## 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 June 30, 2021

OR

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

For the transition period from to

Commission file number: 001-37526

# **TELA Bio, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation or organization)

1 Great Valley Parkway, Suite 24 Malvern, Pennsylvania **45-5320061** (I.R.S. Employer Identification Number)

> **19355** (Zip Code)

(Address of principal executive offices)

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

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

Title of each class:Trading SymbolName of each exchange on which registered:Common Stock, \$0.001 par value per shareTELAThe 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.  $\square$  Yes  $\square$  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 (222.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  $\square$  Yes  $\square$  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  $\Box$ 

Non-accelerated filer 🛛

Accelerated filer  $\Box$ Smaller reporting company  $\boxtimes$ Emerging growth company  $\boxtimes$ 

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 🗆 No 🖾

As of August 3, 2021, the registrant had 14,472,095 shares of Common Stock, \$0.001 par value per share, outstanding.

# TABLE OF CONTENTS

# PART I FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Financial Statements</u>	4
<u>Item 2.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	17
<u>Item 3.</u>	Quantitative and Qualitative Disclosures About Market Risk	27
<u>Item 4.</u>	Controls and Procedures	28
<u>PART II</u>	OTHER INFORMATION	
<u>Item 1.</u>	Legal Proceedings	28
<u>Item 1A.</u>	Risk Factors	28
<u>Item 2.</u>	Unregistered Sales of Equity Securities and Use of Proceeds	28
<u>Item 3.</u>	Defaults Upon Senior Securities	29
<u>Item 4.</u>	Mine Safety Disclosures	29
<u>Item 5.</u>	Other Information	29
<u>Item 6.</u>	Exhibits	30
	Signatures	31

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 ("Quarterly Report") that are not statements of historical or current facts, such as those under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that "we believe" or similar statements reflect our beliefs and opinions on the relevant subject. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

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

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

- our ability to establish and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others;
- our expectations regarding the use of proceeds from our public offerings of common stock;
- 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, 2020 (our "Annual Report"), our Quarterly Reports on Form 10-Q and the other documents we file with the Securities and Exchange Commission (the "SEC").

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

# PART I — FINANCIAL INFORMATION

## **Item 1. Financial Statements**

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

		June 30, 2021	De	cember 31, 2020
Assets				
Current assets:				
Cash and cash equivalents	\$	60,292	\$	74,394
Accounts receivable, net		3,545		2,683
Inventory		4,503		3,907
Prepaid expenses and other assets		2,395		2,241
Total current assets		70,735		83,225
Property and equipment, net		609		626
Intangible assets, net		2,455		2,607
Total assets	\$	73,799	\$	86,458
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	1,277	\$	652
Accrued expenses and other current liabilities		6,017		5,953
Total current liabilities		7,294		6,605
Long-term debt with related party		31,145		30,827
Other long-term liabilities		395		
Total liabilities		38,834		37,432
Stockholders' equity:				
Preferred stock; \$0.001 par value: 10,000,000 shares authorized; no shares issued and				
outstanding				
Common stock; \$0.001 par value: 200,000,000 shares authorized; 14,471,874 and				
14,437,289 shares issued and 14,471,774 and 14,437,107 shares outstanding at June 30,				
2021 and December 31, 2020, respectively		14		14
Additional paid-in capital		248,076		245,736
Accumulated other comprehensive loss		(81)		(71)
Accumulated deficit	(	(213,044)	,	(196,653)
Total stockholders' equity		34,965		49,026
Total liabilities and stockholders' equity	\$	73,799	\$	86,458

See accompanying notes to unaudited interim consolidated financial statements.

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

	Three months ended June 30,			ended			ths ended e 30,		
		2021		2020		2021		2020	
Revenue	\$	7,558	\$	3,507	\$	13,435	\$	7,233	
Cost of revenue (excluding amortization of intangible									
assets)		2,395		1,346		4,731		2,796	
Amortization of intangible assets		76		76		152		152	
Gross profit		5,087		2,085		8,552		4,285	
Operating expenses:									
Sales and marketing		7,502		4,123		13,801		9,392	
General and administrative		2,966		2,149		5,722		4,667	
Research and development		1,930		979		3,609		1,891	
Total operating expenses		12,398		7,251		23,132		15,950	
Loss from operations		(7,311)		(5,166)		(14,580)		(11,665)	
Other (expense) income:									
Interest expense		(864)		(884)		(1,753)		(1,763)	
Other (expense) income		(80)		(31)		(58)		127	
Total other expense		(944)		(915)		(1,811)		(1,636)	
Net loss	\$	(8,255)	\$	(6,081)	\$	(16,391)	\$	(13,301)	
Net loss per common share, basic and diluted	\$	(0.57)	\$	(0.53)	\$	(1.13)	\$	(1.16)	
Weighted average common shares outstanding, basic and			_						
diluted	1	4,458,911		11,443,122	1	4,448,715	1	1,424,952	
Comprehensive loss:									
Net loss	\$	(8,255)	\$	(6,081)	\$	(16,391)	\$	(13,301)	
Foreign currency translation adjustment		1		4		(10)		31	
Comprehensive loss	\$	(8,254)	\$	(6,077)	\$	(16,401)	\$	(13,270)	

See accompanying notes to unaudited interim consolidated financial statements.

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

	Commo	on sto	ck	dditional paid-in	(	imulated other rehensive	A	ccumulated	
	Shares	A	mount	capital	(loss	) income		deficit	Total
Balance at April 1, 2021	14,440,275	\$	14	\$ 246,548	\$	(82)	\$	(204,789)	\$ 41,691
Vesting of common stock previously subject to repurchase	36		_	_		_		_	
Exercise of stock options	19,463		_	116				_	116
Foreign currency translation adjustment	_		_	_		1		_	1
Stock-based compensation expense	12,000		—	1,412					1,412
Net loss	—		—	—				(8,255)	(8,255)
Balance at June 30, 2021	14,471,774	\$	14	\$ 248,076	\$	(81)	\$	(213,044)	\$ 34,965

	Commo			1	Additional paid-in	 ccumulated other nprehensive A		
	Shares	Aı	nount		capital	loss	deficit	 Total
Balance at January 1, 2021	14,437,107	\$	14	\$	245,736	\$ (71) \$	(196,653)	\$ 49,026
Vesting of common stock previously subject to repurchase	82		_		_	<u> </u>		_
Exercise of stock options	22,585		_		152	_		152
Foreign currency translation adjustment	—					(10)		(10)
Stock-based compensation expense	12,000		—		2,106	_		2,106
Reclassification of liability-classified stock-based								
compensation awards	—		—		82	—	—	82
Net loss			—				(16,391)	(16, 391)
Balance at June 30, 2021	14,471,774	\$	14	\$	248,076	\$ (81) \$	(213,044)	\$ 34,965

See accompanying notes to unaudited interim consolidated financial statements.

## TELA Bio, Inc. Consolidated Statements of Stockholders' Equity Three and Six Months Ended June 30, 2020 (In thousands, except share amounts) (Unaudited)

				Additional	Accumulated other			
	Commo	Common stock		paid-in comprehen		e Accumulated		
	Shares	Amount		capital	income		deficit	Total
Balance at April 1, 2020	11,407,600	\$ 11	\$	199,287	\$ 8	\$	(175,079)	\$ 24,227
Vesting of common stock previously subject to repurchase	73	_		1	_			1
Exercise of stock options	5,017			36				36
Foreign currency translation adjustment	_	_		_	4			4
Stock-based compensation expense		_		494				494
Issuance of common stock upon follow-on offering, net of								
underwriting discounts, commissions and offering costs	3,000,000	3		44,719	—			44,722
Net loss							(6,081)	(6,081)
Balance at June 30, 2020	14,412,690	\$ 14	\$	244,537	\$ 12	\$	(181,160)	\$ 63,403

	<u>Commo</u> Shares	on stock Amount	Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total
Balance at January 1, 2020	11,406,221	\$ 11	\$ 198,829	\$ (19) \$	(167,859)	\$ 30,962
Vesting of common stock previously subject to				, í		
repurchase	163	_	2	_	_	2
Exercise of stock options	6,306	—	44	—	—	44
Foreign currency translation adjustment	_		_	31		31
Stock-based compensation expense	_		943	_		943
Issuance of common stock upon follow-on offering, net of underwriting discounts, commissions and offering						
costs	3,000,000	3	44,719	—	—	44,722
Net loss	_	—	—	—	(13,301)	(13,301)
Balance at June 30, 2020	14,412,690	\$ 14	\$ 244,537	<u>\$ 12</u> \$	(181,160)	\$ 63,403

See accompanying notes to unaudited interim consolidated financial statements.

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

(Unaudited)				
	Si	ix months er	ided	
Cash flows from operating activities:		2021		2020
Net loss	\$	(16,391)	\$	(13,301)
Adjustments to reconcile net loss to net cash used in operating activities:	Ψ	(10,001)	Ψ	(10,001)
Depreciation expense		119		95
Noncash interest expense		318		281
Amortization of intangible assets		152		152
Inventory excess and obsolescence charge		682		767
Stock-based compensation expense		2,106		943
Change in operating assets and liabilities:				
Accounts receivable, net		(862)		238
Inventory		(1,275)		(750)
Prepaid expenses and other assets		(154)		823
Accounts payable		570		(2,096)
Accrued expenses and other current liabilities		538		(859)
Foreign currency remeasurement (gain) loss		(17)		45
Net cash used in operating activities		(14,214)		(13,662)
Cash flows from investing activities:				
Proceeds from the sale and maturity of short-term investments		_		9,289
Purchase of property and equipment		(47)		(96)
Net cash (used in) provided by investing activities		(47)		9,193
Cash flows from financing activities:				
Proceeds from follow-on offering, net of underwriting discounts, commissions and offering costs		_		45,120
Payment of initial public offering costs		—		(522)
Proceeds from exercise of stock options		152		44
Net cash provided by financing activities		152		44,642
Effect of exchange rate on cash and cash equivalents		7		(4)
Net (decrease) increase in cash and cash equivalents		(14,102)		40,169
Cash and cash equivalents, beginning of period		74,394		45,302
Cash and cash equivalents, end of period	\$	60,292	\$	85,471
Supplemental disclosure of cash flow information:				
Cash paid during the period for interest	\$	1,435	\$	1,482
Supplemental disclosures of noncash investing and financing activities:			_	
Offering costs in accounts payable and accrued expenses and other current liabilities	\$	_	\$	398
Property and equipment in accounts payable	\$	55	\$	
Issuance of common stock for early exercised stock options	\$	_	\$	2
Reclassification of liability-classified stock-based compensation awards to equity-classified	\$	82	\$	

See accompanying notes to unaudited interim consolidated financial statements.

#### Notes to Unaudited Interim Consolidated Financial Statements

## (1) Background

TELA Bio, Inc. (the "Company") was incorporated in the state of Delaware on April 17, 2012 and wholly owns TELA Bio Limited, a company incorporated in the United Kingdom. The Company is focused on the commercialization and sale of OviTex Reinforced Tissue Matrix ("OviTex"), which utilizes surgical reconstruction medical device technology licensed from a strategic partner, Aroa Biosurgery Ltd. ("Aroa") and on the research and development of additional medical devices with Aroa and on other internally developed technologies. In April 2019, the Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for OviTex PRS Reinforced Tissue Matrix ("OviTex PRS"), which 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 \$213.0 million as of June 30, 2021. The Company anticipates incurring additional losses until such time, if ever, it can generate sufficient revenue from its products to cover its expenses.

The operations of the Company are subject to certain risks and uncertainties including, among others, uncertainty of product development, the impact of COVID-19 and the development of variants of COVID-19, including the delta variant, on the business, ongoing economic uncertainty, 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, 2020. Any reference in these notes to applicable guidance is meant to refer to generally accepted accounting principles ("GAAP") in the United States as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

#### Interim Financial Statements

The accompanying unaudited interim consolidated financial statements have been prepared from the books and records of the Company in accordance with GAAP for interim financial information and Rule 10-01 of Regulation S-X promulgated by the SEC, which permits reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the accompanying consolidated balance sheets and statements of operations and comprehensive loss, stockholders' equity and cash flows have been made. Although these interim consolidated financial statements do not include all of the information and footnotes required for complete annual consolidated financial statements, management believes the disclosures are adequate to make the information presented not misleading. Unaudited interim results of operations and cash flows are not necessarily indicative of the results that may be expected for the full year. Unaudited interim consolidated financial statements and footnotes included in the Annual Report on Form 10-K for the year ended December 31, 2020.

#### 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

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

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

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenue, expenses, manufacturing capability, supply chain integrity, research and development costs and employee-related compensation, will depend on future developments that are highly uncertain, including new information that may emerge concerning COVID-19 and the actions taken to mitigate the spread of or treat COVID-19, the emergence of new variants of COVID-19, such as the delta variant, as well as the economic impact on local, regional, national and international customers and markets. Management has made estimates of the impact of COVID-19 within the Company's consolidated financial statements and there may be changes to those estimates in future periods. Actual results may differ from these estimates.

#### Revenue Recognition

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

A significant portion of the Company's revenue is generated from product shipped to a customer or from consigned inventory maintained at hospitals. Revenue from the sale of consigned products is recognized when control is transferred to the customer, which occurs at the time the product is used in a surgical procedure. For product that is not held on consignment, the Company recognizes revenue when control transfers to the customer which occurs at the time the product is shipped or delivered. For all of the Company's 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 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 these rebates and records 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 its arrangements. There are no incremental costs of obtaining a contract that would rise to or enhance an asset other than product costs, which are a component of inventory. The Company expenses incremental costs of obtaining a contract with a customer (e.g., sales commissions) when incurred as the period of benefit is less than one year. Fees charged to customers for shipping are recognized as revenue.

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

	Three months	ended Ju	une 30,	Six months e	nded June 30,			
	2021 2020			 2021		2020		
OviTex	\$ 5,761	\$	2,942	\$ 10,428	\$	6,181		
OviTex PRS	1,797		565	3,007		1,052		
Total revenue	\$ 7,558	\$	3,507	\$ 13,435	\$	7,233		

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

Sales outside of the United States were immaterial for the three and six months ended June 30, 2021 and 2020.

## 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 and other assets, and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. Due to the related-party relationship of the credit facility (the "OrbiMed Credit Facility") with OrbiMed Royalty Opportunities IP, LP ("OrbiMed") (Note 5), it is impractical to determine the fair value of the debt.

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

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

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

	Quot activ for	air value mea ed prices in ve markets identical assets Level 1)	surement at reportin Significant other observable inputs (Level 2)		ng date using Significant unobservable inputs (Level 3)	
June 30, 2021:						<u>erer 5</u>
Cash equivalents – money market fund	\$	55,394	\$	—	\$	-
December 31, 2020:						
Cash equivalents – money market fund	\$	72,889	\$		\$	—

#### Net loss per share

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

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

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

	Three and six mor	ths ended June 30,
	2021	2020
Stock options (including shares subject to repurchase)	1,589,243	1,538,954
Unvested restricted stock units	159,849	—
Common stock warrants	88,556	88,556
Total	1,837,648	1,627,510

#### **Recently Issued Accounting Pronouncements**

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the consolidated financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The standard is effective for the Company beginning January 1, 2022, with early adoption permitted. The Company plans to adopt this standard on January 1, 2022 and is currently evaluating the expected impact that the standard will have on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*. This guidance applies to all entities and aims to reduce the complexity of tax accounting standards while enhancing reporting disclosures. This guidance is effective for fiscal years beginning after December 15, 2020 and interim periods therein. Early adoption is permitted for any annual periods for which financial statements have not been issued and interim periods therein. The adoption of this guidance did not have any impact on the Company's 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):

	J	June 30, 2021		ember 31, 2020
Compensation and related benefits	\$	3,448	\$	3,666
Interest				40
Third-party and professional fees		1,654		1,626
Amounts due to Aroa		808		498
Research and development expenses		12		7
Other		95		116
Total accrued expenses and other current liabilities	\$	6,017	\$	5,953

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

## (5) Long-term Debt

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

	June 30, 2021		cember 31, 2020
OrbiMed Term Loan (related party)	\$ 30,000	\$	30,000
End of term charge	3,000		3,000
Unamortized end of term charge and issuance costs	(1,855)		(2,173)
Long-term debt with related party	\$ 31,145	\$	30,827

## OrbiMed Term Loan (Related Party)

In November 2018, the Company entered into the OrbiMed Credit Facility with OrbiMed, a related party as the lender is affiliated with a stockholder of the Company, which consists of up to \$35.0 million in term loans (the "OrbiMed Term Loans"). The OrbiMed Term Loans consist of two tranches, a \$30.0 million Tranche 1 ("Tranche 1") and a \$5.0 million Tranche 2 ("Tranche 2"). In November 2018, the Company borrowed \$30.0 million of Tranche 1. The Company elected not to borrow Tranche 2 prior to its expiration on December 31, 2019.

Pursuant to the OrbiMed Credit Facility, the Company provided a first priority security interest in all existing and future acquired assets, excluding intellectual property and certain other assets, owned by the Company. The OrbiMed Credit Facility also contains a negative pledge on intellectual property owned by the Company. The OrbiMed Credit Facility also contains customary indemnification obligations and customary events of default, including, among other things, (i) nonpayment, (ii) breach of warranty, (iii) nonperformance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (iv) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) key person events, (xi) regulatory matters, (xii) and key contracts. In addition, the Company must maintain a minimum cash balance of \$2.0 million. If an event of default occurs under the OrbiMed Credit Facility, the Company may become obligated to immediately pay all outstanding principal and interest and all other due and unpaid obligations at the current rate in effect plus 3%.

The OrbiMed Term Loan matures on November 16, 2023 and bears interest at a rate equal to 7.75% plus the greater of onemonth LIBOR or 2.0%. At June 30, 2021, the interest rate was 9.75%. The Company is required to make 60 monthly interest payments beginning on November 30, 2018, with the entire principal payment due at maturity. The OrbiMed Term Loans have a prepayment penalty equal to 10.0% of the prepaid principal amount prior to the second anniversary of the Term Loans, 5.0% of the prepaid principal amount after the second anniversary but prior to the third anniversary and 2.5% of the prepaid principal amount after the third anniversary. The Company is also required to pay an exit fee at the time of maturity or prepayment event equal to 10.0% of all principal borrowings (the "End of Term Charge") and an administration fee equal to \$10,000 on the last day of each quarter until all obligations have been paid in full. In conjunction with the closing of the OrbiMed Term Loans, the Company incurred \$0.3 million of third-party and lender fees, which along with the End of Term charge of \$3.0 million were recorded as debt issuance costs, and are being recognized as interest expense over the term of the loan using the effective-interest method. Interest expense associated with the OrbiMed Credit Facility recorded for both the six months ended June 30, 2021 and 2020, was \$1.8 million, of which \$0.3 million was related to the amortization of debt issuance costs.

## (6) Stockholders' Equity

In December 2020, the Company entered into an Equity Distribution Agreement (the "Equity Agreement") with Piper Sandler & Co (the "Agent") in connection with the establishment of an at-the-market offering program under which it may sell up to an aggregate of \$50.0 million of shares of the Company's common stock, from time to time through the Agent as sales agent. No sales were made under the Equity Agreement during the six months ended June 30, 2021.

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

Warrants

The Company had the following warrants outstanding to purchase common stock at June 30, 2021:

	Outstanding	Exercise price	Expiration dates
Common stock warrants issued to MidCap	8,379	\$ 28.65	2028
Common stock warrants issued to note payable holders	15,712	28.65	2027
Common stock warrants issued to convertible promissory note holders	64,465	\$ 28.65	2027
	88,556		

## (7) 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 June 30, 2021, 897,947 shares 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 June 30,		Siz	x months e	ended June 30,		
		2021	2020		2021		2020
Sales and marketing	\$	253	\$ 172	\$	437	\$	333
General and administrative		385	240		751		449
Research and development		774	82		918		161
Total stock-based compensation	\$	1,412	\$ 494	\$	2,106	\$	943

#### Stock Options

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

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2021	1,498,208	10.87	
Granted	256,000	15.89	
Exercised	(22,585)	6.70	
Canceled/forfeited	(142,480)	12.77	
Outstanding at June 30, 2021	1,589,143	\$ 11.57	7.18
Vested and expected to vest at June 30, 2021	1,542,430	\$ 11.50	7.13
Exercisable at June 30, 2021	884,493	\$ 9.94	5.92

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

At June 30, 2021, the aggregate intrinsic value of outstanding options and exercisable options was \$7.4 million and \$5.5 million, respectively.

The 2012 Stock Incentive Plan provided the holders of stock options an election to early exercise prior to vesting. The Company has the right, but not the obligation, to repurchase early exercised options without transferring any appreciation to the employee if the employee terminates employment before the end of the original vesting period. The repurchase price is the lesser of the original exercise price or the then fair value of the common stock. At June 30, 2021, \$1,000 of proceeds from early exercised options were recognized as a current liability in other current liabilities in the accompanying consolidated balance sheet.

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

	Number of shares
Unvested balance at January 1, 2021	182
Vested	(82)
Unvested balance at June 30, 2021	100

The weighted average grant-date fair value per share of options granted was \$9.27 during the six months ended June 30, 2021. The aggregate intrinsic value of options exercised was \$0.1 million for both the three and six months ended June 30, 2021. At June 30, 2021, the total unrecognized compensation expense related to unvested employee and nonemployee stock option awards was \$4.7 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.5 years.

#### Estimating Fair Value of Stock Options

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

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

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

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

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

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

The fair value of each option was estimated on the date of grant using the weighted average assumptions in the table below:

	Six months ended June 30, 2021
Expected dividend yield	—
Expected volatility	64.2 %
Risk-free interest rate	0.89 %
Expected term (in years)	6.08

## Restricted Stock Units

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

	Number of shares
Outstanding at January 1, 2021	_
Granted	186,732
Vested	(12,000)
Canceled/forfeited	(14,883)
Outstanding at June 30, 2021	159,849

The weighted average grant-date fair value per RSU granted was \$16.63 during the six months ended June 30, 2021. The aggregate intrinsic value of RSUs outstanding was \$2.6 million at June 30, 2021. The total unrecognized compensation expense at June 30, 2021 related to RSUs was \$1.8 million, which is expected to be recognized in expense over a weighted-average period of approximately 3.7 years.

## (8) Related-Party Transactions

On November 16, 2018, the Company entered into a senior secured term loan facility with OrbiMed, an entity affiliated with an owner of a material amount of the Company's outstanding voting securities. The terms of the debt and related components are further described in more detail in Note 5.



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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as other sections in this Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (the "Quarterly Report"), should be read in conjunction with our unaudited interim consolidated financial statements and related notes thereto included elsewhere herein and the consolidated financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operation, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "Annual Report") filed with the Securities and Exchange Commission ("SEC") on March 25, 2021. In addition to historical financial information, some of the information contained in the following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, business strategy, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties, assumptions and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

#### Overview

We are a commercial-stage medical technology company focused on designing, developing and marketing innovative tissue reinforcement materials to address unmet needs in soft tissue reconstruction. We are committed to providing patients with advanced, economically effective biologic material repair solutions to minimize long-term exposure to permanent synthetic materials and improve clinical outcomes. Our products are purposefully designed to address the shortcomings of existing reinforcement materials in hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery.

Our first portfolio of products, the OviTex Reinforced Tissue Matrix ("OviTex"), addresses unmet needs in hernia repair and abdominal wall reconstruction by combining the benefits of biologic matrices and polymer materials while minimizing their shortcomings, at a cost-effective price. Our OviTex products have received 510(k) clearance from the U.S. Food and Drug Administration ("FDA"), which clearance was obtained and is currently held by Aroa Biosurgery Ltd. ("Aroa"), our exclusive manufacturer and supplier. Interim results of our ongoing prospective, single arm, multicenter post-market clinical study, which we refer to as our BRAVO study, suggest that OviTex is safe and clinically effective for treatment of ventral hernias. Our BRAVO study was fully enrolled at 92 patients. The interim analysis includes patient cohorts at the 90day, 12-month and 24-month follow-up periods. At 90 days post-operative, there were no recurrences or reoperations among the 84 patients analyzed and one implant removal due to a bowel perforation. The final 12-month analysis includes 76 patients, of whom two patients experienced a recurrence, both adjacent to the original repair, with the OviTex repairs remaining intact. Of the 51 patients that have reached 24-month follow-up, one patient experienced a surgical site occurrence from a superficial infection, and none experienced a recurrence or long-term complication. Additional results from the 30-day and 24-month patient cohorts showing low rates of surgical site occurrences requiring treatment were presented in September 2020 at the Americas Hernia Society Annual Meeting. Our second portfolio of products, the OviTex PRS Reinforced Tissue Matrix ("OviTex PRS"), addresses unmet needs in plastic and reconstructive surgery. In April 2019, our OviTex PRS products received 510(k) clearance from the FDA, which clearance was obtained by Aroa and is currently held by us.

We began commercialization of our OviTex products in the United States in July 2016 and they are now used by more than 374 hospital accounts. Our OviTex portfolio consists of multiple products for hernia repair and abdominal wall reconstruction, inguinal hernia repair and hiatal hernia repair. In addition, to address the significant increase in the number of robotic-assisted hernia repairs over the last several years, we have designed an OviTex product line for use in laparoscopic and robotic-assisted surgery ("OviTex LPR"), which we began commercializing in November 2018. We subsequently expanded the OviTex LPR product line in December 2019.

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

We market our products through a single direct sales force, predominantly in the United States. We have invested in our direct sales and marketing infrastructure in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2021, we had 45 sales territories in the United States. As part of our commercial strategy, we plan to continue to invest in our commercial organization by hiring additional account managers, clinical development specialists and administrative support staff to support and service new accounts for soft tissue reconstruction procedures. Additionally, we believe we can enhance the productivity of our sales force by improving customer segmentation and targeting, leveraging digital channels to engage customers and utilizing engagement analytics to support development.

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

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

Substantially all our revenue to date has been generated by the sale of our OviTex products. Our revenue increased by \$4.1 million, or 116%, from \$3.5 million for the three months ended June 30, 2020 to \$7.6 million for the three months ended June 30, 2021, and by \$6.2 million, or 86%, from \$7.2 million for the six months ended June 30, 2020 to \$13.4 million for the six months ended June 30, 2020 to \$13.4 million for the six months ended June 30, 2020 to \$8.3 million for the three months ended June 30, 2020 to \$8.3 million for the three months ended June 30, 2020 to \$8.3 million for the three months ended June 30, 2020 to \$13.4 million, or 23%, from \$13.3 million for the six months ended June 30, 2020 to \$16.4 million for the six months ended June 30, 2021. We have not been profitable since inception and as of June 30, 2021, we had an accumulated deficit of \$213.0 million. We expect to incur losses for the foreseeable future.

#### **Business Update Regarding COVID-19**

Our business has been impacted by the COVID-19 pandemic and the development of variants of COVID-19, including the delta variant. We continue to closely monitor developments related to the COVID-19 pandemic and our decisions will continue to be driven by the health and well-being of our employees, hospital and physician customers, and their patients while maintaining operations to support our customers and their patients in the near-term. These developments include:

• *Surgery Deferrals*: We believe our revenue was slightly impacted during the first quarter of 2021, mostly in January 2021, due to COVID-19 resurgences and lower surgical procedural volumes, though not the levels seen in early 2020. This impact subsided throughout the remaining months of the first quarter and the second quarter of 2021 but the extent of future elective surgery deferrals and the timing and extent of the economic impact of the pandemic, and the pace at which the economy recovers therefrom, cannot be determined at this time, particularly in light of the surge of new COVID-19 cases relating to new variants, such as the delta variant. We

continue to work closely with our hospital and physician customers and suppliers to navigate through this unforeseen event while maintaining flexible operations. The reallocation of hospital resources to treat COVID-19 may continue to cause a financial strain on healthcare systems and reduce procedural volumes.

- *Operations*: Our sales, marketing and research and development efforts have continued since the outbreak of the pandemic. As the hospital access environment continues to evolve throughout this pandemic and practices vary from hospital to hospital and state to state, our sales team has continued to adapt and remain flexible to adjust to changing conditions within their regions. Most of our sales professionals have used a virtual selling program, which includes virtual sales calls with physicians, peer-to-peer discussions with key opinion leaders, physician webinars and sales professional training, instead of in-person sales and marketing programs. We expect to continue to adapt our sales and marketing plans as we continue to gain better visibility into the effects of the COVID-19 pandemic on our business. As Aroa is located and headquartered in Auckland, New Zealand, where COVID-19 mitigation efforts have to date been effective, our manufacturing and supply chain has largely been uninterrupted. However, it could be disrupted in the future because of the pandemic due to staffing shortages, production slowdowns, stoppages, travel and shipping restrictions or disruptions in delivery systems.
- *Product Development*: We continue to evaluate the timing and scope of planned next generation product development and commercialization initiatives in light of the COVID-19 pandemic, and we plan to continue to prioritize and invest in our critical R&D and clinical programs.
- 2021 Results. During January 2021, we experienced increased volatility in demand for our products as COVID-19 cases and hospitalizations increased. We saw improvement in our business during the second half of the first quarter and during the second quarter of 2021. The timing, extent and continuation of any increase in procedures, any corresponding increase in sales of our products, and whether there could be a future decrease in the current level of procedures being performed, remain uncertain and are subject to a variety of factors, including:
  - A material increase in COVID-19 cases in one or more locations, including as a result of the development of new variants of COVID-19, such as the delta variant, may result in an increase in hospitalizations and a corresponding decrease in elective procedures in such impacted locations.
  - O The availability and perceived safety of COVID-19 vaccines, the speed of COVID-19 vaccine distribution and administration, the timing and extent to which the vaccination process will affect the progression of the virus, and the efficacy of such vaccines against the new variants of the virus, such as the delta variant.
  - O Government restrictions on elective procedures may change over time and may vary in different geographic locations due to localized increases or decreases in the number of COVID-19 cases.
  - Patients electing to defer or avoid treatment for elective procedures due to concerns about being exposed to COVID-19, loss of employer-sponsored health insurance related to unemployment in the United States or other reasons.
  - O Hospitals may reserve increased space, personal protective equipment and staff for potential COVID-19 patients, especially if the number of COVID-19 cases in a particular region spikes or a new variant of COVID-19, such as the delta variant, emerges in such region, limiting the space and resources allocated to inpatient and outpatient elective procedures.
  - O Hospitals may continue to preserve cash and may not immediately replenish their inventories of our products, which would impact our future sales and revenue and make it difficult to accurately predict our inventory requirements.

We continue to closely monitor local, regional and global COVID-19 surges as well as new variants of the virus for an impact on procedures during the third quarter of 2021 and beyond.

Outlook. There remains uncertainty and lack of visibility regarding our near-term revenue growth prospects and
product development plans due to the rapidly evolving environment and continued uncertainties resulting from
the COVID-19 pandemic. At this time, the full extent of the impact of the COVID-19 pandemic on our business,
financial condition and results of operations is uncertain and cannot be predicted with reasonable accuracy and
will depend on future developments that are also uncertain, such as the potential development of new variants of
COVID-19, and the future geographic scope of COVID-19, and cannot be predicted with reasonable accuracy.

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

#### Revenue

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

## Cost of Revenue

Cost of revenue primarily consists of the costs of licensed products, charges related to excess and obsolete inventory adjustments and costs related to shipping. We purchase product from Aroa at a fixed cost equal to 27% of our net sales of licensed products. The initial term of our Aroa License terminates on the later of (i) August 3, 2022, or (ii) the expiration of the last patent covering bovine and ovine products, with an option to extend for an additional ten-year period. We expect our cost of revenue to increase in absolute dollars as, and to the extent, our sales volume grows, although it is unclear at this point what long-term effect, if any, the COVID-19 pandemic will have on product demand which could lead to additional charges to excess and obsolete inventory.

#### Amortization of Intangible Assets

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

#### Gross Profit and Gross Margin

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

#### Sales and Marketing Expenses

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

Over time we expect our sales and marketing expenses to increase in absolute dollars as we continue to expand our commercial organization to both drive and support our planned growth in revenue. It is unclear at this point, however,

what long-term effect, if any, the COVID-19 pandemic will have on these expansion plans. We expect our sales and marketing expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

#### General and Administrative Expenses

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

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

## **Research and Development Expenses**

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

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

## Interest Expense

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

## Other (Expense) Income

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

## **Results of Operations**

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

	Three Months Ended June 30,		Cha	lange		
	_	2021	-1	2020	Dollar	Percentage
Descence	¢				t percentages)	110.0/
Revenue	\$	7,558	\$	3,507	\$ 4,051	116 %
Cost of revenue (excluding amortization of intangible assets)		2,395		1,346	1,049	78
Amortization of intangible assets		76		76	—	—
Gross profit		5,087		2,085	3,002	144
Gross margin		67 %	6	59 %	Ď	
Operating expenses:						
Sales and marketing		7,502		4,123	3,379	82
General and administrative		2,966		2,149	817	38
Research and development		1,930		979	951	97
Total operating expenses		12,398		7,251	5,147	71
Loss from operations		(7,311)		(5,166)	(2,145)	42
Other (expense) income:						
Interest expense		(864)		(884)	20	(2)
Other expense		(80)		(31)	(49)	158
Total other expense		(944)		(915)	(29)	3
Net loss	\$	(8,255)	\$	(6,081)	\$ (2,174)	36 %

#### Revenue

Revenue increased by \$4.1 million, or 116%, to \$7.6 million for the three months ended June 30, 2021 from \$3.5 million for the three months ended June 30, 2020. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization, growth of new accounts and increased penetration within existing customer accounts. During the three months ended June 30, 2021, we sold 1,864 units of OviTex compared to 869 units of OviTex during the three months ended June 30, 2020, a 114% increase in unit sales volume. Additionally, we sold 337 units of OviTex PRS during the three months ended June 30, 2021 as compared to 115 units during the three months ended June 30, 2021.

#### Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by \$1.0 million, or 78%, to \$2.4 million for the three months ended June 30, 2021 from \$1.3 million for the three months ended June 30, 2020. The increase in cost of revenue for the three months ended June 30, 2021 was primarily the result of an increase in products purchased to support our higher unit sales partially offset by a decrease in our excess and obsolete inventory adjustment.

## Amortization of Intangible Assets

Amortization of intangible assets was \$76,000 for both the three months ended June 30, 2021 and 2020.

#### **Gross Margin**

Gross margin increased to 67% for the three months ended June 30, 2021 from 59% for the three months ended June 30, 2020. The increase was primarily due to the decrease in the charge recognized for excess and obsolete inventory adjustments as a percentage of revenue for the three months ended June 30, 2021 as compared to the prior year period.

## Sales and Marketing

Sales and marketing expenses increased by \$3.4 million, or 82%, to \$7.5 million for the three months ended June 30, 2021 from \$4.1 million for the three months ended June 30, 2020. The increase was primarily due to higher salary, benefits and commission costs as a result of an expansion of our commercialization activities, including an increase in headcount and higher travel and consulting expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions and reduced traveling which were not repeated in 2021.

## General and Administrative

General and administrative expenses increased by \$0.8 million, or 38%, to \$3.0 million for the three months ended June 30, 2021 from \$2.1 million for the three months ended June 30, 2020. The increase was primarily due to higher salary and benefits, increased professional, consulting and legal expenses, higher non-cash stock-based compensation expense and increased facilities related expenses due to expansion. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions which were not repeated in 2021.

#### **Research and Development**

Research and development expenses increased by \$1.0 million, or 97%, to \$1.9 million for the three months ended June 30, 2021 from \$1.0 million for the three months ended June 30, 2020. The increase was primarily due to a non-cash stockbased compensation expense of \$0.7 million related to amendments to certain equity award agreements following the death of our co-founder and former Chief Medical Officer, higher salary and benefits and increased testing and development expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions which were not repeated in 2021.

## Interest Expense

Interest expense remained relatively flat and was \$0.9 million for both the three months ended June 30, 2021 and 2020.

#### **Other Expense**

Other expense increased \$49,000, or 158%, to \$80,000 for the three months ended June 30, 2021 from other expense of \$31,000 for the three months ended June 30, 2020. The increase was primarily due to miscellaneous tax expenses.

## Comparison of the Six Months Ended June 30, 2021 and 2020

	Six Months Ended June 30,		Cha	ange	
	2021	2020	Dollar	Percentage	
Revenue	\$ 13,435	thousands, exce \$ 7,233	s 6,202	86 %	
Cost of revenue (excluding amortization of intangible assets)	4,731	2,796	1,935	69	
		,	1,955	09	
Amortization of intangible assets	152	152			
Gross profit	8,552	4,285	4,267	100	
Gross margin	64 %	59 %	)		
Operating expenses:					
Sales and marketing	13,801	9,392	4,409	47	
General and administrative	5,722	4,667	1,055	23	
Research and development	3,609	1,891	1,718	91	
Total operating expenses	23,132	15,950	7,182	45	
Loss from operations	(14,580)	(11,665)	(2,915)	25	
Other (expense) income:					
Interest expense	(1,753)	(1,763)	10	(1)	
Other (expense) income	(58)	127	(185)	(146)	
Total other expense	(1,811)	(1,636)	(175)	11	
Net loss	\$ (16,391)	\$ (13,301)	\$ (3,090)	23 %	

## Revenue

Revenue increased by \$6.2 million, or 86%, to \$13.4 million for the six months ended June 30, 2021 from \$7.2 million for the six months ended June 30, 2020. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization, growth of new accounts and increased penetration within existing customer accounts. During the six months ended June 30, 2021, we sold 3,350 units of OviTex compared to 1,950 units of OviTex during the six months ended June 30, 2020, a 72% increase in unit sales volume. Additionally, we sold 607 units of OviTex PRS during the six months ended June 30, 2021 as compared to 216 units during the six months ended June 30, 2020.

#### Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by \$1.9 million, or 69%, to \$4.7 million for the six months ended June 30, 2021 from \$2.8 million for the six months ended June 30, 2020. The increase in cost of revenue for the six months ended June 30, 2021 was primarily the result of an increase in products purchased to support our higher unit sales partially offset by a decrease in our excess and obsolete inventory adjustment.

#### Amortization of Intangible Assets

Amortization of intangible assets was \$0.2 million for both the six months ended June 30, 2021 and 2020.

#### **Gross Margin**

Gross margin increased to 64% for the six months ended June 30, 2021 from 59% for the six months ended June 30, 2020. The increase was primarily due to the decrease in the charge recognized for excess and obsolete inventory adjustments as a percentage of revenue for the six months ended June 30, 2021 as compared to the prior year period.

## Sales and Marketing

Sales and marketing expenses increased by \$4.4 million, or 47%, to \$13.8 million for the six months ended June 30, 2021 from \$9.4 million for the six months ended June 30, 2020. The increase was primarily due to higher salary, benefits and commission costs as a result of an expansion of our commercialization activities, including an increase in headcount,

and increased travel and consulting expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions and reduced traveling which were not repeated in 2021.

#### General and Administrative

General and administrative expenses increased by \$1.1 million, or 23%, to \$5.7 million for the six months ended June 30, 2021 from \$4.7 million for the six months ended June 30, 2020. The increase was primarily due to higher salary and benefits, increased professional, consulting and legal expenses and higher non-cash stock-based compensation expense. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions which were not repeated in 2021.

### **Research and Development**

Research and development expenses increased by \$1.7 million, or 91%, to \$3.6 million for the six months ended June 30, 2021 from \$1.9 million for the six months ended June 30, 2020. The increase was primarily due to a non-cash stock-based compensation expense of \$0.7 million related to amendments to certain equity award agreements following the death of our co-founder and former Chief Medical Officer, higher salary and benefits and increased testing and development expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions which were not repeated in 2021.

#### Interest Expense

Interest expense remained relatively flat and was \$1.8 million for both the six months ended June 30, 2021 and 2020.

#### Other (Expense) Income

Other (expense) income decreased \$0.2 million, or 146%, to expense of \$58,000 for the six months ended June 30, 2021 from \$0.1 million of income for the six months ended June 30, 2020. The decrease was primarily due to lower interest income.

## Liquidity and Capital Resources

#### Overview

As of June 30, 2021, we had cash and cash equivalents of \$60.3 million, working capital of \$63.4 million and an accumulated deficit of \$213.0 million. As of December 31, 2020, we had cash and cash equivalents of \$74.4 million, working capital of \$76.6 million and an accumulated deficit of \$196.7 million.

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 June 30, 2021, we had \$30.0 million of borrowings outstanding under our credit facility (the "OrbiMed Credit Facility") with OrbiMed Royalty Opportunities IP, LP ("OrbiMed"). The OrbiMed Credit Facility matures in November 2023 and requires that we maintain a minimum cash balance of \$2.0 million.

Based on our current business plan, we believe that our existing cash resources will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months from the issuance of this Quarterly Report. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional common or preferred equity or debt securities or enter into a new credit facility. In December 2020, we entered into an Equity Distribution Agreement (the "Equity Agreement") with Piper Sandler & Co (the "Agent") in connection with the establishment of an at-the-market offering program under which it may sell up to an aggregate of \$50.0 million of shares of our common stock, from time to time through the Agent as sales agent. No sales were made under the Equity Agreement during the six months ended June 30, 2021. If we raise additional funds by issuing equity or equity-linked securities, our stockholders would experience dilution and any new equity securities could have rights, preferences and privileges

superior to those of holders of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We cannot be assured that additional equity, equity-linked or debt financing will be available on terms favorable to us or our stockholders, or at all, including as a result of market volatility following the COVID-19 pandemic. If we are unable to obtain adequate financing, we may be required to delay the development, commercialization and marketing of our products.

#### **Cash Flows**

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

	Six months ended June 30,		
(in thousands)	2021	2020	
Cash used in operating activities	\$ (14,214)	\$ (13,662)	
Cash (used in) provided by investing activities	(47)	9,193	
Cash provided by financing activities	152	44,642	
Effect of exchange rate on cash	7	(4)	
Net (decrease) increase in cash and cash equivalents	\$ (14,102)	\$ 40,169	

#### **Operating Activities**

During the six months ended June 30, 2021, we used \$14.2 million of cash in operating activities, resulting from our net loss of \$16.4 million and the change in operating assets and liabilities of \$1.2 million, offset by non-cash charges of \$3.4 million. Our non-cash charges were comprised of stock-based compensation expense of \$2.1 million, our excess and obsolete inventory charge of \$0.7 million, noncash interest expense of \$0.3 million and depreciation and amortization expense of \$0.3 million. The change in our operating assets and liabilities was primarily related to an increase in our inventory and accounts receivable partially offset by increases in accounts payable and accrued expenses and other current liabilities.

During the six months ended June 30, 2020, we used \$13.7 million of cash in operating activities, resulting from our net loss of \$13.3 million and the change in operating assets and liabilities of \$2.6 million, offset by non-cash charges of \$2.2 million. Our non-cash charges were comprised of stock-based compensation expense of \$0.9 million, our excess and obsolete inventory charge of \$0.8 million, noncash interest expense of \$0.3 million and depreciation and amortization expense of \$0.2 million. The change in our operating assets was primarily related to a decrease in our accounts payable and accrued expenses and other liabilities, offset by an increase in inventory.

## **Investing Activities**

During the six months ended June 30, 2021, cash used in investing activities was \$47,000 consisting of purchases of property and equipment.

During the six months ended June 30, 2020, cash provided by investing activities was \$9.2 million, consisting primarily of the proceeds from the sale and maturity of short-term investments.

## **Financing Activities**

During the six months ended June 30, 2021, cash provided by financing activities was \$0.2 million, consisting of proceeds received from the exercise of stock options.

During the six months ended June 30, 2020, cash provided by financing activities was \$44.6 million, consisting primarily of the net proceeds received from a follow-on public offering of our common stock.

#### Indebtedness

In November 2018, we entered into the OrbiMed Credit Facility, which consists of up to \$35.0 million in term loans (the "OrbiMed Term Loans"). The OrbiMed Term Loans consist of two tranches, a \$30.0 million Tranche 1 ("Tranche 1") and a \$5.0 million Tranche 2 ("Tranche 2"). Upon closing, we borrowed \$30.0 million of Tranche 1. We elected not to borrow Tranche 2 prior to its expiration on December 31, 2019.

Pursuant to the OrbiMed Credit Facility, we provided a first priority security interest in all existing and future acquired assets, excluding intellectual property and certain other assets, owned by us. The OrbiMed Credit Facility contains a negative pledge on intellectual property owned by us. The OrbiMed Credit Facility 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, (iv) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) key person events, (xi) regulatory matters, and (xii) key contracts. In addition, we must maintain a minimum cash balance of \$2.0 million. If an event of default occurs under the OrbiMed Credit Facility, we may become obligated to immediately pay all outstanding principal and interest and all other due and unpaid obligations at the current rate in effect plus 3%.

The OrbiMed Term Loans mature on November 16, 2023 and bear interest at a rate equal to 7.75% plus the greater of onemonth LIBOR or 2.0%. We are required to make 60 monthly interest payments beginning on November 30, 2018 with the entire principal payment due at maturity. The OrbiMed Term Loans have a prepayment penalty equal to 10.0% of the prepaid principal amount prior to the second anniversary of the OrbiMed Term Loans, 5.0% of the prepaid principal amount after the second anniversary but prior to the third anniversary and 2.5% of the prepaid principal amount after the third anniversary. We are also required to pay an exit fee at the time of maturity or prepayment event equal to 10% of all principal borrowings and an administration fee equal to \$10,000 on the last day of each quarter until all obligations have been paid in full.

## **Contractual Obligations and Commitments**

As of June 30, 2021, 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 Judgements 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. We have reviewed the consolidated financial statements of these institutions and believe they have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

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

As discussed above in the section entitled "Liquidity and Capital Resources — Indebtedness," the OrbiMed Credit Facility bears interest at a floating rate of interest, which resets monthly and is equal to 7.75% plus the greater of one-month LIBOR or 2.0%. As of June 30, 2021, LIBOR was below 1.0%. Therefore, a 1.0% increase in interest rates would not increase the annual interest payments.

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 Principal Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and Principal 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 Principal 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 2020 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 and Use of Proceeds.

#### **Recent Sales of Unregistered Securities**

None.

#### **Use of Proceeds**

The registration statement on Form S-1 (File No. 333-234217) relating to the IPO of shares of our common stock, became effective on November 7, 2019. The registration statement registered the offer and sale of 4,000,000 shares of our common stock (including 600,000 shares of our common stock subject to the underwriters' option to purchase additional shares). In November 2019, we completed the sale of 4,398,700 of the shares of our common stock registered thereunder at an initial public offering price of \$13.00 per share for an aggregate offering price of approximately \$57.2 million, which included 398,700 shares of our common stock pursuant to the underwriters' option to purchase additional shares. The underwriters of the offering were Jefferies LLC, Piper Sandler Companies (formerly Piper Jaffray & Co.), Canaccord Genuity LLC and JMP Securities LLC. Following the sale of the shares in connection with the closing of the IPO, the offering terminated.

We received net proceeds of approximately \$50.6 million after deducting underwriting discount and commissions of \$4.0 million and offering costs of \$2.6 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

As of June 30, 2021, we have used approximately \$36.0 million of the net proceeds from our IPO for working capital and general corporate purposes, including hiring additional sales and marketing personnel and expanding marketing activities to support the ongoing commercialization of our OviTex and OviTex PRS product lines and to fund product development and research and development activities. No amount of the net proceeds from our IPO have been paid directly or indirectly to (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board and board committee service. There has been no material change in the planned use of proceeds from our IPO from that described in our prospectus dated November 7, 2019 as filed with the SEC pursuant to Rule 424(b) (4).

## **Purchase of Equity Securities**

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

#### Item 5. Other Information.

Not applicable.

## Item 6. Exhibits.

The following exhibits are being filed herewith:

# EXHIBIT INDEX

#### Exhibit No.

#### Exhibit

- 31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- **31.2** Certification of Principal 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 <u>Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906</u> of the Sarbanes-Oxley Act of 2002 (furnished herewith).
- 32.2 <u>Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section</u> 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
- 101 INS Inline XBRL Instance Document (filed herewith).
- 101 SCH Inline XBRL Taxonomy Extension Schema Document (filed herewith).
- 101 CAL Inline XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).
- 101 DEF Inline XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
- 101 LAB Inline XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
- 101 PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).
  - 104 Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

## SIGNATURES

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

# TELA BIO, INC.

Date: August 12, 2021

/s/ ANTONY KOBLISH By:

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

Date: August 12, 2021

By: /s/ MEGAN SMEYKAL

Megan Smeykal Vice President and Corporate Controller (Principal financial 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, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2021

/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, Megan Smeykal, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2021

/s/ Megan Smeykal Megan Smeykal Vice President and Corporate Controller (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 June 30, 2021, 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: August 12, 2021

/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: Megan Smeykal, Vice President and Corporate Controller of TELA Bio, Inc. (the "Company"), hereby certifies that, to the best of her knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, 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: August 12, 2021

/s/ Megan Smeykal

Megan Smeykal Vice President and Corporate Controller (Principal Financial Officer)