	(40)	
Total other expense		(1,007)		(776)	(231)	30	
Net loss	\$	(10,372)	\$	(10,957)	\$ 585	(5)%	

#### Revenue

Revenue increased by \$3.9 million, or 26%, to \$19.0 million for the three months ended September 30, 2024 from \$15.1 million for the three months ended September 30, 2023. The increase in revenue was primarily driven by an increase in unit sales of our products, which resulted in the addition of new customers and growing international sales. This growth was partially offset by a decrease in average selling prices caused by product mix as the share of smaller-sized units

increased. During the three months ended September 30, 2024, we sold 4,767 units of OviTex as compared to 3,426 units of OviTex during the three months ended September 30, 2023, a 39% increase in unit sales volume. Additionally, we sold 1,293 units of OviTex PRS during the three months ended September 30, 2024 as compared to 896 units during the three months ended September 30, 2023, a 44% increase in unit sales volume.

#### Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by \$1.4 million, or 31%, to \$6.0 million for the three months ended September 30, 2024 from \$4.6 million for the three months ended September 30, 2023. The increase in cost of revenue was primarily the result of an increase in products purchased to support demand from our higher unit sales and a higher charge for excess and obsolete inventory.

#### Amortization of Intangible Assets

Amortization of intangible assets was \$95,000 for both the three months ended September 30, 2024 and 2023.

#### Gross Margin

Gross margin decreased to 68% for the three months ended September 30, 2024 from 69% for the three months ended September 30, 2023. The decrease was primarily due to a higher charge for excess and obsolete inventory as a percentage of revenue.

#### Sales and Marketing

Sales and marketing expenses increased by \$2.0 million, or 14%, to \$16.5 million for the three months ended September 30, 2024 from \$14.5 million for the three months ended September 30, 2023. The increase was primarily due to higher compensation costs, including increased severance costs, and additional consulting and travel expenses.

#### General and Administrative

General and administrative expenses were \$3.7 million for both the three months ended September 30, 2024 and 2023. The slight decrease was due to lower insurance expense, professional fees and compensation and benefits which offset higher software-related costs and banking fees.

#### Research and Development

Research and development expenses decreased by \$0.3 million, or 13%, to \$2.1 million for the three months ended September 30, 2024 from \$2.4 million for the three months ended September 30, 2023. The decrease was primarily due to lower study and development costs which offset higher compensation and benefits.

#### Interest Expense

Interest expense was \$1.3 million for both the three months ended September 30, 2024 and 2023.

#### Other Income

Other income decreased by \$0.2 million, or 40%, to \$0.3 million for the three months ended September 30, 2024 from \$0.6 million for the three months ended September 30, 2023. The decrease was primarily due to lower interest income as a result of lower cash balances.

#### **Results of Operations**

#### Comparison of the Nine months Ended September 30, 2024 and 2023

	Nine months ended September 30,				Change		
	2024		in thousands, except		<u>Dollar</u>	<u>Percentage</u>	
Revenue	\$	51,651	\$	41,455	\$ 10,196	25 %	
Cost of revenue (excluding amortization of intangible assets)		16,099		12,682	3,417	27	
Amortization of intangible assets		285		285		_	
Gross profit		35,267		28,488	6,779	24	
Gross margin		68 %	6	69 %			
Operating expenses:							
Sales and marketing		50,691		42,517	8,174	19	
General and administrative		11,133		10,834	299	3	
Research and development		6,784		6,934	(150)	(2)	
Total operating expenses		68,608		60,285	8,323	14	
Other operating income:							
Gain on sale of product line		7,580		_	7,580	NA	
Loss from operations		(25,761)		(31,797)	6,036	(19)	
Other expense:							
Interest expense		(4,007)		(3,878)	(129)	3	
Other income		1,135		1,901	(766)	(40)	
Total other expense		(2,872)		(1,977)	(895)	45	
Net loss	\$	(28,633)	\$	(33,774)	\$ 5,141	(15)%	

#### Revenue

Revenue increased by \$10.2 million, or 25%, to \$51.7 million for the nine months ended September 30, 2024 from \$41.5 million for the nine months ended September 30, 2023. The increase in revenue was primarily driven by an increase in unit sales of our products due to our expanded commercial organization, which resulted in the addition of new customers and growing international sales. This growth was partially offset by a decrease in average selling prices caused by product mix as the share of smaller-sized units increased. In addition, we estimate that additional forecasted revenue was negatively impacted as a result of two external cybersecurity events, each of which reduced surgeries at certain facilities during the second quarter of 2024. During the nine months ended September 30, 2024, we sold 13,034 units of OviTex as compared to 9,704 units of OviTex during the nine months ended September 30, 2023, a 34% increase in unit sales volume.

Additionally, we sold 3,467 units of OviTex PRS during the nine months ended September 30, 2024 as compared to 2,484 units during the nine months ended September 30, 2023, a 40% increase in unit sales volume.

#### Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by \$3.4 million, or 27%, to \$16.1 million for the nine months ended September 30, 2024 from \$12.7 million for the nine months ended September 30, 2023. The increase in cost of revenue was primarily the result of an increase in products purchased to support demand from our higher unit sales and a higher charge for excess and obsolete inventory.

#### Amortization of Intangible Assets

Amortization of intangible assets was \$0.3 million for both the nine months ended September 30, 2024 and 2023.

#### Gross Margin

Gross margin decreased to 68% for the nine months ended September 30, 2024 from 69% for the nine months ended September 30, 2023. The decrease was primarily due to a higher charge for excess and obsolete inventory as a percentage of revenue.

#### Sales and Marketing

Sales and marketing expenses increased by \$8.2 million, or 19%, to \$50.7 million for the nine months ended September 30, 2024 from \$42.5 million for the nine months ended September 30, 2023. The increase was primarily due to higher compensation costs, including increased severance costs from a third quarter reorganization, additional travel and consulting expenses, additional employee-related costs due to an increase in headcount and a marketing distribution fee which offset a decrease in marketing expenses.

#### General and Administrative

General and administrative expenses increased by \$0.3 million, or 3%, to \$11.1 million for the nine months ended September 30, 2024 from \$10.8 million for the nine months ended September 30, 2023. The increase was primarily due to higher compensation costs and employee-related costs due to an increase in headcount which offset a decrease in professional fees and insurance.

#### Research and Development

Research and development expenses decreased by \$0.2 million, or 2%, to \$6.8 million for the nine months ended September 30, 2024 from \$6.9 million for the nine months ended September 30, 2023. The decrease was primarily due to lower study and outsourced development costs which offset higher compensation costs due to an increase in headcount.

#### Gain on Sale of Product Line

In March 2024, we entered into an asset purchase agreement with MiMedx Group, Inc. to sell certain assets related to NIVIS. These assets mainly included our existing inventory of NIVIS, with a net carrying value of \$0.8 million, and certain intellectual property rights to sell NIVIS, with no carrying value. We transferred control of the nonfinancial asset group in March 2024 and recognized a gain of \$7.6 million during the nine months ended September 30, 2024.

#### Interest Expense

Interest expense increased by \$0.1 million, or 3%, to \$4.0 million for the nine months ended September 30, 2024 from \$3.9 million for the nine months ended September 30, 2023 due to an increase to the variable component of our interest rate.

#### Other Income

Other income decreased by \$0.8 million, or 40%, to \$1.1 million for the nine months ended September 30, 2024 from \$1.9 million for the nine months ended September 30, 2023. The decrease was primarily due to lower interest income as a result of lower cash balances.

#### **Liquidity and Capital Resources**

#### Overview

As of September 30, 2024, we had cash and cash equivalents of \$17.3 million, working capital of \$27.3 million and an accumulated deficit of \$349.5 million. As of December 31, 2023, we had cash and cash equivalents of \$46.7 million, working capital of \$54.8 million and an accumulated deficit of \$320.9 million.

In March 2024, we sold our distribution rights for NIVIS to MiMedx Group, Inc. in exchange for an initial \$5.0 million payment and additional future payments aggregating between a minimum of \$3.0 million and a maximum of \$7.0 million based on net sales of NIVIS during the first two years following its launch by MiMedx Group, Inc.

Subsequent to September 30, 2024, we completed an underwritten public offering of 14,670,000 shares of our common stock, including the exercise in full of the underwriters' option to purchase additional shares, at a price to the public of \$2.25 per share and, in lieu of common stock to investors who so chose, pre-funded warrants to purchase 5,800,000 shares of common stock at a public offering price of \$2.2499 per pre-funded warrant, which represents the per share public offering price for the shares of common stock less the \$0.0001 per share exercise price for each pre-funded warrant. The offering resulted in gross proceeds of \$46.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses and assuming no exercise of the pre-funded warrants. The exercise of the pre-funded warrants, if any, is not expected to provide significant additional funding to us.

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, 2024, 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. Upon closing, we used a portion of the proceeds to repay borrowings under a previous credit facility and intend to use the remaining proceeds to fund operations and other general corporate purposes.

Based on our current business plan, we believe that our existing cash resources, inclusive of the proceeds received in the underwritten public offering described above, 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. Cash used in operating activities during the remaining interim period of 2024 is expected to decrease primarily due to the combination of our forecasted growth in revenue and constraint of operating spend, however, we can provide no assurance that our expectations will be achieved. Starting in the third quarter of 2024, we implemented certain cost-cutting measures which are expected to result in reduced operating expenses in future periods. To the extent that these sources are insufficient to satisfy our liquidity requirements, despite our recent cost-cutting measures, we may seek to sell common or preferred equity or debt securities or enter into a new credit facility. In November 2023, we entered into a new Equity Distribution Agreement (the "2023 Equity Agreement") with Piper Sandler & Co. ("Piper") in connection with the establishment of an at-the-market offering program under which we may sell shares of our common stock, from time to time through Piper as sales agent, in an initial amount of up to \$50.0 million. No sales were made under the 2023 Equity Agreement during the nine months ended September 30, 2024. 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 stemming from macroeconomic conditions, including those related to banking instability, monetary policy changes, increasing interest rates or other factors. If we are unable to obtain adequate financing, when needed, 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)		2024		2023
Cash used in operating activities	\$	(34,064)	\$	(29,806)
Cash provided by (used in) investing activities		4,641		(406)
Cash provided by financing activities		149		46,245
Effect of exchange rate changes on cash and cash equivalents		(154)		150
Net (decrease) increase in cash and cash equivalents and restricted		,		
cash	\$	(29,428)	\$	16,183

#### **Operating Activities**

During the nine months ended September 30, 2024, we used \$34.1 million of cash in operating activities, resulting from our net loss of \$28.6 million, non-cash items of \$1.6 million and the change in operating assets and liabilities of \$3.8 million. Our non-cash items were comprised of the gain on sale of NIVIS of \$7.6 million offset by stock-based compensation expense of \$3.3 million, our excess and obsolete inventory charge of \$1.6 million, depreciation and amortization expense of \$0.7 million and noncash interest expense of \$0.5 million. The change in our operating assets and liabilities was primarily related to changes in inventory and accounts receivable partially offset by increases in accounts payable.

During the nine months ended September 30, 2023, we used \$29.8 million of cash in operating activities, resulting from our net loss of \$33.8 million and the change in operating assets and liabilities of \$1.9 million, offset by non-cash items of \$5.8 million. Our non-cash items were comprised of stock-based compensation expense of \$3.8 million, our excess and obsolete inventory charge of \$1.0 million, depreciation and amortization expense of \$0.6 million and noncash interest expense of \$0.4 million. The change in our operating assets and liabilities was primarily related to increases in accounts receivable and inventory 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, 2024, cash provided by investing activities was \$4.6 million consisting of proceeds received from the sale of NIVIS of \$5.4 million offset by \$0.7 million in purchases of property and equipment.

During the nine months ended September 30, 2023, cash used in investing activities was \$0.4 million consisting of purchases of property and equipment.

#### Financing Activities

During the nine months ended September 30, 2024, cash provided by financing activities was \$0.1 million, consisting primarily of proceeds received from the exercise of stock options and from the issuance of common stock under the employee stock purchase plan partially offset by the payment of withholding taxes related to stock-based compensation to employees.

During the nine months ended September 30, 2023, cash provided by financing activities was \$46.2 million, consisting primarily of \$46.3 million in proceeds received from the sale of our common stock partially offset by the payment of withholding taxes related to stock-based compensation to employees.

#### 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 consists of \$40.0 million in a term loan. Upon closing, we used a

portion of the proceeds to repay borrowings under a previous credit facility and intend to use the remaining proceeds to fund operations and other general corporate purposes.

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 loan matures on May 1, 2027 and bears 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 loan has a prepayment fee equal to 3.0% of the prepaid principal amount for the first year following the closing date of the MidCap term loan, 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, 2024, there were no significant changes to our commitments and future minimum contractual obligations as set forth in our Annual Report.

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

The Critical Accounting Policies and Significant Judgments and Estimates included in our 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. Following the events relating to Silicon Valley Bank in 2023, we established a redundant account at a high-credit-quality financial institution to mitigate liquidity risk to our cash and cash equivalents from any

further instability in the financial industry. We have reviewed the consolidated financial statements of these financial 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. 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 of this Quarterly Report 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 \$0.3 million increase to our interest expense for the nine months ended September 30, 2024.

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

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

**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.

#### Rule 10b5-1 and Non-Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2024, none of our directors or officers adopted, terminated or modified a "Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K of the Exchange Act.

#### Item 6. Exhibits.

The following exhibits are being filed herewith:

#### **EXHIBIT INDEX**

Exhibit No.	<u>Exhibit</u>
10.1*	Addendum to the Second Amended and Restated License, Product Development and Supply Umbrella
	Agreement, dated August 1, 2024, by and between the Company and Aroa Biosurgery Ltd. (filed herewith).
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).

<sup>\*</sup>Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

#### **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.

[\*\*\*] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

### ADDENDUM TO THE SECOND AMENDED AND RESTATED LICENSE, PRODUCT DEVELOPMENT AND SUPPLY UMBRELLA AGREEMENT

This Addendum to the Second Amended and Restated License, Product Development and Supply Umbrella Agreement (this "Addendum"), is made as of the 1<sup>st</sup> day of August, 2024, by and between TELA Bio, Inc. ("TELA Bio"), and Aroa Biosurgery Limited ("Aroa"), and sets out the terms of TELA Bio's and Aroa's agreement with respect to certain terms applicable to the LPR, PRS and IHR Product lines (as defined below in this Addendum).

WHEREAS, TELA Bio and Aroa are parties to that certain Second Amended and Restated License, Product Development and Supply Umbrella Agreement dated as of July 16, 2015, as amended through the date hereof and which includes (but without limitation) the addenda thereto dated as of September 21, 2017, January 3, 2019, August 27, 2019, February 21, 2020, and August 13, 2020 (together, the "Umbrella Agreement");

WHEREAS, TELA Bio and Aroa will, contemporaneously with this Addendum, enter into three separate Development Agreements and Exhibits (Nos. 13, 14 and 15) relating to the development of new product configurations, including those relating to extensions of the parties' LPR, PRS and IHR Product lines; and

WHEREAS, TELA Bio and Aroa desire to amend the Umbrella Agreement in connection with entering into such Development Agreements to consolidate and clarify the application of certain terms relating to such LPR, PRS and IHR Product lines.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, TELA Bio and Aroa hereby agree as follows:

1. All prior references to the "Restella Product" (plural or singular) in the Umbrella Agreement, including any Addenda thereto, shall be deleted and replaced with reference to the "PRS Product", provided however that the name of each PRS Product for the purposes of, or within, the Product Exhibit for that Product shall remain unchanged.

Reference to "Restella Product Clearance" in clauses 4 and 5 of the 21 February 2020 addendum to the Umbrella Agreement shall be deleted and replaced with "the regulatory clearance or approval for the PRS Product", provided however that the definition of "Aroa Restella Obligations" shall remain unchanged.

For purposes of the Umbrella Agreement, "PRS Product" shall mean any Product configuration set forth on Exhibit A hereto and any future Products that are expressly identified as a "PRS Product" in any future Addenda, Development Agreements and/or Product Exhibits between the Parties.

- References to "LPR Product" (plural or singular) in section 8.5(b) of the Umbrella Agreement shall
  mean any Product configuration set forth on Exhibit B hereto and any future Products that are
  expressly identified as a "LPR Product" in any future Addenda, Development Agreements and/or
  Product Exhibits between the Parties.
- 3. The parties agree that the following clarifications and amendments to the Umbrella Agreement, including any Addenda thereto, shall apply to each IHR Product (as defined below):

- a. [\*\*\*].
- b. With respect to the IHR Products, the Transfer Price shall equal [\*\*\*] % of COGS for each such unit of Product, but if agreed by the parties the Transfer Price shall be [\*\*\*].
- c. Solely with respect to the IHR Products, the third and fourth sentences of clause 8.5(b) are hereby amended and restated as follows:

"If the Annual Revenue Sharing Amount attributable to IHR Products is more than the Actual CY Payments, TELA Bio shall pay such difference to Aroa within thirty (30) days following the date of such summary. If the Annual Revenue Sharing Amount is less than the Actual CY Payments, then, within thirty (30) days following the date of such summary, Aroa shall pay to TELA Bio an amount equal to the lesser of (i) the Actual CY Payments less the aggregate Transfer Prices paid for the IHR Products sold by TELA Bio during such calendar year, or (ii) the Actual CY Payments less the Annual Revenue Sharing Amount attributable to IHR Products. For the purposes of this clause 8.5(b), the "Actual CY Payments" means the sum of (i) the aggregate Transfer Prices paid for the IHR Products sold by TELA Bio during such calendar year and (ii) the aggregate Quarterly True Up Amounts attributable to the IHR Products paid to Aroa for such calendar year."

- d. For purposes of the Umbrella Agreement, "IHR Product" shall mean any Product configuration set forth on Exhibit C hereto and any future Products that are expressly identified as a "IHR Product" in any future Addenda, Development Agreements and/or Product Exhibits between the Parties.
- e. For the avoidance of doubt, this clause 4 of this Addendum shall supersede the terms set forth in clause 9 of the Development Agreement for ERT-G INGUINAL, effective 1 March 2024, in its entirety.

Capitalized terms used but not defined in this Addendum have the meanings given to those terms in the Umbrella Agreement.

Except as agreed herein, the provisions of the Umbrella Agreement (including any prior addenda thereto) are not amended and continue to be in full force and effect.

This Addendum shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to any conflict of law provisions.

This Addendum may be executed in separate counterparts, each of which shall be an original and all of which taken together shall constitute one and the same agreement.

Executed signature pages to this Addendum may be delivered by facsimile or electronic mail and any signature page so delivered shall be deemed to be an original.

In Witness Whereof, and intending to be legally bound, the parties have caused this Agreement to be executed by their respective authorized officers as of the date first set forth above.

TELA BIO, INC.

By: /s/ Antony Koblish

Name: Antony Koblish

Title: President & CEO

AROA BIOSURGERY LIMITED

By: /s/ Brian Ward

Name: Brian Ward

Title: Chief Executive Officer

Exhibit A

**PRS Products** 

[\*\*\*]

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***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.
Exhibit B
LPR Products
***]
5

Exhibit C

**IHR Products** 

[\*\*\*]

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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 8, 2024

/s/ Antony Koblish

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

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 8, 2024

/s/ Roberto Cuca

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

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, 2024, 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 8, 2024

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

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, 2024, 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 8, 2024

/s/ Roberto Cuca

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