# 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, 2023

OR

 $\hfill \square$  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: 001-35570

# **SONNET BIOTHERAPEUTICS HOLDINGS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

	(Exact)	Name of Registrant as specified in its Cha	inter)					
	Delaware		20-2932652					
	or Other Jurisdiction of		(I.R.S. Employer					
Incorp	oration or Organization)		Identification No.)					
100 Overlook (	Center, Suite 102, Princeton, NJ		08540					
(Address of	Principal Executive Offices)		(Zip Code)					
	(Registr	(609) 375-2227 ant's Telephone Number, Including Area G	Code)					
	(Former Name, Former	<b>Not applicable</b> Address and Former Fiscal Year, if Change	ed Since Last Report)					
Securities registered pursuant to Se	ection 12(b) of the Act:							
Title of	each class	Trading Symbol(s)	Name of each exchange on	which registered				
Common Stock, par v	value \$0.0001 per share	SONN	The Nasdaq Stock Ma	arket LLC				
		rts required to be filed by Section 13 or 1. to file such reports), and (2) has been sub						
3	$\mathcal{E}$	tronically every Interactive Data File rec ch shorter period that the registrant was re	1	$\mathcal{C}$				
		d filer, an accelerated filer, a non-accele filer," "smaller reporting company," and						
Large accelerated filer			Accelerated filer					
Non-accelerated filer	$\boxtimes$		Smaller reporting company					
			Emerging growth company					
If an emerging growth company, i accounting standards provided pur		strant has elected not to use the extended ange Act. $\Box$	transition period for complying with an	y new or revised financial				
Indicate by check mark whether th $\square$ Yes $\boxtimes$ No	e registrant is a shell company (as	defined in Rule 12b-2 of the Exchange Ad	et).					
There were 38,511,014 shares of c	ommon stock, par value \$0.0001 p	per share of Sonnet BioTherapeutics Holdi	ngs, Inc. issued and outstanding as of A	ugust 7, 2023.				

# $Sonnet\ BioTherapeutics\ Holdings,\ Inc.\ and\ Subsidiaries$

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# SONNET BIOTHERAPEUTICS HOLDINGS, INC.

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# PART I – FINANCIAL INFORMATION

# ITEM 1: FINANCIAL STATEMENTS.

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# Sonnet BioTherapeutics Holdings, Inc. Consolidated Balance Sheets (unaudited)

	June 30, 2023		Se	eptember 30, 2022
Assets				
Current assets:				
Cash	\$	7,021,071	\$	3,052,879
Incentive tax receivable		749,169		717,305
Prepaid expenses and other current assets		1,862,683		1,643,743
Total current assets		9,632,923		5,413,927
Property and equipment, net		36,577		46,211
Operating lease right-of-use asset		209,944		256,594
Deferred offering costs		_		113,280
Other assets		155,366		_
Total assets	\$	10,034,810	\$	5,830,012
Liabilities and stockholders' equity (deficit)	<u></u>			
Current liabilities:				
Related-party notes payable	\$	_	\$	748
Accounts payable		3,024,441		4,752,340
Accrued expenses and other current liabilities		3,315,404		3,193,972
Operating lease liability		70,446		51,328
Deferred income		55,882		166,431
Total current liabilities		6,466,173		8,164,819
Operating lease liability		150,185		203,912
Total liabilities		6,616,358		8,368,731
Commitments and contingencies (Note 4)				
Stockholders' equity (deficit):				
Preferred stock; \$0.0001 par value: 5,000,000 shares authorized. No shares issued or outstanding		_		_
Common stock; \$0.0001 par value: 125,000,000 shares authorized; 38,389,648 and 5,544,528 issued and				
outstanding at June 30, 2023 and September 30, 2022		3,839		554
Additional paid-in capital		109,981,627		88,871,786
Accumulated deficit		(106,567,014)		(91,411,059)
Total stockholders' equity (deficit)		3,418,452		(2,538,719)
Total liabilities and stockholders' equity (deficit)	\$	10,034,810	\$	5,830,012

# Sonnet BioTherapeutics Holdings, Inc. Consolidated Statements of Operations (unaudited)

	Three Months Ended June 30,				Nine Months Ended June 30,			
	2023	2022		2023		2022		
Collaboration revenue	\$ 36,850	\$	62,071	\$	110,550	\$	287,190	
Operating expenses:								
Research and development	2,409,471		5,648,952		9,972,055		16,320,090	
General and administrative	1,542,689		2,280,345		5,330,967		6,259,494	
Total operating expenses	3,952,160		7,929,297		15,303,022		22,579,584	
Loss from operations	(3,915,310)		(7,867,226)		(15,192,472)		(22,292,394)	
Foreign exchange (loss) gain	(31,432)		(9,794)		36,517		5,894	
Net loss	\$ (3,946,742)	\$	(7,877,020)	\$	(15,155,955)	\$	(22,286,500)	
Per share information:	 							
Net loss per share, basic and diluted	\$ (0.13)	\$	(1.82)	\$	(0.86)	\$	(5.17)	
Weighted average shares outstanding, basic and diluted	29,376,018		4,330,489		17,568,549		4,314,635	

# Sonnet BioTherapeutics Holdings, Inc. Consolidated Statements of Changes in Stockholders' (Deficit) Equity (unaudited)

Additional paid-Accumulated Common stock in Shares Amount capital deficit Total Balance at October 1, 2022 5,544,528 (91,411,059) (2,538,719) 554 88,871,786 \$ Sale of common stock, net of issuance costs 2,416,487 242 4,451,770 4,452,012 Net share settlement of warrants 3,026 Share-based compensation 91,617 91,617 Net loss (5,542,142) (5,542,142)Balance at December 31, 2022 7,964,041 796 93,415,173 (96,953,201) (3,537,232)14,515,968 Sale of common stock, net of issuance costs 12,255,830 1,226 14,514,742 Net share settlement of warrants 231,481 23 (23)Issuance of common stock on vesting of restricted stock units 47,018 5 (5) 56,998 56,998 Share-based compensation Net loss (5,667,071)(5,667,071) 5,368,663 Balance at March 31, 2023 20,498,370 2,050 107,986,885 (102,620,272)Sale of common stock, net of issuance costs 3,660,000 366 1,945,311 1,945,677 Net share settlement of warrants 11,194,493 1,119 (1,119)Issuance of common stock on vesting of restricted stock units 785 3,036,000 304 545 849 Exercise of warrants 50,005 Share-based compensation 50,005 Net loss (3,946,742)(3,946,742) Balance at June 30, 2023 38,389,648 3,839 109,981,627 (106,567,014) 3,418,452

# Sonnet BioTherapeutics Holdings, Inc. Consolidated Statements of Changes in Stockholders' (Deficit) Equity (unaudited)

				Ad	ditional paid-			
_	Commo	on stock	ζ		in	Α	ccumulated	
	Shares		Amount	capital		deficit		Total
Balance at October 1, 2021	4,303,617	\$	430	\$	83,948,635	\$	(61,689,218)	\$ 22,259,847
Share-based compensation	_		_		332,075		_	332,075
Net loss	_		_		_		(6,200,981)	(6,200,981)
Balance at December 31, 2021	4,303,617		430		84,280,710		(67,890,199)	16,390,941
Issuance of common stock on vesting of restricted stock units	893		_		_		_	_
Share-based compensation	_		_		350,891		_	350,891
Net loss	_		_		_		(8,208,499)	(8,208,499)
Balance at March 31, 2022	4,304,510		430		84,631,601		(76,098,698)	8,533,333
Issuance of common stock on vesting of restricted stock units	324,768		32		(32)		_	_
Share-based compensation	_		_		107,892		_	107,892
Net loss	_		<u> </u>				(7,877,020)	(7,877,020)
Balance at June 30, 2022	4,629,278	\$	462	\$	84,739,461	\$	(83,975,718)	\$ 764,205

# Sonnet BioTherapeutics Holdings, Inc. Consolidated Statements of Cash Flows (unaudited)

		Nine Months Ended June 30,				
		2023		2022		
Cash flows from operating activities:						
Net loss	\$	(15,155,955)	\$	(22,286,500)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation		9,634		9,634		
Acquired in-process research and development		282,000		871,877		
Amortization of operating lease right-of-use asset		46,650		65,695		
Share-based compensation		198,620		790,858		
Change in operating assets and liabilities:						
Incentive tax receivable		(31,864)		_		
Prepaid expenses and other current assets		(218,940)		(754,872)		
Other assets		(155,366)		_		
Accounts payable		(1,877,222)		(761,833)		
Accrued expenses and other current liabilities		264,872		893,728		
Operating lease liability		(34,609)		(66,991)		
Deferred income		(110,549)		(287,190)		
Net cash used in operating activities		(16,782,729)		(21,525,594)		
Cash flows from investing activities:						
Purchase of in-process research and development		(273,250)		(871,877)		
Net cash used in investing activities		(273,250)		(871,877)		
Cash flows from financing activities:						
Proceeds from sale of common stock, net of issuance costs		21,024,070		_		
Proceeds from the exercise of warrants		849		_		
Repayments of related party note		(748)		_		
Net cash provided by financing activities		21,024,171				
Net increase (decrease) in cash		3,968,192		(22,397,471)		
Cash, beginning of period		3,052,879		27,622,067		
Cash, end of period	\$	7,021,071	\$	5,224,596		
Complemental displaceurs of non-cock argusting investing and financing activities.		_				
Supplemental disclosure of non-cash operating, investing and financing activities:  Net settlement of warrants	Ф	1 140	Φ			
	\$	1,142	\$	_		
Acquired in-process research and development in accounts payable	\$	170,000	\$			
Change in operating right-of-use asset and liability due to amended lease	\$	_	\$	213,793		
Deferred offering costs charged against proceeds from sale of common stock	\$	32,340	\$	_		
Issuance of common stock on vesting of restricted stock units	\$	5	\$	33		
Common stock issuance costs in accrued expenses and accounts payable	\$	78,073	\$	_		

# 1. Organization and Description of Business

#### Description of business

Sonnet BioTherapeutics, Inc. ("Prior Sonnet") was incorporated as a New Jersey corporation on April 6, 2015. Prior Sonnet completed a merger with publicly-held Chanticleer Holdings, Inc. ("Chanticleer") on April 1, 2020. After the merger, Chanticleer changed its name to Sonnet BioTherapeutics Holdings, Inc. ("Sonnet" or the "Company"). Sonnet is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single- or bi-specific action. Known as  $F_HAB^{TM}$  (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin ("HSA") for transport to target tissues.

Sonnet's lead proprietary asset, SON-1010, is a fully human version of Interleukin 12 ("IL-12"), covalently linked to the F<sub>H</sub>AB construct, for which Sonnet intends to pursue clinical development in solid tumor indications, including ovarian cancer, non-small cell lung cancer and head and neck cancer. In March 2022, the FDA cleared Sonnet's Investigational New Drug ("IND") application for SON-1010. This allowed the Company to initiate a U.S. clinical trial (SB101) in oncology patients with solid tumors during the second calendar quarter of 2022. In September 2021, the Company created a wholly-owned Australian subsidiary, SonnetBio Pty Ltd ("Subsidiary"), for the purpose of conducting certain clinical trials. Sonnet received approval and initiated an Australian clinical study (SB102) of SON-1010 in healthy volunteers during the third calendar quarter of 2022. Interim safety and tolerability data from the SB101 and SB102 studies were reported in April 2023.

In January 2023, Sonnet announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). The companies have entered into a Master Clinical Trial and Supply Agreement ("MCSA"), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer ("PROC") patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). Part 1 of this 2-part study was recently approved by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. Recruitment is expected to begin imminently. As part of the ongoing cost-cutting evaluations, all antiviral development with SON-1010 has been suspended.

The Company acquired the global development rights to its most advanced compound, SON-080, a fully human version of Interleukin 6 ("IL-6"), in April 2020 through its acquisition of the outstanding shares of Relief Therapeutics SA. Sonnet is advancing SON-080 in target indications of Chemotherapy-Induced Peripheral Neuropathy ("CIPN") and Diabetic Peripheral Neuropathy ("DPN"). Sonnet received approval to initiate an ex-U.S. Phase 1b/2a study with SON-080 in CIPN during the third quarter of 2022. The Data Safety Monitoring Board (DSMB) overseeing the study is expected to meet during the third quarter of 2023. Following the completion of the DSMB review, we anticipate announcing initial safety data from the CIPN study. Pursuant to a license agreement the Company entered with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, Sonnet and New Life will be jointly responsible for developing SON-080 in DPN. The objective will be to analyze the data and to consider initiating a Phase 2 study once the CIPN safety data has been evaluated.

SON-1210 (IL12-F<sub>H</sub>AB-IL15), Sonnet's lead bi-specific construct, combines F<sub>H</sub>AB with fully human IL-12 and fully human Interleukin 15 ("IL-15"). This compound is being developed for solid tumor indications, including colorectal cancer. In February 2023, the Company announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. Sonnet is prepared to initiate the regulatory authorization process for SON-1210 in 2023, subject to having a partnering opportunity in place.

SON-1410 (IL18-F<sub>H</sub>AB-IL12) is a bi-specific combination of Interleukins 18 ("IL-18") and 12 (IL-12) for solid tumor cancers. Cell line development for GMP application is underway. After some delays in 2023, process development activities will continue into 2024, with the potential to generate a drug suitable for initial *in vivo* mice studies during the second half of calendar year 2024.

The Company has completed sequence confirmation for SON-3015 (anti-IL6-F<sub>H</sub>AB-anti-TGFβ). Early stage bi-specific drug has been generated and is being stored for future use in *in vivo* mice studies. Sonnet has elected to place the SON-3015 development program on hold for expense reduction purposes.

#### Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and it expects to generate losses from operations for the foreseeable future primarily due to research and development costs for its potential product candidates. The Company believes its cash of \$7.0 million at June 30, 2023 will fund the Company's projected operations into 2024. Substantial additional financing will be needed by the Company to fund its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company plans to secure additional capital in the future through equity or debt financings, partnerships, collaborations, or other sources to carry out the Company's planned development activities. If additional capital is not available when required, the Company may need to delay or curtail its operations until such funding is received. Various internal and external factors will affect whether and when the Company's product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company's product candidates, length of time and cost of developing and commercializing these product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations.

Operations since inception have consisted primarily of organizing the Company, securing financing, developing its technologies through performing research and development and conducting preclinical studies. The Company faces risks associated with companies whose products are in development. These risks include the need for additional financing to complete its research and development, achieving its research and development objectives, defending its intellectual property rights, recruiting and retaining skilled personnel, and dependence on key members of management.

### 2. Summary of Significant Accounting Policies

# a. Basis of presentation

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates (ASUs") of the Financial Accounting Standards Board ("FASB"). In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2023 and its results of operations for the three and nine months ended June 30, 2023 and 2022 and cash flows for the nine months ended June 30, 2023 and 2022. The unaudited interim consolidated financial statements presented herein do not contain the required disclosures under U.S. GAAP for annual financial statements and should be read in conjunction with the annual audited financial statements and related notes of Sonnet as of and for the year ended September 30, 2022 included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

# b. Consolidation

The unaudited interim consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

#### c. Use of estimates

The preparation of the interim unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant estimates and assumptions reflected in these unaudited interim consolidated financial statements include the accrual of research and development expenses. Estimates and assumptions are periodically reviewed in-light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from management's estimates.

#### d. Reclassifications

Certain amounts from the prior period have been reclassified to conform with the current period presentation.

#### e. Incentive tax receivable

Subsidiary is eligible to participate in an Australian research and development tax incentive program. As part of this program, Subsidiary is eligible to receive a cash refund from the Australian Taxation Office for a percentage of the research and development costs expended by Subsidiary in Australia. The cash refund is available to eligible companies with annual aggregate revenues of less than \$20.0 million (Australian) during the reimbursable period. The Company estimates the amount of cash refund it expects to receive related to the Australian research and development tax incentive program and records the incentive when it is probable (i) the Company will comply with relevant conditions of the program and (ii) the incentive will be received. As of June 30, 2023, the Company's estimate of the amount of cash refund it expects to receive for eligible spending related to the Australian research and development tax incentive program was \$0.7 million. For the three months ended June 30, 2023 and 2022, \$0.3 million and \$0.3 million, respectively, for the expected net cash (payment) refund related to the tax incentive program was included as an offset to research and development expenses. For the months ended June 30, 2023 and 2022, \$0.8 million and \$0.4 million, respectively, for the expected net cash refund related to the tax incentive program was included in research and development expenses. In January 2023, the Company received \$1.1 million from the Australian government related to eligible research and development expenses for the year ended September 30, 2022. In April 2023, the Company refunded the Australian government for \$0.2 million due to new information on the Company's clinical trial studies.

R&D tax credit is an opportunity available with the State of New Jersey. The company seeks to apply for such tax credits. There is no assurance that such tax credit could be made available.

# f. Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets. Expenditures for repairs and maintenance that do not extend the estimated useful life or improve an asset are expensed as incurred. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts, and any resulting gain or loss is included in the consolidated statement of operations.

# g. Collaboration revenue

Collaboration arrangements may contain multiple components, which may include (i) licenses; (ii) research and development activities; and (iii) the manufacturing and supply of certain materials. Payments pursuant to these arrangements may include non-refundable payments, upfront payments, milestone payments upon the achievement of significant regulatory and development events, sales milestones and royalties on product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under a collaboration arrangement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue as the Company satisfies each performance obligation.

The Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, and assessing the recognition of variable consideration. When consideration is received prior to the Company completing its performance obligation under the terms of a contract, a contract liability is recorded as deferred income. Deferred income expected to be recognized as revenue within the twelve months following the balance sheet date is classified as a current liability. In May 2021, the Company entered into a License Agreement (the "New Life Agreement") with New Life. See Note 5 for further discussion of the New Life Agreement.

### h. Research and development expense

Research and development expenses include all direct and indirect costs associated with the development of the Company's biopharmaceutical products. These expenses include personnel costs, consulting fees, and payments to third parties for research, development, and manufacturing services. These costs are charged to expense as incurred.

At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the related project, based on the measure of progress as defined in the contract. Factors the Company considers in preparing the estimates include costs incurred by the service provider, milestones achieved, and other criteria related to the efforts of its service providers. Such estimates are subject to change as additional information becomes available. Depending on the timing of payment to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company will record a prepaid expense or accrued liability relating to these costs. Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Contingent development or regulatory milestone payments are recognized upon the related resolution of such contingencies.

# i. Reverse stock split

On September 16, 2022, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware, which effected a 1-for-14 reverse stock split of the Company's issued and outstanding shares of common stock. As a result of the reverse stock split, every 14 shares of common stock issued and outstanding was converted into one share of common stock. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity. No fractional shares were issued in connection with the reverse stock split. Stockholders who would otherwise be entitled to a fractional share of common stock were instead entitled to receive a proportional cash payment. The reverse stock split did not change the par value or authorized number of shares of common stock. All common share and per share amounts presented in the unaudited interim consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

### j. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period (and potential shares of common stock that are exercisable for little or no consideration). Included in basic weighted-average number of shares of common stock outstanding during the three and nine months ended June 30, 2023 are the pre-funded February 2023 and June 2023 warrants with an exercise price of \$0.0001 per share. Included in basic weighted-average number of shares of common stock outstanding during the nine months ended June 30, 2023 and the three and nine months ended June 30, 2022 are the Series B warrants with an exercise price of \$0.0014 per share.

Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities such as common stock warrants and stock options which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted shares of common stock outstanding as they would be anti-dilutive:

	Jun	June 30,			
	2023	2022			
Common stock warrants August 2021	2,827,708	2,827,708			
Underwriter warrants August 2021	50,416	50,416			
Private warrants	_	7,549			
Chanticleer warrants	1,267	1,267			
Series C warrants	809,243	809,243			
Series 3 warrants	276,140	_			
Unvested restricted stock units and awards	172,667	48,156			
Common stock warrants February 2023	5,981,482	_			
Underwriter warrants February 2023	972,222	_			
Common stock private placement warrants June 2023	5,000,000	_			
PA warrants June 2023	150,000				
	16,241,145	3,744,339			

# k. Recent accounting pronouncements

Recently adopted

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The amendments in ASU 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The adoption of ASU 2021-04 on October 1, 2022 did not have any impact on the unaudited interim consolidated financial statements.

#### 3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 202	September 30, 2022		
Compensation and benefits	\$	2,137,223	\$	1,218,530
Research and development		854,280		1,593,922
Professional fees		321,396		378,890
Other		2,505		2,630
	\$	3,315,404	\$	3,193,972

# 4. Commitments and Contingencies

### Legal proceedings

From time to time, the Company is a party to various lawsuits, claims, and other legal proceedings that arise in the ordinary course of its business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company's consolidated financial position, results of operations, or cash flows.

#### License agreements

In July 2012, the Company entered into a Discovery Collaboration Agreement (the "Collaboration Agreement") with XOMA (US) LLC ("XOMA"), pursuant to which XOMA granted to the Company a non-exclusive, non-transferable license and/or right to use certain materials, technologies and related information related to discovery, optimization and development of antibodies and related proteins and to develop and commercialize products thereunder. The Company is obligated to make contingent milestone payments to XOMA totaling \$3.8 million on a product-by-product basis upon the achievement of certain development and approval milestones related to a product. The Company has also agreed to pay XOMA low single-digit royalties on net sales of products sold by the Company. Royalties on each product are payable on a country-by-country basis until the later of (i) a specified period of time after the first commercial sale, and (ii) the date of expiration of the last valid claim in the last-to-expire of the issued patents covered by the Collaboration Agreement. The first milestone was achieved in April 2022, at which time the Company incurred a \$0.5 million license fee which was recorded as acquired in-process research and development.

In August 2015, the Company entered into a License Agreement (the "ARES License Agreement") with Ares Trading, a wholly-owned subsidiary of Merck KGaA ("ARES"). Under the terms of the ARES License Agreement, ARES has granted the Company a sublicensable, exclusive, worldwide, royalty-bearing license on proprietary patents to research, develop, use and commercialize products using atexakin alfa ("Atexakin"), a low dose formulation of human IL-6 in peripheral neuropathies and vascular complications. Pursuant to the ARES License Agreement, the Company will pay ARES high single-digit royalties on net sales of products sold by the Company. Royalties are payable on a product-by-product and country-by-country basis until the later of (i) a specified period of time after the first commercial sale in such country, and (ii) the last date on which such product is covered by a valid claim in such country.

In January 2019, the Company entered into a Frame Services and License Agreement (the "Cellca Agreement") with Sartorius Stedim Cellca GMBH ("Cellca"), pursuant to which Cellca has granted the Company a worldwide, non-exclusive, perpetual, non-transferable license to develop, manufacture or have manufactured, use, sell, import, export and/or otherwise commercialize product based on Cellca's work to generate a specified transfected cell line and develop an upstream production process for such cell line. The Cellca Agreement is effective unless terminated by either party by giving six months notice, or by giving 14 days notice if terminated for good cause. The Company is obligated to make milestone payments to Cellca totaling up to \$0.7 million upon the achievement of certain development and approval milestones if the Buy-Out Option is not exercised. The Company has a Buy-Out Option that will be effective between the time of completion of a clinical trial and the receipt of regulatory approval for commercialization of product. The cost to exercise the Buy-Out Option will replace the \$0.6 million contingent milestone payment due upon final regulatory approval. The first milestone was achieved in April 2022, at which time the Company incurred a \$0.1 million license fee which was recorded as acquired in-process research and development.

In October 2021, the Company entered into a Non-Exclusive License Agreement (the "Brink Agreement") with Brink Biologics Inc. ("Brink"), pursuant to which Brink has granted the Company a non-exclusive, non-transferable license and limited right to sublicense certain materials and related information to develop cell-based assays for batch, quality control, stability, efficacy, potency or any other type of assay required for production and commercialization of products. During the product development phase, the Company was obligated to make annual product development license fee payments of approximately \$0.1 million. In April 2023, the Brink Agreement was amended, effective November 2022, to reduce the annual license fee payments to \$12,000 for storage. If materials are removed from storage during the product development phase, the annual product development license fee of approximately \$0.1 million will apply. If a product achieves commercial status, the Company is obligated to make a commercial product license fee payment of approximately \$0.1 million per commercial product. The amended agreement has an initial term of one year and will automatically renew for one additional year unless terminated or converted to a product development license. After the second year, the license will automatically convert to a full license requiring a product development or a commercial product license fee unless the parties mutually agree to terminate the agreement. The Company incurred \$12,000 in license fees during the nine months ended June 30, 2023, which was recorded as acquired in-process research and development and included in research and development expenses in the unaudited interim consolidated statement of operations. The Company incurred a \$0.1 million license fee which was recorded as acquired in-process research and development and included in research and development expenses in the unaudited interim consolidated statement of operations for the nine months ended June 30, 2022.

In February 2022, the Company entered into a Biological Materials License Agreement (the "InvivoGen Agreement") with InvivoGen SAS ("InvivoGen"), pursuant to which InvivoGen has granted the Company a worldwide, non-exclusive license to use certain reporter cells for research, development and/or quality control purposes. The InvivoGen Agreement has an initial term of three years and may be extended for two additional three-year periods upon written notice by the Company and payment of an approximately €0.1 million fee per extension (approximately \$0.1 million as of June 30, 2023). No license fees were incurred during the three and nine months ended June 30, 2023. The Company incurred a \$0.1 million license fee which was recorded as acquired in-process research and development and included in research and development expenses in the unaudited interim consolidated statements of operations for the three and nine months ended June 30, 2022.

In March 2022, the Company entered into a Material Transfer and License Agreement (the "ProteoNic Agreement") with ProteoNic B.V. ("ProteoNic"), pursuant to which ProteoNic has granted to the Company a non-exclusive, non-transferable, non-sublicensable (except as provided for in the ProteoNic Agreement) license for certain materials, including plasmids and DNA sequences used to generate the vectors used in the Company's cell lines, for the Company's use in research, development and commercialization of product. The license will continue until terminated by either party. The Company incurred a \$24,600 license fee upon obtaining the license. The Company is obligated to make contingent milestone payments to ProteoNic totaling up to €1.2 million (approximately \$1.3 million as of June 30, 2023) upon the achievement of certain development and commercialization milestones as outlined in the ProteoNic Agreement. No license fees were incurred during the three and nine months ended June 30, 2023 or 2022.

### Research and development agreement

In December 2021, the Company entered into a Research and Development Agreement (the "Navigo Agreement") with Navigo Proteins GmbH ("Navigo"), pursuant to which Navigo will perform specified evaluation and development procedures to evaluate certain materials to determine their commercial potential. Under the terms of the Navigo Agreement, the Company has granted Navigo a royalty-free, non-exclusive, worldwide, non-sublicensable, non-transferable right and license to use certain technology to perform the evaluation and development activities, and Navigo has granted the Company (i) an exclusive, worldwide, perpetual, irrevocable, sublicensable, transferable, royalty-free right and license to research, develop, use, sell, have sold, distribute, import or otherwise commercially exploit certain materials, and (ii) a non-exclusive, worldwide, perpetual, sublicensable, non-transferable right and license to make or have made such materials. The Company incurred a \$0.1 million technology access fee upon execution of the Navigo Agreement, at which time it was recorded as acquired in-process research and development milestones as outlined in the Navigo Agreement. The first milestone was achieved in December 2023, totaling up to \$1.0 million upon the achievement of certain evaluation and development milestones as outlined in the Navigo Agreement. The first milestone was achieved in December 2022, at which time the Company incurred a \$0.1 million license fee which was recorded as acquired in-process research and development and included as research and development expenses in the unaudited interim consolidated statement of operations for the three months ended June 30, 2023. The remaining evaluation milestones were achieved in April 2023, at which time the Company incurred \$0.2 million which was recorded as acquired in-process research and development and included as research and development expenses in the unaudited interim consolidated statement of operations for the three months ended June 30, 2023.

### Employment agreements

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the contract. In addition, in the event of termination of employment following a change in control, as defined, either by the Company without cause or by the employee for good reason, any unvested portion of the employee's initial stock option grant becomes immediately vested.

# 5. Collaboration Revenue

Under the New Life Agreement, the Company granted New Life an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in Malaysia, Singapore, Indonesia, Thailand, Philippines, Vietnam, Brunei, Myanmar, Lao PDR and Cambodia (the "Exclusive Territory"). New Life had the option to expand (1) the field of the exclusive license to include the prevention, treatment or palliation of chemotherapy-induced peripheral neuropathy in humans (the "CIPN Field"), which option was non-exclusive and expired on December 31, 2021; and/or (2) the territorial scope of the license to include the People's Republic of China, Hong Kong and/or India, which option was exclusive and expired on December 31, 2021.

The Company will retain all rights to manufacture Compounds and Products anywhere in the world. The Company and New Life shall enter into a follow-on supply agreement pursuant to which the Company shall supply to New Life Products for development and commercialization thereof in the DPN Field in the Exclusive Territory on terms to be negotiated by the parties. The Company will also assist in transferring certain preclinical and clinical development know-how that is instrumental in New Life's ability to benefit from the license.

New Life will bear the cost of, and be responsible for, among other things, conducting clinical studies and additional non-clinical studies and other developmental and regulatory activities for and commercializing Products in the DPN Field in the Exclusive Territory.

New Life paid the Company a \$0.5 million non-refundable upfront cash payment in August 2020 upon executing a letter of intent to negotiate a license agreement and a \$0.5 million non-refundable upfront cash payment in June 2021 in connection with the execution of the New Life Agreement. New Life is also obligated to pay a non-refundable deferred license fee of an additional \$1.0 million at the time of the satisfaction of certain milestones, as well as potential additional milestone payments to the Company of up to \$19.0 million subject to the achievement of certain development and commercialization milestones. In addition, during the Royalty Term (as defined below), New Life is obligated to pay the Company tiered double-digit royalties ranging from 12% to 30% based on annual net sales of Products in the Exclusive Territory. The "Royalty Term" means, on a Product-by-Product and a country-by-country basis in the Exclusive Territory, the period commencing on the date of the first commercial sale (subject to certain conditions) of such Product in such country in the Exclusive Territory and continuing until New Life ceases commercialization of such Product in the DIPN Field.

The New Life Agreement will remain in effect on a Product-by-Product, country-by-country basis and will expire upon the expiration of the Royalty Term for the last-to-expire Product in the last-to-expire country, subject to (i) each party's early termination rights including for material breach or insolvency or bankruptcy of the other party and (ii) the Company's Buy Back Right and New Life's Give Back Right (as defined below).

In addition, New Life granted to the Company an exclusive option to buy back the rights granted by the Company to New Life and the Company granted New Life the right to give back the rights with respect to Products in the DPN Field in one or more countries in the Exclusive Territory on terms to be agreed upon, which options will expire upon the initiation of a Phase III Trial for the applicable Product.

# Revenue recognition

The Company first assessed the New Life Agreement under ASC 808, Collaborative Arrangements ("ASC 808") to determine whether the New Life Agreement or units of accounts within the New Life Agreement represent a collaborative arrangement based on the risks and rewards and activities of the parties. The Company applied relevant guidance from ASC 606, Revenue from Contracts with Customers ("ASC 606"), to evaluate the appropriate accounting for the collaborative arrangement with New Life. In accordance with this guidance, the Company identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the "License"); and (ii) transfer of know-how and clinical development and regulatory activities ("R&D Activities"). The options to expand the CIPN Field and territory as well as the future supply agreement represent optional purchases, which are accounted for as separate contracts. The Company evaluated these separate contracts and did not identify any material right to be present. The Company determined that License and the R&D services are not distinct from each other and therefore combined these material promises into a single performance obligation.

The Company determined the initial transaction price of the single performance obligation to be \$1.0 million, as the future development and commercialization milestones, which represent variable consideration, are subject to constraint at inception. At the end of each subsequent reporting period, the Company will reevaluate the probability of achievement of the future development and commercialization milestones subject to constraint and, if necessary, will adjust its estimate of the overall transaction price. Any such adjustments will be recorded on a cumulative catch-up basis. For the sales-based royalties, the Company will recognize revenue when the related sales occur.

Collaboration revenue from the single performance obligation is being recognized over the estimated performance of the R&D services. The Company recognized \$36,850 and \$0.1 million of collaboration revenue for the three and nine months ended June 30, 2023, respectively. The Company recognized \$0.1 million and \$0.3 million of collaboration revenue for the three and nine months ended June 30, 2022, respectively.

### 6. Stockholders' Equity (Deficit)

The Company entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") on August 15, 2022 (the "2022 Sales Agreement"). Pursuant to the 2022 Sales Agreement, the Company may offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of its common stock having an aggregate offering price of up to \$25.0 million, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the 2022 Sales Agreement. Due to the offering limitations applicable to the Company, the Company filed prospectus supplements for the sale of shares of its common stock for an aggregate offering price of up to \$7.8 million pursuant to the 2022 Sales Agreement. During the nine months ended June 30, 2023, the Company sold an aggregate of 3,007,429 shares of common stock pursuant to the 2022 Sales Agreement with BTIG for gross proceeds of \$5.8 million and net proceeds of \$5.4 million. No shares were sold during the three months ended June 30, 2023. As of June 30, 2023, there are no registered shares remaining to be sold under the 2022 Sales Agreement.

On February 10, 2023, the Company closed a public offering of common stock and certain warrants through Chardan Capital Markets, LLC and EF Hutton, division of Benchmark Investments LLC as underwriters, for gross proceeds of \$15.0 million and net proceeds of \$13.6 million through the issuance and sale of 11,664,888 shares of its common stock and, to certain investors, pre-funded warrants to purchase 2,224,000 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 27,777,776 shares of its common stock (the "February Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was \$1.08 and the public offering price of each pre-funded warrant and accompanying common warrant was \$1.0799.

The common stock warrants are immediately exercisable at a price of \$1.08 per share of common stock, expire five years from the date of issuance and contain an alternative cashless exercise provision whereby, subject to certain conditions, a warrant may be exercised in a cashless transaction for shares of common stock at the rate of half a share of common stock per full share otherwise issuable upon a cash exercise. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of \$0.0001 per share of common stock.

In addition, warrants to purchase 972,222 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of \$1.35 per share and expire five years from the date of issuance.

On June 30, 2023, the Company closed a registered direct offering of common stock (and common stock equivalents in lieu thereof) and a concurrent private placement of certain common stock warrants through Chardan Capital Markets, LLC as placement agent, for gross proceeds of \$2.3 million and net proceeds of \$1.9 million through the issuance and sale of 3,660,000 shares of its common stock, pre-funded warrants to purchase 1,340,000 shares of common stock and accompanying common warrants to purchase up to an aggregate of 5,000,000 shares of its common stock (the "June Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The effective offering price of each share of common stock (or common stock equivalent) and accompanying common warrant was \$0.45.

The common stock warrants are exercisable beginning December 30, 2023 at a price of \$0.6749 per share of common stock and expire three and half years from the date of issuance. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of \$0.0001 per share of common stock. All of the pre-funded warrants were exercised as of June 30, 2023.

In addition, warrants to purchase 150,000 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants have an exercise price of \$0.6749 per share, are exercisable beginning December 30, 2023 and expire three and a half years from the date of issuance.

### Common stock warrants

As of June 30, 2023, the following equity-classified warrants and related terms were outstanding:

	Warrants Outstanding	Exercise Price	<b>Expiration Date</b>
Common stock warrants August 2021	2,827,708	\$ 11.90	August 24, 2024
Underwriter warrants August 2021	50,416	\$ 14.875	August 19, 2024
Chanticleer warrants	1,267	\$ 819.00 - \$ 1,274.00	April 30, 2027 - December 17, 2028
Series C warrants	809,243	\$ 44.66	October 16, 2025
Series 3 warrants	276,140	\$ 4.074	August 15, 2027
Common stock warrants February 2023	5,981,482	\$ 1.08	February 10, 2028
Underwriter warrants February 2023	972,222	\$ 1.35	February 8, 2028
Common stock private placement warrants June 2023	5,000,000	\$ 0.6749	December 30, 2026
PA warrants June 2023	150,000	\$ 0.6749	December 30, 2026
	16,068,478		
	19		

During the three months ended June 30, 2023, 21,861,332 of common stock warrants were net share settled, resulting in the issuance of 11,194,493 shares of common stock.

During the nine months ended June 30, 2023, 22,324,294 of common stock warrants were net share settled, resulting in the issuance of 11,425,974 shares of common stock.

During the three and nine months ended June 30, 2023, 3,036,000 of the pre-funded warrants were exercised on a cash basis. The Company received de minimus proceeds in exchange for the issuance of 3,036,000 shares of common stock.

During the nine months ended June 30, 2023, 3,026 of Series B warrants were net share settled, resulting in the issuance of 3,026 shares of common stock.

During the nine months ended June 30, 2023, 7,549 of private warrants expired.

### 7. Share-Based Compensation

In April 2020, the Company adopted the 2020 Omnibus Equity Incentive Plan (the "Plan"). On January 1, 2023, the total number of shares authorized under the Plan increased to 318,561. There were 318,561 shares available for issuance under the Plan as of June 30, 2023. The Plan increases the amount of shares issuable under the Plan by four percent of the outstanding shares of common stock at each January 1, each year. The Plan permits the granting of share-based awards, including stock options, restricted stock units and awards, stock appreciation rights and other types of awards as deemed appropriate, in each case, in accordance with the terms of the Plan. The terms of the awards are determined by the Company's Board of Directors.

# Restricted stock units

In July of 2020, 46,703 restricted stock units ("RSUs") were granted, 50% of which vested on April 2, 2021 and the remaining 50% vested on April 2, 2022. In March of 2021, an additional 3,357 RSUs were granted, 50% of which vested on March 25, 2022 and the remaining 50% vested on March 25, 2023. In December of 2021, 46,478 RSUs were granted, 100% of which vested on January 1, 2023. In December of 2022, 172,672 RSUs were granted, 100% of which vest on January 1, 2024.

In January 2023, 121,366 of the RSUs granted in December 2022 were cancelled and subsequently reissued as restricted shares of the Company's common stock ("Restricted Stock Awards" or "RSAs"). The RSAs have the same vesting conditions as the original RSUs issued in December 2022. The Company accounted for this as a stock compensation modification resulting in \$38,837 of incremental expense which will be recognized over the remaining vesting period.

Any unvested RSUs or RSAs will be forfeited upon termination of services. The fair value of an RSU or RSA is equal to the fair market value of the Company's common stock on the date of grant. RSU and RSA expense is amortized straight-line over the vesting period.

The Company recorded share-based compensation expense associated with the RSUs and RSAs in its accompanying unaudited interim consolidated statements of operations as follows:

	Three Months Ended June 30, 2023  Nine Months Ended June 30, 2023		Three Months Ended June 30, 2022		Nine Months Ended June 30, 2022		
Research and development	\$	24,554	\$ 102,807	\$	64,476	\$	394,558
General and administrative		25,451	95,813		43,416		396,300
	\$	50,005	\$ 198,620	\$	107,892	\$	790,858

The following table summarizes RSU activity under the Plan:

		Wei	ighted Average Grant
_	RSU		Date Fair Value
Unvested balance at October 1, 2022	47,798	\$	7.89
Granted	172,672	\$	0.98
Vested	(47,803)	\$	0.57
Forfeited/cancelled	(121,366)	\$	0.97
Unvested balance at June 30, 2023	51,301	\$	0.54

As of June 30, 2023, total unrecognized compensation expense relating to unvested RSUs granted was \$24,389, which is expected to be recognized over a weighted-average period of less than one year.

The following table summarizes RSA activity under the Plan:

		Wei	ghted Average Grant
	RSA	Date Fair Value	
Unvested balance at October 1, 2022	<del>-</del>	\$	_
Granted	121,366	\$	1.29
Vested	_	\$	_
Forfeited/cancelled	_	\$	_
Unvested balance at June 30, 2023	121,366	\$	1.29

As of June 30, 2023, total unrecognized compensation expense relating to unvested RSUs granted was \$75,623, which is expected to be recognized over a weighted-average period of less than one year.

# 8. Income Taxes

In August 2022, the U.S. enacted the Inflation Reduction Act of 2022 ("IRA"). The IRA contains a number of tax-related provisions that will be effective for tax years beginning after December 31, 2022, including a corporate alternative minimum tax of 15% on certain large corporations and an excise tax of 1% on corporate stock repurchases. The Company is currently evaluating the various provisions of the IRA and does not anticipate a material impact on its consolidated financial statements.

# 9. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through the date the unaudited interim consolidated financial statements were available to be issued.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Quarterly Report, particularly those under "Risk Factors."

# CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history and history of operating losses;
- our need for significant additional capital and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our products and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- · acceptance of our business model by investors;
- the potential impact of the recent COVID-19 pandemic on our operations, including on our clinical development plans and timelines;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

### Overview

Sonnet BioTherapeutics Holdings, Inc. ("Sonnet," "we," "us," "our" or the "Company"), is a clinical stage, oncology-focused biotechnology company with a proprietary platform for innovating biologic medicines of single- or bi-specific action. Known as  $F_HAB^{TM}$  (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment that binds to and "hitch-hikes" on human serum albumin for transport to target tissues. We designed the construct to improve drug accumulation in specific tissues, as well as to extend the duration of activity in the body.  $F_HAB$  development candidates are produced in a mammalian cell culture, which enables glycosylation, thereby reducing the risk of immunogenicity. We believe our  $F_HAB$  technology, for which we received a U.S. patent in June 2021, is a distinguishing feature of our biopharmaceutical platform that is well suited for future drug development across a range of human disease areas, including in oncology, autoimmune, pathogenic, inflammatory, and hematological conditions.

Our current internal pipeline development activities are focused on cytokines, a class of cell signaling peptides that, among other important functions, serve as potent immunomodulatory agents. Working both independently and synergistically, specific cytokines have shown the ability to modulate the activation and maturation of immune cells that fight cancer and pathogens. However, because they do not preferentially accumulate in specific tissues and are quickly eliminated from the body, the conventional approach to achieving a treatment effect with cytokine therapy typically requires the administration of high and frequent doses. This can result in a reduced treatment effect accompanied by the potential for systemic toxicity, which poses challenges to the therapeutic application of this class of drugs.

Our lead proprietary asset, SON-1010, is a fully human version of Interleukin 12 ("IL-12"), covalently linked to the F<sub>H</sub>AB construct, for which we intend to pursue clinical development in solid tumor indications, including ovarian cancer, non-small cell lung cancer and head and neck cancer. In March 2022, the FDA cleared our Investigational New Drug ("IND") application for SON-1010. This allowed us to initiate a U.S. clinical trial (SB101) in oncology patients with solid tumors during the second calendar quarter of 2022. In September 2021, we created a wholly-owned Australian subsidiary, SonnetBio Pty Ltd, for the purpose of conducting certain clinical trials. We received approval and initiated an Australian clinical study (SB102) of SON-1010 in healthy volunteers during the third calendar quarter of 2022. Interim safety and tolerability data from the SB101 and SB102 studies were reported in April 2023.

In January 2023, we announced a collaboration agreement with Roche for the clinical evaluation of SON-1010 with atezolizumab (Tecentriq®). The companies have entered into a Master Clinical Trial and Supply Agreement ("MCSA"), along with ancillary Quality and Safety Agreements, to study the safety and efficacy of the combination of SON-1010 and atezolizumab in a platinum-resistant ovarian cancer ("PROC") patient setting. Further, the companies will provide SON-1010 and atezolizumab, respectively, for use in the Phase 1b/Phase 2a combination safety, dose-escalation, and efficacy study (SB221). Part 1 of this 2-part study was recently approved by the local Human Research Ethics Committee in Australia under CT-2023-CTN-01399-1 and the Therapeutic Goods Administration has been notified. Recruitment is expected to begin imminently.

We acquired the global development rights to its most advanced compound, SON-080, a fully human version of Interleukin 6 ("IL-6"), in April 2020 through its acquisition of the outstanding shares of Relief Therapeutics SA. Sonnet is advancing SON-080 in target indications of Chemotherapy-Induced Peripheral Neuropathy ("CIPN") and Diabetic Peripheral Neuropathy ("DPN"). We received approval to initiate an ex-U.S. Phase 1b/2a study with SON-080 in CIPN during the third quarter of 2022. The Data Safety Monitoring Board (DSMB) overseeing the study is expected to meet during the third quarter of 2023. Following the completion of the DSMB review, we anticipate announcing initial safety data from the CIPN study. Pursuant to a license agreement we entered with New Life Therapeutics Pte, Ltd. ("New Life") of Singapore in May 2021, Sonnet and New Life will be jointly responsible for developing SON-080 in DPN. The objective will be to analyze the data and to consider initiating a Phase 2 study, once the CIPN safety data has been evaluated.

SON-1210 (IL12-F<sub>H</sub>AB-IL15), Sonnet's lead bi-specific construct, combines F<sub>H</sub>AB with fully human IL-12 and fully human Interleukin 15 ("IL-15"). This compound is being developed for solid tumor indications, including colorectal cancer. In February 2023, we announced the successful completion of two IND-enabling toxicology studies with SON-1210 in non-human primates. We are is prepared to initiate the regulatory authorization process for SON-1210 in 2023, subject to having a partnering opportunity in place.

SON-1410 (IL18-F<sub>H</sub>AB-IL12) is a bi-specific combination of Interleukins 18 ("IL-18") and 12 (IL-12) for solid tumor cancers. Cell line development for GMP application is underway. After some delays in 2023, process development activities will continue into 2024, with the potential to generate a drug suitable for initial *in vivo* mice studies during the second half of the 2024 calendar year.

We have completed sequence confirmation for SON-3015 (anti-IL6-F<sub>H</sub>AB-anti-TGFβ). Early stage bi-specific drug has been generated and is being stored for future use in *in vivo* mice studies. We have elected to place the SON-3015 development program on hold for expense reduction purposes.

As part of the ongoing cost-cutting evaluations, all antiviral development with SON-1010 has been suspended.

We have incurred recurring operating losses and negative cash flows since inception. Our ability to generate product or licensing revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were \$15.2 million and \$22.3 million for the nine months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had cash of \$7.0 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct additional clinical trials for product candidates;
- continue to discover and develop additional product candidates;
- · acquire or in-license other product candidates and technologies;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we
  may obtain regulatory approval;
- seek regulatory approval for product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our operation as a public reporting company.

We will not generate revenue from product sales, if any, unless and until we receive licensing revenue and/or successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. We will continue to incur significant costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate operations.

Since our inception in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing the Company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights and conducting discovery, research and development activities for product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from sales of common stock, warrants and proceeds from the issuance of convertible debt.

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

### Collaboration Revenue

Collaboration revenue is currently earned from the license arrangement entered into with New Life in May 2021, which granted New Life rights to an exclusive license (with the right to sublicense) to develop and commercialize pharmaceutical preparations containing a specific recombinant human IL-6, SON-080 (the "Compound") (such preparations, the "Products") for the prevention, treatment or palliation of diabetic peripheral neuropathy in humans (the "DPN Field") in the Exclusive Territory. We identified the following obligations under the arrangement: (i) License to develop, market, import, use and commercialize the Product in the Field in the Exclusive Territory (the "License"); and (ii) transfer of know-how and clinical development and regulatory activities ("R&D Activities"). We determined that the License and the R&D Activities are not distinct from each other and, therefore, combined these material promises into a single performance obligation. Under this agreement, we received upfront cash payments totaling \$1.0 million, which were fully allocated to the single performance obligation and are being recognized over the estimated performance period of R&D services.

# **Operating Expenses**

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred and such costs include:

- employee-related expenses, including salaries, share-based compensation and related benefits, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and clinical research organizations;
- the cost of manufacturing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations;
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance;
- costs related to compliance with regulatory requirements; and
- · payments made under third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided by our service providers. This process involves reviewing open contracts and purchase orders, communicating with their personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense when the goods have been delivered or the services have been performed.

Our direct research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under third-party license agreements. We do not allocate employee costs and costs associated with discovery efforts, laboratory supplies and facilities, including depreciation or other indirect costs, to specific product candidates because these costs are deployed across multiple programs and as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and therefore, we do not track costs by product candidate.

We will continue to incur research and development expenses for the foreseeable future as we attempt to advance development of our product candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our current pipeline or any future product candidates we may develop due to the numerous risks and uncertainties associated with clinical development, including risk and uncertainties related to:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs that we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with investigational new drug-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;

- our ability to establish new licensing or collaboration arrangements;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of product candidates, if approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- the potential impact of COVID-19 on operations which may affect among other things, the timing of clinical trials, availability of raw materials, and the ability to access and secure testing facilities.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

# General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation, in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting, and audit services.

Our general and administrative expenses will increase in the future as we increase our headcount to support continued research activities and development of product candidates. We will continue to incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

## Foreign Exchange Gain (Loss)

Foreign exchange gain (loss) consists of exchange rate changes on transactions denominated in currencies other than the U.S. dollar.

### **Results of Operations**

# Comparison of the Three Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30,						
		2023		2022		Change	
Collaboration revenue	\$	36,850	\$	62,071	\$	(25,221)	
Operating expenses:							
Research and development		2,409,471		5,648,952		(3,239,481)	
General and administrative		1,542,689		2,280,345		(737,656)	
Total operating expenses		3,952,160		7,929,297		(3,977,137)	
Loss from operations		(3,915,310)		(7,867,226)		3,951,916	
Foreign exchange (loss) gain		(31,432)		(9,794)		(21,638)	
Net loss	\$	(3,946,742)	\$	(7,877,020)	\$	3,930,278	

### Collaboration Revenue

We recognized \$36,850 of revenue related to the New Life Agreement during the three months ended June 30, 2023 compared to \$62,071 during the three months ended June 30, 2022. The decrease of \$25,221 was due to a delay in timing in the performance of R&D services.

# Research and Development Expenses

Research and development expenses were \$2.4 million for the three months ended June 30, 2023, compared to \$5.6 million for the three months ended June 30, 2022. The decrease of \$3.2 million was primarily due to the establishment of cost savings by transitioning product development activities to cost advantaged locations such as India and Australia and by reducing expenditures on tertiary programs such as SON-3015, which has been placed on a development hold, as well as a decrease in share-based compensation expense.

# General and Administrative Expenses

General and administrative expenses were \$1.5 million and \$2.3 million for the three months ended June 30, 2023 and 2022, respectively. The decrease in general and administrative expenses is a result of cost saving initiatives.

### Comparison of the Nine Months Ended June 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended June 30, 2023 and 2022:

	Nine Months Ended June 30,				
		2023		2022	 Change
Collaboration revenue	\$	110,550	\$	287,190	\$ (176,640)
Operating expenses	'				
Research and development		9,972,055		16,320,090	(6,348,035)
General and administrative		5,330,967		6,259,494	(928,527)
Total operating expenses		15,303,022		22,579,584	(7,276,562)
Loss from operations		(15,192,472)		(22,292,394)	7,099,922
Foreign exchange gain		36,517		5,894	30,623
Net loss	\$	(15,155,955)	\$	(22,286,500)	\$ 7,130,545

### Collaboration Revenue

We recognized \$0.1 million of revenue related to the New Life Agreement during the nine months ended June 30, 2023 compared to \$0.3 million during the nine months ended June 30, 2022. The decrease of \$0.2 million was due to a delay in timing in the performance of R&D services.

# Research and Development Expenses

Research and development expenses were \$10.0 million for the nine months ended June 30, 2023, compared to \$16.3 million for the nine months ended June 30, 2022. The decrease of \$6.3 million was primarily due to the establishment of cost savings by transitioning product development activities to cost advantaged locations such as India and Australia and by reducing expenditures on tertiary programs such as SON-3015, which has been placed on a development hold, as well as a decrease in share-based compensation expense.

# General and Administrative Expenses

General and administrative expenses were \$5.3 million for the nine months ended June 30, 2023, compared to \$6.3 million for the nine months ended June 30, 2022. The decrease of \$0.9 million relates primarily to a decrease in share-based compensation expense and consulting expense related to investor relations. In addition, we are managing expenses for liquidity purposes.

# **Liquidity and Capital Resources**

We have funded operations to date primarily with proceeds from sales of our equity securities. We will need to offer additional securities for sale in response to market conditions or other circumstances if we believe such a plan of financing is required to advance our business plans and is in the best interests of our stockholders. There is no certainty that equity or debt financing will be available in the future or that it will be at acceptable terms and at this time, it is not possible to predict the outcome of these matters.

We have incurred net losses of \$15.2 million and \$22.3 million for the nine months ended June 30, 2023 and 2022, respectively. We expect to continue to incur significant operational expenses and net losses in the upcoming 12 months and beyond. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the stage and complexity of our R&D studies and related expenditures, the receipt of additional payments on the licensing of our technology, if any, and the receipt of payments under any current or future collaborations we may enter into.

We have evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We believe our cash of \$7.0 million at June 30, 2023 will fund our projected operations into 2024. We also expect about \$1.5 Million to be received as tax credit, as in the previous years from Australia. Substantial additional financing will be needed by us to fund our operations. These factors raise substantial doubt about our ability to continue as a going concern.

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

	 Nine Months Ended June 30,			
	2023		2022	
Net cash used in operating activities	\$ (16,782,729)	\$	(21,525,594)	
Net cash used in investing activities	(273,250)		(871,877)	
Net cash provided by financing activities	21,024,171		_	
Net increase (decrease) in cash	\$ 3,968,192	\$	(22,397,471)	

### Operating Activities

During the nine months ended June 30, 2023, we used \$16.8 million of cash in operating activities which was primarily attributable to our net loss of \$15.2 million, a \$0.3 million increase in prepaid expenses and other current assets primarily due to cash outflows for research and development activities, a \$1.7 million net decrease in accounts payable accrued expenses and a \$0.1 million reduction in deferred income as we recognized collaboration revenue from the New Life Agreement, offset by \$0.3 million in acquired in-process research and development and \$0.2 million in share-based compensation expense.

During the nine months ended June 30, 2022, we used \$21.5 million of cash in operating activities which was primarily attributable to our net loss of \$22.3 million, a \$0.8 million increase in prepaid expenses and other current assets primarily due to cash outflows for research and development activities, and a \$0.3 million reduction in deferred income as we recognized collaboration revenue from the New Life Agreement, offset by \$0.9 million in acquired in-process research and development and \$0.8 million in share-based compensation expense.

### Investing Activities

During the nine months ended June 30, 2023, we used \$0.3 million for the purchase of acquired in-process research and development.

During the nine months ended June 30, 2022, we used \$0.9 million for the purchase of acquired in-process research and development.

### Financing Activities

During the nine months ended June 30, 2023, net cash provided by financing activities was \$21.0 million, consisting of net proceeds from the sale of common stock under an at-the-market facility and through registered public offerings.

During the nine months ended June 30, 2022, we did not incur any cash inflows or outflows relating to financing activities.

# **Funding Requirements**

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we advance preclinical activities and clinical trials of product candidates in development. In addition, we expect to continue to incur costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the scope, number, initiation, progress, timing, costs, design, duration, any potential delays, and results of clinical trials and nonclinical studies for our current or future product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates and programs that we develop or may in-license;
- the outcome, timing and cost of regulatory reviews, approvals or other actions to meet regulatory requirements established by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies for our product candidates than those that we currently expect;
- our ability to obtain marketing approval for product candidates;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights covering our product candidates;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the cost of defending intellectual property disputes, including
  patent infringement actions brought by third parties against us or our product candidates;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities with respect to product candidates;
- our ability to establish and maintain licensing, collaboration or similar arrangements on favorable terms and whether and to what extent we retain development or commercialization responsibilities under any new licensing, collaboration or similar arrangement;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the success of any other business, product or technology that we acquire or in which we invest;

- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our need and ability to hire additional management and scientific and medical personnel;
- the costs to operate as a public company in the United States, including the need to implement additional financial and reporting systems and other internal systems and infrastructure for our business;
- market acceptance of our product candidates, to the extent any are approved for commercial sale;
- the effect of competing technological and market developments; and
- the potential impact of the COVID-19 pandemic on our clinical trials and operations.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of ours may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate product development or future commercialization efforts, sell off assets, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market.

# February 2023 Offering

On February 10, 2023, we closed a public offering of common stock and certain warrants through Chardan Capital Markets, LLC and EF Hutton, division of Benchmark Investments LLC as underwriters, for net proceeds of \$13.6 million through the issuance and sale of 11,664,888 shares of our common stock and, to certain investors, prefunded warrants to purchase 2,224,000 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 27,777,776 shares of our common stock (the "February Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase two shares of common stock. The public offering price of each share of common stock and accompanying common warrant was \$1.08 and the public offering price of each pre-funded warrant and accompanying common warrant was \$1.0799. The common warrants are immediately exercisable at a price of \$1.08 per share of common stock, expire five years from the date of issuance and contain an alternative ashless exercise provision whereby, subject to certain conditions, a warrant may be exercised in a cashless transaction for shares of common stock at the rate of half a share of common stock per full share otherwise issuable upon a cash exercise. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of \$0.0001 per share of common stock. In addition, warrants to purchase 972,222 shares of common stock were issued to the underwriters as compensation for their services related to the offering. These common stock warrants have an exercise price of \$1.35 per share and expire five years from the date of issuance.

### June 2023 Offering

On June 30, 2023, the Company closed a registered direct offering of common stock (and common stock equivalents in lieu thereof) and a concurrent private placement of certain common stock warrants through Chardan Capital Markets, LLC as placement agent, for gross proceeds of \$2.3 million and net proceeds of \$1.9 million through the issuance and sale of 3,660,000 shares of its common stock, pre-funded warrants to purchase 1,340,000 shares of common stock and accompanying common warrants to purchase up to an aggregate of 5,000,000 shares of its common stock (the "June Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock. The effective offering price of each share of common stock (or common stock equivalent) and accompanying common warrant was \$0.45. The common stock warrants are exercisable beginning December 30, 2023 at a price of \$0.6749 per share of common stock and expire three and half years from the date of issuance. The pre-funded warrants are immediately exercisable at any time, until exercised in full, at a price of \$0.0001 per share of common stock. All of the pre-funded warrants were exercised as of June 30, 2023. In addition, warrants to purchase 150,000 shares of common stock were issued to the placement agent as compensation for its services related to the offering. These common stock warrants have an exercise price of \$0.6749 per share, are exercisable beginning December 30, 2023 and expire three and a half years from the date of issuance.

# At-the-Market Offering of Common Stock

We entered into an At-the-Market Sales Agreement with BTIG, LLC ("BTIG") on August 15, 2022 (the "2022 Sales Agreement"). Pursuant to the 2022 Sales Agreement, we may offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to \$25.0 million, subject to certain limitations on the amount of common stock that may be offered and sold by us set forth in the 2022 Sales Agreement. Due to the offering limitations applicable to us, we filed prospectus supplements for the sale of shares of our common stock for an aggregate offering price of up to \$7.8 million pursuant to the 2022 Sales Agreement. During the nine months ended June 30, 2023, we sold an aggregate of 3,007,429 shares of common stock pursuant to the 2022 Sales Agreement with BTIG for gross proceeds of \$5.8 million and net proceeds of \$5.4 million. No shares were sold during the three months ended June 30, 2023. As of June 30, 2023, there are no registered shares remaining to be sold under the 2022 Sales Agreement.

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to the accrual for research and development expenses. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to the unaudited interim consolidated financial statements included elsewhere in this Form 10-Q, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of the consolidated financial statements.

Research and Development Expenses

Research and development expenses include all direct and indirect costs associated with the development of our biopharmaceutical products. These expenses include personnel costs, consulting fees, and payments to third parties for research, development and manufacturing services. These costs are charged to expense as incurred.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the related project, based on the measure of progress as defined in the contract. Factors we consider in preparing the estimates include costs incurred by the service provider, milestones achieved, and other criteria related to the efforts of our service providers. Such estimates are subject to change as additional information becomes available. Depending on the timing of payment to the third-party service providers and the progress we estimate has been made as a result of the service provided, we will record a prepaid expense or accrued liability related to these costs. Contingent development or regulatory milestone payments are recognized upon the related resolution of such contingencies. As of June 30, 2023, we did not make any material adjustments to our prior estimates of accrued research and development expenses.

## **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to the unaudited interim consolidated financial statements included elsewhere in this Form 10-Q.

# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

#### ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We evaluated, under the supervision and with the participation of the principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended ("Exchange Act")) as of June 30, 2023, the end of the period covered by this report on Form 10-Q. Based on this evaluation, our Chairman, President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial officer) have concluded that our disclosure controls and procedures were effective at the reasonable assurance level at June 30, 2023.

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) is accumulated and communicated to management, including the principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### PART II - OTHER INFORMATION

# ITEM 1. LEGAL PROCEEDINGS.

We are subject to various legal proceedings from time to time in the ordinary course of business, which may not be required to be disclosed under this Item 1. For the three-month period ending June 30, 2023 covered by this Quarterly Report, there have been no reportable legal proceedings or material developments to previously reported legal proceedings.

#### ITEM 1A. RISK FACTORS.

As a smaller reporting company, we are not required to provide the information required by this item. However, we direct you to the risk factors included in the Risk Factors section in our Annual Report on Form 10-K for the year ended September 30, 2022 filed with the Securities and Exchange Commission on December 15, 2022.

# ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None noted.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None

# ITEM 6: EXHIBITS.

Exhibit No.	Description
4.1	Form of Warrant (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed with the SEC on June 30, 2023).
4.2	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to our Current Report on Form 8-K filed with the SEC on June 30, 2023).
10.1	Form of Securities Purchase Agreement, dated June 28, 2023, by and between the Company and the Purchaser (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on June 30, 2023).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).
32.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101).

<sup>\*</sup> XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

<sup>\*\*</sup> Furnished, not filed.

# **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.

SONNET BIOTHERAPEUTICS HOLDINGS, INC.

Date: August 14, 2023

By: /s/ Pankaj Mohan

Pankaj Mohan President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Jay Cross

Jay Cross Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

# CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

### I, Pankaj Mohan, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2023 of Sonnet BioTherapeutics Holdings, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - 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;
  - designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Pankaj Mohan

Pankaj Mohan Chief Executive Officer (Principal Executive Officer)

Date: August 14, 2023

# CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

# I, Jay Cross, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2023 of Sonnet BioTherapeutics Holdings, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - 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;
  - designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Jay Cross
Jay Cross
Chief Financial Officer

(Principal Financial Officer)

Date: August 14, 2023

# CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

# I, Pankaj Mohan, certify that:

- 1. I am the Chief Executive Officer of Sonnet BioTherapeutics Holdings, Inc. (the "Issuer").
- 2. Attached to this certification is the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the "Report") filed by the Issuer with the Securities Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), which contains financial statements.
- 3. I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:
  - The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
  - The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Issuer.

August 14, 2023

/s/ Pankaj Mohan
Pankaj Mohan
Chief Executive Officer
(Principal Executive Officer)

# CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

# I, Jay Cross, certify that:

- 1. I am the Chief Financial Officer of Sonnet BioTherapeutics Holdings, Inc. (the "Issuer").
- 2. Attached to this certification is the Quarterly Report on Form 10-Q for the quarter year ended June 30, 2023 (the "Report") filed by the Issuer with the Securities Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), which contains financial statements.
- 3. I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:
  - The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
  - The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Issuer.

August 14, 2023

/s/ Jay Cross
Jay Cross
Chief Financial Officer
(Principal Financial Officer)