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## DELTA REPORT

10-Q

DARIO - DARIOHEALTH CORP.

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

**TOTAL DELTAS** 2358

CHANGES	221
DELETIONS	1730
ADDITIONS	407

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** **September** 30, 2023

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-37704

**DarioHealth Corp.**

(Exact name of registrant as specified in its charter)

**Delaware**

**45-2973162**

(State or other jurisdiction of  
incorporation or organization)

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

**18 W. 18th St.**

**New York, New York**

**10011**

(Address of Principal Executive Offices)

(Zip Code)

**(972) 4 770-6377**

(Registrant's telephone number, including area code)

**n/a**

(Former name, former address and former fiscal year, if changed since last report)

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

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of exchange on which registered</b>
Common Stock, par value \$0.0001 per share	DRIO	The Nasdaq Capital Market LLC

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

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

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

Large accelerated filer  Accelerated filer

<input type="checkbox"/> Non-accelerated filer	<input type="checkbox"/> Smaller reporting company
	<input type="checkbox"/> Emerging growth company

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

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

As of **October****August** **8, 31**, 2023, the registrant had **27,229,544** **27,214,670** shares of common stock outstanding.

When used in this quarterly report, the terms "DarioHealth," the "Company," "we," "our," and "us" refer to DarioHealth Corp., a Delaware corporation, our subsidiaries LabStyle Innovation Ltd., an Israeli company, PsyInnovations Inc., a Delaware company, and DarioHealth India Services Pvt. Ltd., an Indian company. "Dario" is registered as a trademark in the United States, Israel, China, Canada, Hong Kong, South Africa, Japan, Costa Rica and Panama. "DarioHealth" is registered as a trademark in the United States and Israel.

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**DarioHealth Corp.**

**Quarterly Report on Form 10-Q**

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**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere herein may address or relate to future events and expectations and as such constitutes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Statements which are not historical reflect our current expectations and projections about our future results, performance, liquidity, financial condition, prospects and opportunities and are based upon information currently available to us and our management and their interpretation of what is believed to be significant factors affecting our business, including many assumptions regarding future events. Such forward-looking statements include statements regarding, among other things:

- our current and future capital requirements and our ability to satisfy our capital needs through financing transactions or otherwise;
- our product launches and market penetration plans;
- the execution of agreements with various providers for our solution;
- our ability to maintain our relationships with key partners, including Sanofi U.S. Services Inc. ("Sanofi");
- our ability to complete required clinical trials of our product and obtain clearance or approval from the United States Food and Drug Administration (the "FDA"), or other regulatory agencies in different jurisdictions;
- our ability to maintain or protect the validity of our U.S. and other patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy;
- interpretations of current laws and the passages of future laws; and
- acceptance of our business model by investors.

Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "should," "would," "could," "scheduled," "expect," "anticipate," "estimate," "believe," "intend," "seek," or "project" or the negative of these words or other variations on these words or comparable terminology. Actual results, performance, liquidity, financial condition and results of operations, prospects and opportunities could differ materially and perhaps substantially from those expressed in, or implied by, these forward-looking statements as a result of various risks, uncertainties and other factors. These statements may be found under the section of our Annual Report on Form 10-K for the year ended December 31, 2022 (filed on March 9, 2022) entitled "Risk Factors" as well as in our other public filings.

In light of these risks and uncertainties, and especially given the start-up nature of our business, there can be no assurance that the forward-looking statements contained herein will in fact occur. Readers should not place undue reliance on any forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason.

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**AS OF JUNE SEPTEMBER 30, 2023**
**UNAUDITED**
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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**
**INTERIM CONSOLIDATED BALANCE SHEETS**
**U.S. dollars in thousands**

	June 30, 2023		December 31, 2022		September 30, 2023		December 31, 2022	
	<u>Unaudited</u>		<u>Unaudited</u>		<u>Unaudited</u>		<u>Unaudited</u>	
<b>ASSETS</b>								
<b>CURRENT ASSETS:</b>								
Cash and cash equivalents	\$ 52,602	\$ 49,357	\$ 43,878	\$ 49,357				
Short-term restricted bank deposits	393	165	395	165				
Trade receivables	4,821	6,416	4,533	6,416				
Inventories	5,914	7,956	5,471	7,956				

Other accounts receivable and prepaid expenses	2,047	1,630	1,934	1,630
<b>Total current assets</b>	<b>65,777</b>	<b>65,524</b>	<b>56,211</b>	<b>65,524</b>
<b>NON-CURRENT ASSETS:</b>				
Deposits	6	6	5	6
Operating lease right of use assets	1,071	1,206	978	1,206
Long-term assets	170	111	131	111
Property and equipment, net	817	788	999	788
Intangible assets, net	7,678	9,916	6,541	9,916
Goodwill	41,640	41,640	41,640	41,640
<b>Total non-current assets</b>	<b>51,382</b>	<b>53,667</b>	<b>50,294</b>	<b>53,667</b>
<b>Total assets</b>	<b>\$ 117,159</b>	<b>\$ 119,191</b>	<b>\$ 106,505</b>	<b>\$ 119,191</b>

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**INTERIM CONSOLIDATED BALANCE SHEETS**

**U.S. dollars in thousands (except stock and stock data)**

	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
	Unaudited		Unaudited	
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>				
<b>CURRENT LIABILITIES:</b>				
Trade payables	\$ 1,451	\$ 2,322	\$ 1,929	\$ 2,322
Deferred revenues	789	1,320	684	1,320
Operating lease liabilities	145	293	119	293
Other accounts payable and accrued expenses	5,691	6,592	5,374	6,592
Loan, current	—	8,823	—	8,823
<b>Total current liabilities</b>	<b>8,076</b>	<b>19,350</b>	<b>8,106</b>	<b>19,350</b>
<b>NON-CURRENT LIABILITIES</b>				
Operating lease liabilities	885	827	804	827
Long-term loan	29,094	18,105	29,000	18,105
Warrant liability	664	910	524	910
Other long-term liabilities	36	—	36	—
<b>Total non-current liabilities</b>	<b>30,679</b>	<b>19,842</b>	<b>30,364</b>	<b>19,842</b>

STOCKHOLDERS' EQUITY				
Common stock of \$0.0001 par value - authorized: 160,000,000 shares; issued and outstanding: 26,784,674 and 25,724,470 shares on June 30, 2023 and December 31, 2022, respectively		3	3	
Preferred stock of \$0.0001 par value - authorized: 5,000,000 shares; issued and outstanding: 18,959 and 3,567 shares on June 30, 2023 and December 31, 2022, respectively		*) -	*) -	
Common stock of \$0.0001 par value - authorized: 160,000,000 shares; issued and outstanding: 27,215,157 and 25,724,470 shares on September 30, 2023 and December 31, 2022, respectively			3	3
Preferred stock of \$0.0001 par value - authorized: 5,000,000 shares; issued and outstanding: 18,959 and 3,567 shares on September 30, 2023 and December 31, 2022, respectively			*) -	*) -
Additional paid-in capital	395,352	365,846	401,887	365,846
Accumulated deficit	(316,951)	(285,850)	(333,855)	(285,850)
<b>Total stockholders' equity</b>	<b>78,404</b>	<b>79,999</b>	<b>68,035</b>	<b>79,999</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 117,159</b>	<b>\$ 119,191</b>	<b>\$ 106,505</b>	<b>\$ 119,191</b>

\*) Represents an amount lower than \$1

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
U.S. dollars in thousands (except stock and stock data)

	Three months ended				Six months ended			
	June 30,		June 30,		June 30,		June 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
	Unaudited		Unaudited		Unaudited		Unaudited	
Revenues:								
Services	\$ 4,149	\$ 3,265	\$ 9,406	\$ 8,249				
Consumer hardware	2,003	2,918	3,812	5,993				
Total revenues	6,152	6,183	13,218	14,242				
Cost of revenues:								
Services	1,625	1,259	3,102	1,711				
Consumer hardware	1,359	2,692	2,699	5,382				
Amortization of acquired intangible assets	1,094	1,094	2,175	2,026				
Total cost of revenues	4,078	5,045	7,976	9,119				

Gross profit	2,074	1,138	5,242	5,123
Operating expenses:				
Research and development	\$ 5,222	\$ 4,137	\$ 10,387	\$ 10,064
Sales and marketing	6,460	9,297	12,800	18,832
General and administrative	4,412	5,059	8,483	9,454
Total operating expenses	16,094	18,493	31,670	38,350
Operating loss	14,020	17,355	26,428	33,227
Total financial expenses, net	2,565	672	2,982	716
Loss before taxes	16,585	18,027	29,410	33,943
Income Tax	—	1	—	1
Net loss	\$ 16,585	\$ 18,028	\$ 29,410	\$ 33,944
Other comprehensive loss:				
Deemed dividend	\$ 1,691	\$ 433	\$ 1,691	\$ 884
Net loss attributable to shareholders	\$ 18,276	\$ 18,461	\$ 31,101	\$ 34,828
Net loss per share:				
Basic and diluted loss per share of common stock	\$ 0.58	\$ 0.74	\$ 1.03	\$ 1.43
Weighted average number of common stock used in computing basic and diluted net loss per share	28,186,345	22,426,019	27,879,881	21,925,089
	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2023</b>		<b>2022</b>	
	<b>Unaudited</b>		<b>Unaudited</b>	
Revenues:				
Services	\$ 1,765	\$ 4,553	\$ 11,171	\$ 12,802
Consumer hardware	1,753	2,052	5,565	8,045
Total revenues	3,518	6,605	16,736	20,847
Cost of revenues:				
Services	599	1,827	3,701	3,538
Consumer hardware	1,203	1,873	3,902	7,255
Amortization of acquired intangible assets	1,106	1,105	3,281	3,131
Total cost of revenues	2,908	4,805	10,884	13,924
Gross profit	610	1,800	5,852	6,923
Operating expenses:				
Research and development	\$ 5,665	\$ 4,803	\$ 16,052	\$ 14,867
Sales and marketing	6,363	7,571	19,163	26,403
General and administrative	4,128	3,999	12,611	13,453
Total operating expenses	16,156	16,373	47,826	54,723
Operating loss	15,546	14,573	41,974	47,800

Total financial expenses, net	186	1,059	3,168	1,775
Loss before taxes	15,732	15,632	45,142	49,575
Income Tax	—	—	—	1
Net loss	\$ 15,732	\$ 15,632	\$ 45,142	\$ 49,576
Other comprehensive loss:				
Deemed dividend	\$ 1,172	\$ 494	\$ 2,863	\$ 1,378
Net loss attributable to shareholders	\$ 16,904	\$ 16,126	\$ 48,005	\$ 50,954
Net loss per share:				
Basic and diluted loss per share of common stock	\$ 0.49	\$ 0.64	\$ 1.52	\$ 2.02
Weighted average number of common stock used in computing basic and diluted net loss per share	28,815,604	22,973,197	28,195,216	22,876,397

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**INTERIM STATEMENTS OF STOCKHOLDERS' EQUITY (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

	Additional				Total		Additional			
	Common Stock	Preferred Stock	paid-in	Accumulated	stockholders'	Common Stock	Preferred Stock	paid-in	Accumulated	
<b>Three Months</b>										
<b>Ended June 30,</b>										
<b>2023</b>	<b>Number</b>	<b>Amount</b>	<b>Number</b>	<b>Amount</b>	<b>capital</b>	<b>deficit</b>	<b>equity</b>			
Balance as of										
March 31,										
2023 (audited)	25,875,295	\$ 3	3,557	\$ *)-	\$ 370,702	\$ (298,675)	\$ 72,030			
<b>Three Months</b>										
<b>Ended</b>										
<b>September 30,</b>										
<b>2023</b>	<b>Number</b>	<b>Amount</b>	<b>Number</b>	<b>Amount</b>	<b>capital</b>	<b>deficit</b>				
Balance as of										
June 30, 2023										
(unaudited)										
Exercise of										
options	4,800	\$ *)-	—	—	\$ *)-	—	—			



Balance as of December 31, 2022 (audited)	25,724,470	\$	3	3,567	\$	*)-	\$365,846	\$	(285,850)	\$	79,999	25,724,470	\$	3	3,567	\$	*)-	\$365,846	\$	(285,850)
Exercise of options	4,800		*)-	—	—	*)-	—	—	—	—	—	4,800		*)-	—	—	—	*)-	—	—
Exercise of warrants											86,983		*)-	—	—	—	—	—	—	—
Extinguishment of preferred stock in connection with preferred stock modification	—	—	—	—	—	984		(984)	—	—	—	—	—	—	—	—	—	984	(984)	
Deemed dividend related to issuance of preferred stock	—	—	—	—	707		(707)	—	—	—	—	—	—	—	—	—	—	1,879	(1,879)	
Issuance of warrants to service providers	—	—	—	—	1,225		—	1,225	—	—	—	—	—	—	—	—	—	1,738	—	
Issuance of warrants related to loan agreement, net of issuance cost	—	—	—	—	1,389		—	1,389	—	—	—	—	—	—	—	—	—	1,389	—	
Stock-based compensation	619,442		—	—	8,923		—	8,923	910,642		—	—	—	—	—	—	—	13,569	—	
Conversion of preferred stock to common stock	3,582		*)-	(10)	—	—	—	—	—	—	—	3,582		*)-	(10)	—	—	—	—	
Issuance of common stock and preferred stock, net of issuance cost	355,743		*)-	15,402		*)-	16,278	—	16,278	408,043		*)-	15,402		*)-	16,482	—	—	—	
Release of common stock related to earnout consideration	76,637		*)-	—	—	—	—	—	—	76,637		*)-	—	—	—	—	—	—	—	
Net loss	—	—	—	—	—	—	(29,410)	(29,410)	—	—	—	—	—	—	—	—	—	(45,142)	—	
Balance as of June 30, 2023 (unaudited)	26,784,674	\$	3	18,959	\$	*)-	\$395,352	\$	(316,951)	\$	78,404									
Balance as of September 30, 2023 (unaudited)	27,215,157	\$	3	18,959	\$	*)-	\$401,887	\$	(333,855)	\$										

\*) Represents an amount lower than \$1.

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**INTERIM STATEMENTS OF STOCKHOLDERS' EQUITY (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

	Additional						Total			Additional					
	Common Stock		Preferred Stock		paid-in	Accumulated	stockholders'	Common Stock		Preferred Stock		paid-in	Accumulated	stockholders'	
Three Months	Number	Amount	Number	Amount	capital	deficit	equity	Number	Amount	Number	Amount	capital	deficit	equity	
Ended June 30, 2022															
Balance as of March 31, 2022															
(audited)	22,070,963	\$ 2	10,897	\$ *)-	\$ 352,564	\$ (238,381)	\$ 114,185								
Three Months															
Ended September 30, 2022															
Balance as of June 30, 2022															
(unaudited)								22,860,044	\$ 2	10,797	\$ *)-	\$ 356,492	\$ (256,842)	\$	
Conversion of preferred stock to common stock	23,365	*)-	(100)	*)-	—	—	*)-	308,711	*)-	(885)	*)-	—	—	—	
Deemed dividend related to issuance of preferred stock	—	—	—	—	433	(433)	—	—	—	—	—	—	494	(494)	
Issuance of warrants to service providers	—	—	—	—	557	—	557	—	—	—	—	—	609	—	
Stock-based compensation	824,373	*)-	—	—	3,072	—	3,072	122,253	*)-	—	—	—	4,317	—	
Repurchase and retirement of common stock	(58,657)	*)-	—	—	(134)	—	(134)								



Issuance of common stock, net of issuance cost upon													
Acquisition of Physimax Technologies Ltd.	256,660	*)-	—	—	1,186	—	1,186	256,660	*)-	—	—	1,186	—
Repurchase and retirement of common stock	(58,657)	*)-	—	—	(134)	—	(134)	(58,657)	*)-	—	—	(134)	—
Net loss	—	—	—	—	—	(33,944)	(33,944)	—	—	—	—	—	(49,576)
Balance as of June 30, 2022 (unaudited)	<u>22,860,044</u>	<u>\$ 2</u>	<u>10,797</u>	<u>\$ *)-</u>	<u>\$ 356,492</u>	<u>\$ (256,842)</u>	<u>\$ 99,652</u>						
Balance as of September 30, 2022 (unaudited)								<u>23,291,008</u>	<u>\$ 2</u>	<u>9,912</u>	<u>\$ *)-</u>	<u>\$ 361,912</u>	<u>\$ (272,968)</u>

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS**

**U.S. dollars in thousands**

	Six months ended		Nine months ended	
	June 30,		September 30,	
	2023	2022	2023	2022
Unaudited				
<u><b>Cash flows from operating activities:</b></u>				
Net loss	\$ (29,410)	\$ (33,944)	\$ (45,142)	\$ (49,576)
Adjustments required to reconcile net loss to net cash used in operating activities:				
Stock-based compensation, common stock, and payment in stock to directors, employees, consultants, and service providers	10,148	8,972	15,307	13,898
Depreciation	191	154	290	243
Change in operating lease right of use assets	135	75	228	(887)
Amortization of acquired intangible assets	2,238	2,087	3,375	3,224
Decrease (increase) in trade receivables	1,595	(1,828)	1,883	(3,211)

Increase in other accounts receivable, prepaid expense and long-term assets	(476)	(562)		
Decrease (increase) in other accounts receivable, prepaid expense and long-term assets			(324)	129
Decrease (increase) in inventories	2,042	(2,119)	2,485	(1,534)
Decrease in trade payables	(871)	(1,838)	(393)	(3,136)
Decrease in other accounts payable and accrued expenses	(865)	(1,107)	(1,182)	(1,401)
Decrease in deferred revenues	(531)	(196)	(636)	(205)
Change in operating lease liabilities	(90)	(98)	(196)	800
Remeasurement of earn-out	—	939	—	945
Non cash financial expenses	1,501	256	1,267	807
Net cash used in operating activities	(14,393)	(29,209)	(23,038)	(39,904)
<b>Cash flows from investing activities:</b>				
Purchase of property and equipment	(220)	(225)	(501)	(399)
Purchase of short-term investments	(4,996)	-	(4,996)	—
Proceeds from redemption of short-term investments	5,033	-	5,033	—
Cash paid as part of Upright Technologies Ltd. acquisition	—	(115)	—	(115)
Purchase of intangible assets			—	(115)
Net cash used in investing activities	(183)	(340)	(464)	(514)
<b>Cash flows from financing activities:</b>				
Proceeds from issuance of common stock and prefunded warrants, net of issuance costs	1,410	38,023	1,614	38,023
Proceeds from issuance of preferred stock, net of issuance costs	14,868	-	14,868	—
Proceeds from borrowings on credit agreement	29,604	23,786	29,604	23,786
Repayment of long-term loan	(27,833)	-	(27,833)	—
Repurchase and retirement of common stock	—	(134)	—	(134)
Net cash provided by financing activities	18,049	61,675	18,253	61,675
Increase in cash, cash equivalents and restricted cash and cash equivalents	3,473	32,126	(5,249)	21,257
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	49,470	35,948	49,470	35,948
Cash, cash equivalents and restricted cash and cash equivalents at end of period	\$ 52,943	\$ 68,074	\$ 44,221	\$ 57,205
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid during the period for interest on long-term loan	\$ 2,044	\$ 181	\$ 3,035	\$ 969
Non-cash activities:				
Right-of-use assets obtained in exchange for lease liabilities	\$ 14	\$ 58	\$ 14	\$ 1,177

The accompanying notes are an integral part of the unaudited interim consolidated financial statements.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 1: - GENERAL**

a. DarioHealth Corp. (the "Company" or "DarioHealth") was incorporated in the State of Delaware and commenced operations on August 11, 2011.

DarioHealth is a global digital therapeutics (DTx) company delivering personalized evidence-based interventions that are driven by precision data analytics, software, and personalized coaching. DarioHealth has developed an approach with the intent to empower individuals to adjust their lifestyle in holistic way.

DarioHealth's cross-functional team operates at the intersection of life sciences, behavioral science, and software technology to deliver seamlessly integrated and highly engaging digital therapeutics interventions. Our platform and suite of solutions deliver personalized and dynamic interventions driven by data analytics and one-on-one coaching for diabetes, hypertension, weight management, musculoskeletal pain, and behavioral health.

The Company has one reporting unit and one operating segment.

b. The Company has a wholly owned subsidiary, LabStyle Innovation Ltd. ("LabStyle"), which was incorporated and commenced operations on September 14, 2011, in Israel. Its principal business activity is to hold the Company's intellectual property and to perform research and development, manufacturing, marketing, and other business activities.

c. Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents, short-term deposits, restricted deposits, and trade receivables. For cash and cash equivalents, the Company is exposed to credit risks in the event of default by the financial institutions to the extent of the amounts recorded on the accompanying consolidated balance sheets exceed federally insured limits. The Company places its cash and cash equivalents and short-term deposits with financial institutions with high-quality credit ratings and has not experienced any losses in such accounts.

For trade receivables, the Company is exposed to credit risk in the event of non-payment by customers to the extent of the amounts recorded on the accompanying consolidated balance sheets.

As of **June 30, 2023** **September 30, 2023**, the Company's major customer accounted for **68.8%** **77.5%** of the Company's accounts receivable balance.

For the three and **six-month period** **nine-month periods** ended **June 30, 2023** **September 30, 2023**, the Company's major customer accounted for **37.8%** **5.7%** and **40.2%** **32.9%**, respectively, of the Company's revenue in the period.

d. During the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, the Company incurred operating losses and negative cash flows from operating activities amounting to **\$26,428** **\$41,974** and **\$14,393**, **\$23,038**, respectively. On **June 30, 2023** **September 30, 2023**, the Company had **\$52,602** **\$43,878** in available cash and cash equivalents. Management believes that the Company's cash on hand is sufficient to meet its obligations as they come due for at least a period of twelve months from the date of the issuance of these interim condensed consolidated financial statements. There are no assurances, however, that the Company will be able to obtain an adequate level of financial resources that are required for the long-term development and commercialization of its product offerings.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The accompanying unaudited interim consolidated financial statements as of **June 30, 2023** **September 30, 2023**, have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the unaudited interim consolidated financial statements include all adjustments of a normal recurring nature necessary for a fair presentation of the Company's consolidated financial position as of **June 30, 2023** **September 30, 2023**,

and the Company's consolidated results of operations and the Company's consolidated cash flows for the **six** **nine** months ended **June 30, 2023** **September 30, 2023**. Results for the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

#### ***Use of Estimates***

Preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires the use of estimates and judgments that affect the reported amounts in the condensed consolidated financial statements and accompanying notes. These estimates form the basis for judgments we make about the carrying values of our assets and liabilities, which are not readily apparent from other sources. We base our estimates and judgments on historical information and on various other assumptions that we believe are reasonable under the circumstances. These estimates are based on management's knowledge about current events and expectations about actions we may undertake in the future. Actual results could differ materially from those estimates.

#### ***Significant Accounting Policies***

- a. The significant accounting policies applied in the audited annual consolidated financial statements of the Company as disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 are applied consistently in these unaudited interim consolidated financial statements, except as noted in Note 1 (d), statements.
- b. Short-term restricted bank deposits:

The following table provides a reconciliation of the cash balances reported on the balance sheets and the cash, cash equivalents, and short-term restricted bank deposits balances reported in the statements of cash flows:

	June 30,		June 30,		September 30,	
	2023		2022		2023	
	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited
Cash, and cash equivalents as reported on the balance sheets	\$ 52,602		\$ 67,949		\$ 43,878	\$ 57,081
Short-term restricted bank deposits	341		125		343	124
Cash, restricted cash, cash equivalents, and restricted cash and cash equivalents as reported in the statements of cash flows	\$ 52,943		\$ 68,074		\$ 44,221	\$ 57,205

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#### **DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

##### **NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

##### **NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

- c. Revenue recognition

The Company recognizes revenue in accordance with ASC 606, "Revenue from contracts with customers," when (or as) it satisfies performance obligations by transferring promised products or services to its customers in an amount that reflects the consideration the Company expects to receive. The Company applies the following five steps: (1) identify the contract with a customer, (2) identify

the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

The Company applied the practical expedient in ASC 606 and did not evaluate payment terms of one year or less for the existence of a significant financing component.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. For contracts that contain multiple performance obligations, the Company allocates the transaction price to each performance obligation based on the relative standalone selling price ("SSP") for each performance obligation. The Company uses judgment in determining the SSP for its hardware and services. To determine SSP, the Company maximizes the use of observable standalone sales and observable data, where available. In instances where performance obligations do not have observable standalone sales, the Company may use alternative methods to estimate the standalone selling price, such as cost plus margin approach.

#### *Consumers revenue*

The Company considers customer and distributor purchase orders to be contracts with a customer. For each contract, the Company considers the promise to transfer tangible products and/or services, each of which are distinct, to be the identified performance obligations. In determining the transaction price, the Company evaluates whether the price is subject to rebates and adjustments to determine the net consideration to which the Company expects to receive. Revenue from tangible products is recognized when control of the product is transferred to the customer (i.e., when the Company's performance obligation is satisfied), which typically occurs at shipment. The revenues from fixed-price services are recognized ratably over the contract period.

#### *Commercial revenue - B2B2C*

The Company provides a mobile and web-based digital therapeutics health management programs to employers and health plans for their employees or covered individuals. Such programs include live clinical coaching, content, automated journeys, hardware, and lifestyle coaching, currently supporting diabetes, prediabetes and obesity, hypertension, behavioral health (BH) and musculoskeletal health (MSK). At contract inception, the Company assesses the type of services being provided and assesses the performance obligations in the contract. These solutions integrate access to the Company's web-based platform, and clinical and data services to provide an overall health management solution. The promises to transfer these goods and services are not separately identifiable and is considered a single continuous service comprised of a series of distinct services that are substantially the same and have the same pattern of transfer (i.e., distinct days of service). These services are consumed as they are received, and the Company recognizes revenue each month using the variable consideration allocation exception. Revenue is recognized either on a per engaged member per month (PEMPM) or a per employee per month (PEPM) basis. Contracts typically have a duration of more than one year.

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#### **DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

#### **NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

#### **NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

Certain of the Company's contracts include client performance guarantees and a portion of the fees in those contracts are subject to performance-based metrics such as clinical outcomes or minimum member utilization rates. The Company includes in the transaction price some or all of an amount of variable consideration only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Refunds to a customer that results from performance levels that were not met by the end of the measurement period are adjusted to the transaction price, and therefore estimated at the outset of the arrangement.

#### *Commercial revenue - Strategic partnerships*

The Company has also entered into contracts (Note 4) with a preferred partner and a health plan provider in which the Company provides data license, development and implementation services.

d. Recently Adopted Accounting Pronouncements

- (i) In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the **more timely** **timelier** recognition of losses, with an effective date for the first quarter of fiscal year 2020. In November 2019, the FASB issued ASU No. 2019-10 which delayed the effective date of ASU 2016-13 for smaller reporting companies (as defined by the SEC) and other **non-SEC** **non- Securities and Exchange Commission ("SEC")** reporting entities to fiscal years beginning after December 15, 2022, including interim periods within those fiscal periods. The Company adopted the standard effective as of January 1, 2023, and the adoption of this standard did not have an impact on the Company's consolidated financial statements.
- (ii) In August 2020, the FASB issued ASU 2020-06, "Debt - Debt with Conversion and Other Options (subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (subtopic 815-40)" ("ASC470-20"). The new standard reduces the number of accounting models in ASC 470-20 that require separate accounting for non-bifurcated embedded conversion features. As a result, convertible instruments will no longer be subject to the cash conversion features model or to the beneficial conversion features model and be accounted for as a single unit of account as long as no other features require bifurcation and recognition as derivatives. The Company adopted ASU 2020-06, effective January 1, 2023, using the modified retrospective method. The prior period consolidated financial statements have not been retrospectively adjusted and continue to be reported under the accounting standards in effect for those periods. The adoption of this standard did not have a material impact on the Company's interim condensed consolidated financial statements.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 3: - INVENTORIES**

	<b>June 30, 2023</b>	<b>December 31, 2022</b>	<b>September 30, 2023</b>	<b>December 31, 2022</b>
	<b>Unaudited</b>	<b>Unaudited</b>	<b>Unaudited</b>	<b>Unaudited</b>
Raw materials	\$ 1,151	\$ 1,346	\$ 1,009	\$ 1,346
Finished products	4,763	6,610	4,462	6,610
	<b>\$ 5,914</b>	<b>\$ 7,956</b>	<b>\$ 5,471</b>	<b>\$ 7,956</b>

During the **six- nine-**month period ended **June 30, 2023** **September 30, 2023**, and the year ended December 31, 2022, total inventory write-down expenses amounted to **\$51** **\$60** and **\$88**, respectively.

**NOTE 4: - REVENUES**

The Company is operating a multi-condition healthcare business, empowering individuals to manage their chronic conditions and take steps to improve their overall health. The Company generates revenue directly from individuals through a la carte offering and membership plans. The Company also contracts with enterprise business market groups to provide digital therapeutics solutions for individuals to receive access to services through the Company's commercial arrangements.

*Agreement with Preferred Partner*

On February 28, 2022, the Company entered into an exclusive preferred partner, co-promotion, development and license agreement for a term of five (5) years (the "Exclusive Agreement"). Pursuant to the Exclusive Agreement, the Company will provide a license to access and use certain Company data. In addition, the Company may provide development services for new products of the other party.

The aggregate consideration under the contract is up to \$30 million over the initial term of the Exclusive Agreement, consisting of (i) an upfront payment, (ii) payments for development services per development plan to be agreed upon annually and (iii) certain contingent milestone payments upon meeting certain net sales and enrollment rate milestones at any time during the term of the Exclusive Agreement.

Since the contract consideration includes variable consideration, as of **June 30, 2023** **September 30, 2023**, the Company excluded the variable payments from the transaction price since it is not probable that a significant reversal in the amount of cumulative revenue recognized will occur when the uncertainty associated with the variable consideration is resolved.

In 2022, the first development plan was approved and completed. The Company concluded that the first development plan should be accounted for as a separate contract. As such, for the year ended December 31, 2022, the Company recognized \$4,000 in revenues for the completion of the first development plan.

On December 13, 2022, the second development plan was approved by the parties. The Company concluded that the second development plan should be accounted for as a separate contract which includes development services performance obligations, satisfied over time, based on labor hours. As such, for the year ended December 31, 2022, the Company recognized \$1,506 in revenues, and for the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, the Company recognized \$2,494 in revenues for the completion of the second development plan.

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[Table of Contents](#)**DARIOHEALTH CORP. AND ITS SUBSIDIARIES****NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 4: - REVENUES (Cont.)**

On June 15, 2023, the third development plan (initiated in April 2023), was approved by the parties. The Company concluded that the third development plan should be accounted for as a separate contract which includes development services performance obligations, satisfied over time, based on labor hours. As such, for the three and **nine** months ended **June 30, 2023** **September 30, 2023**, the Company recognized **\$1,316** **\$200** and **\$1,516** in revenues, **respectively**, with additional revenues from the third development plan of **\$1,684** **\$1,484** expected to be recognized by the end of June 2024.

In July 2023, the Company entered into an amended and restated strategic agreement with Sanofi. Pursuant to the amendment, the parties adjusted certain pre-agreed economic parameters, including revenue share adjustments and to allow the acceleration of certain development milestones agreed upon in the parties' initial agreement.

*Agreement with National Health Plan*

On October 1, 2021, the Company entered into a Master Service Agreement (the "MSA") and into a statement of work ("SOW", and such SOW, the "October SOW") with a national health plan ("Health Plan"). Pursuant to the October SOW, the Company will provide the Health Plan access to the Company's web and app-based platform for behavioral health. The Company has concluded that the contract contained a single performance obligation – to provide access to the Company's platform. The consideration in the contract was based entirely on customer usage.

On August 2022, the Company entered into an additional SOW (the "August SOW") with the Health Plan according to which the Company will provide implementation services and shall develop additional features to be included in the platform.

The Company concluded that the August SOW should be accounted for as a separate contract. The Company has concluded that the August SOW contained two performance obligations as follows:

- (i) Digital Behavioral Health Navigation Platform Implementation. This performance obligation includes configuration and implementation of the platform.
- (ii) Enhancements to the Digital Behavioral Health Navigation Platform. This performance obligation includes adding additional features and capabilities to the platform.

The August SOW includes a fixed consideration in the amount of \$2,650. The Company allocated the consideration between the two performance obligations based on standalone selling prices. The Company determined the standalone selling prices based on the expected cost plus a margin approach.

On February 21, 2023, the Company entered into a change order with the Health Plan according to which the Company will provide additional implementation services and shall develop additional features to be included in the platform. The change order includes a fixed consideration in the amount of \$90.

For the year ended December 31, 2022, the Company recognized revenues of \$1,778. For the three and six nine months ended June 30, 2023 September 30, 2023, the Company recognized \$255 and \$962 in revenues, respectively, for the completion of the August SOW.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 4: - REVENUES (Cont.)**

*Revenue Source:*

The following tables represent the Company's total revenues for the three and six nine months ended June 30, 2023 September 30, 2023, and 2022 disaggregated by revenue source:

	Three months ended		Six months ended		Three months ended		Nine months ended	
	June 30,		June 30,		September 30,		September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Commercial	\$ 3,915	\$ 2,847	\$ 8,865	\$ 7,396				
	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited

Commercial - Business-to-Business-to-Consumer ("B2B2C")					\$ 1,284	\$ 1,046	\$ 3,877	\$ 2,468
Commercial - Strategic partnerships					209	3,149	6,481	9,123
Consumers	2,237	3,336	4,353	6,846	2,025	2,410	6,378	9,256
	<u>\$ 6,152</u>	<u>\$ 6,183</u>	<u>\$ 13,218</u>	<u>\$ 14,242</u>	<u>\$ 3,518</u>	<u>\$ 6,605</u>	<u>\$ 16,736</u>	<u>\$ 20,847</u>

*Deferred Revenue*

The Company recognizes contract liabilities, or deferred revenues when it receives advance payments from customers prior to the satisfaction of the Company's performance obligations. The balance of deferred revenues approximates the aggregate amount of the transaction price allocated to the unsatisfied performance obligations at the end of the reporting period.

The following table presents the significant changes in the deferred revenue balance during the **six** **nine** months ended **June 30, 2023** **September 30, 2023**:

Balance, beginning of the period	\$ 1,320	\$ 1,320
New performance obligations	13,218	3,853
Reclassification to revenue as a result of satisfying performance obligations	(13,749)	(4,489)
Balance, end of the period	\$ 789	\$ 684

*Costs to Fulfill a Contract*

The Company defers costs incurred to fulfill contracts that: (1) relate directly to the contract; (2) are expected to generate resources that will be used to satisfy the Company's performance obligations under the contract; and (3) are expected to be recovered through revenue generated under the contract. Contract fulfillment costs are expensed as the Company satisfies its performance obligations and recorded into cost of revenue.

Costs to fulfill a contract are recorded in other accounts receivable and prepaid expenses and long-term assets.

Costs to fulfill a contract consist of (1) deferred consumer hardware costs incurred in connection with the delivery of services that are deferred, and (2) deferred costs incurred, related to future performance obligations which are capitalized.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 4: - REVENUES (Cont.)**

Costs to fulfill a contract as of **June 30, 2023** **September 30, 2023**, and December 31, 2022, consisted of the following:

	June 30,	December 31,	September 30,	December 31,
	2023	2022		2022
		Unaudited	2023	
Costs to fulfill a contract, current	\$ 236	\$ 483	\$ 234	\$ 483
Costs to fulfill a contract, noncurrent	76	41	62	41

Total costs to fulfill a contract	\$ 312	\$ 524	\$ 296	\$ 524
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Costs to fulfill a contract were as follows:

	Costs to fulfill a contract	Costs to fulfill a contract
Beginning balance as of December 31, 2022	\$ 524	\$ 524
Additions	325	384
Cost of revenue recognized	(537)	(612)
Ending balance as of June 30, 2023	312	
Ending balance as of September 30, 2023 (unaudited)		296

#### NOTE 5: - FAIR VALUE MEASUREMENTS

Under U.S. GAAP, fair value is defined as the amount that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants and requires that assets and liabilities carried at fair value are classified and disclosed in the following three categories:

- Level 1 - Valuations based on quoted prices in active markets for identical assets that the Company has the ability to access. Valuation adjustments and block discounts are not applied to Level 1 instruments. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.
- Level 2 - Valuations based on one or more quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The availability of observable inputs can vary from instrument to instrument and is affected by a wide variety of factors, including, for example, the type of investment, the liquidity of markets and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment, and the investments are categorized as Level 3.

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#### DARIOHEALTH CORP. AND ITS SUBSIDIARIES

##### NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

**U.S. dollars in thousands (except stock and stock data)**

##### **NOTE 5: - FAIR VALUE MEASUREMENTS (Cont.)**

The carrying amounts of cash and cash equivalents, short-term restricted bank deposits, trade receivables, other accounts receivable and prepaid expenses, trade payables and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments. The Company's Avenue Loan Facility (as defined herein), and warrant liability were measured at fair value using Level 3 unobservable inputs until the payoff date of May 1, 2023. Subsequently, a new loan agreement (Note 6) was obtained, and both the new loan and the warrant liability were measured at fair value.

The following tables present information about the Company's financial liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	June 30, 2023				September 30, 2023			
	Unaudited				Unaudited			
	Fair Value	Level 1	Level 2	Level 3	Fair Value	Level 1	Level 2	Level 3
	(in thousands)				(in thousands)			
Financial liabilities:								
Long term loan	29,094	—	—	29,094	29,000	—	—	29,000
Warrant liability	664	—	—	664	524	—	—	524
Total financial liabilities	\$ 29,758	\$ —	\$ —	\$ 29,758	\$ 29,524	\$ —	\$ —	\$ 29,524

December 31, 2022				
	Fair Value	Level 1	Level 2	Level 3
Financial liabilities:	(in thousands)			
Long term loan	26,928	—	—	26,928
Warrant liability	\$ 910	—	—	910
Total financial liabilities	\$ 27,838	\$ —	\$ —	\$ 27,838

#### Loan Facilities

On June 9, 2022, the Company entered into a Credit Agreement (the "Credit Agreement"), by and between the Company, as borrower, and Orbimed Royalty and Credit Opportunities III, LP, as the lender (the "Orbimed Lender"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to \$50,000 (the "Orbimed Loan"), of which \$25,000 was made available on the closing date (the "Initial Commitment Amount" or "First Tranche") and up to \$25,000 was available on or prior to June 30, 2023, subject to certain revenue requirements (the "Delayed Draw Commitment Amount" or "Second Tranche"). The Delayed Draw Commitment Amount did not materialize due to the repayment of the loan. On June 9, 2022, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Orbimed Lender.

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#### DARIOHEALTH CORP. AND ITS SUBSIDIARIES

##### **NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

##### **NOTE 5: - FAIR VALUE MEASUREMENTS (Cont.)**

On May 1, 2023, the Company entered into a Loan and Security Agreement, and Supplement thereto (the "LSA"), by and between the Company and its subsidiary PsyInnovations Inc. ("PsyInnovations"), collectively as the borrowers (the "Borrowers") and Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., collectively as the lenders (the "Avenue Lenders") (Note 6). Upon the initial closing of the LSA, the Company repaid the Orbimed Loan to the Orbimed Lender. The LSA provides for a four-year secured credit facility in an aggregate principal amount of up to \$40,000 (the "Avenue Loan Facility"), of which \$30,000 was made available on the closing date (the "Initial Tranche") and up to \$10,000 (the "Discretionary Tranche") may be made available on the later of July 1, 2023, or the

date the Avenue Lenders approve the issuance of the Discretionary Tranche. On May 1, 2023, the Borrowers closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders.

The fair value of the Avenue Loan Facility is recognized in connection with the Company's Credit Agreement with respect to the Initial Commitment Amount only (Note 6). The fair value of the Avenue Loan Facility was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the Avenue Loan Facility, which is reported within non-current liabilities (Maturity Date - May 1, 2027) on the consolidated balance sheets, is estimated by the Company at each reporting date based on significant inputs that are generally determined based on relative value analyses.

The Avenue Loan Facility incorporates comparisons to instruments with similar covenants, collateral, and risk profiles and was obtained using a discounted cash flow technique. On the date of Avenue Loan Facility origination, or May 1, 2023, the discount rate was arrived at by calibrating the loan amount of \$30 million with the fair value of the warrants of \$1,413 and the loan terms interest rate equal to the greater of (i) the sum of four and one-half percent (4.50%) plus the Prime Rate, and (ii) twelve and one-half percent (12.50%). The implied internal rate of return of the loan was 19%. The fair value of the Avenue Loan Facility, as of **June 30, 2023** **September 30, 2023**, was estimated using a discount rate of 19% which reflects the internal rate of return of the Avenue Loan Facility at closing, as of **May 1, 2023** **May 1, 2023**. The change in the fair value of the loan was recorded in earnings since the Company concluded that no adjustment related to instrument-specific credit risk was required.

#### *Warrant Liability*

The fair value of the warrant liability is recognized in connection with the Company's Credit Agreement with the Orbimed Lender and with respect to the Initial Commitment Amount only (Note 6). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability, which is reported within non-current liabilities on the consolidated balance sheets, is estimated by the Company based on the Monte-Carlo simulation valuation technique, in order to predict the probability of different outcomes that rely on repeated random variables.

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#### **DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

#### **NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

#### **NOTE 5: - FAIR VALUE MEASUREMENTS (Cont.)**

The fair value of the warrant liability was estimated using a Monte-Carlo simulation valuation technique, with the following significant unobservable inputs (Level 3):

	June 30,	December 31,		September 30,	December 31,
	2023	2022	2023	2022	
Stock price	\$ 4.01	\$ 4.28	\$ 3.28	\$ 4.28	
Exercise price	5.90	6.62	5.80	6.62	
Expected term (in years)	5.94	6.44	5.69	6.44	
Volatility	89.3%	148.1%	91.7%	148.1%	
Dividend rate	-	-	-	-	
Risk-free interest rate	4.08%	4.05%	4.62%	4.05%	

The following tables present the summary of the changes in the fair value of our Level 3 financial instruments:

	Six months ended		Nine months ended	
	June 30, 2023		September 30, 2023	
	Long-Term Loan	Warrant Liability	Long-Term Loan	Warrant Liability
Balance as of January 1, 2023	\$ 26,928	\$ 910	\$ 26,928	\$ 910
Issuance	28,587	—	28,587	—
Principal repayments on long-term loan	(27,833)	—	(27,833)	—
Change in fair value	1,412	(246)	1,318	(386)
Balance as of June 30, 2023	<u>\$ 29,094</u>	<u>\$ 664</u>		
Balance as of September 30, 2023			\$ 29,000	\$ 524

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 6: - DEBT**

*Loan Facility*

On May 1, 2023, the Company refinanced its existing \$25,000 credit facility with a new \$30,000 credit facility in the LSA by and between Borrowers and the Avenue Lenders. The LSA provides for a four-year secured credit facility in an aggregate principal amount of up to \$40,000, of which \$30,000 was made available on the closing date and up to \$10,000 may be made available on the later of July 1, 2023, or the date the Avenue Lenders approve the issuance of the Discretionary Tranche. On May 1, 2023, the Borrowers closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders.

During the term of the Avenue Loan Facility, interest payable in cash by the Borrowers shall accrue on any outstanding balance due under the Avenue Loan Facility at a rate per annum equal to the higher of (x) the sum of four one-half percent (4.50%) plus the prime rate as published in the Wall Street Journal and (y) twelve and one-half percent (12.50%). During an event of default, any outstanding amount under the Avenue Loan Facility will bear interest at a rate of 5.00% in excess of the otherwise applicable rate of interest. The Borrowers will pay certain fees with respect to the Avenue Loan Facility, including an upfront commitment fee, an administration fee, and a prepayment premium, as well as certain other fees and expenses of the Avenue Lenders. On the closing date, and with respect to the Initial Tranche only, the Company agreed to issue for each Avenue Lender a warrant (the "Warrant") to purchase up to 292,442 shares of the Company's common stock, at an exercise price of \$3.334 per share, which shall have a term of five years from the issuance date. The Warrant contains customary share adjustment provisions, as well as adjustments to the number of shares issuable upon exercise of the Warrant and the exercise price in the event of a bona fide equity raise prior to September 30, 2023, at a price less than the then current exercise price. As of September 30, 2023, the customary share adjustment provisions and adjustments related to a bona fide equity raise prior to September 30, 2023, remain unchanged.

The Avenue Lenders have the right, at any time while the Avenue Loan Facility is outstanding, to convert an amount of up to \$2,000 of the principal amount of the outstanding Avenue Loan Facility into Borrower's unrestricted shares of the Company's common stock at a price per share equal to 120% of the then effective exercise price of the Avenue Warrant.

The Company elected to account for the Avenue Loan Facility under the fair value option in accordance with ASC 825, "Financial Instruments." Under the fair value option, changes in fair value are recorded in earnings except for fair value adjustments related to instrument specific credit risk, which are recorded as other comprehensive income or loss.

During the ~~six months~~ three and nine-month periods ended ~~June 30, 2023~~ September 30, 2023, the Company recognized ~~\$320~~ \$94 and \$413 of remeasurement ~~expenses~~ income related to the Initial Commitment Amount, respectively, which was included as part of financial expenses in the Company's statements comprehensive loss. During the ~~three~~ three and ~~six-months~~ nine month periods ended ~~June 30, 2023~~ September 30, 2023, the Company did not recognize any instrument specific credit risk fair value adjustment.

#### *Warrant Liability*

On June 9, 2022 (the closing date of the Orbimed Loan), the Company agreed to issue Orbimed a warrant (the "Orbimed Warrant") to purchase up to 226,586 shares of the Company's common stock, at an exercise price of \$6.62 per share, which shall have a term of 7 years from the issuance date. The Orbimed Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances but in no event will the exercise price of the Warrant be adjusted to a price less than \$4.00 per share.

The Company has concluded that the warrants are not indexed to the Company's own stock and should be recorded as a liability measured at fair value with changes in fair value recognized in earnings.

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#### **DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

#### **NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

#### **NOTE 7: - COMMITMENTS AND CONTINGENT LIABILITIES**

From time to time, the Company is involved in claims and legal proceedings. The Company reviews the status of each matter and assesses its potential financial exposure. If the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated, the Company accrues a liability for the estimated loss.

##### *Royalties*

The company has a liability to pay future royalties to the Israeli Innovation Authority (the "IIA") for participation in programs sponsored by the Israeli government for the support of research and development activities. The Company is obligated to pay royalties to the IIA, amounting to 3% of the sales of the products and other related revenues (based on the U.S. dollar) generated from such projects, up to 100% of the grants received. Royalty payment obligations also bear interest at the LIBOR rate. The obligation to pay these royalties is contingent on actual sales of the products and in the absence of such sales, no payment is required. During the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, the Company did not record IIA royalties related to the acquisition of Physimax Technology.

#### **NOTE 8: - INTANGIBLE ASSETS**

a. Finite-lived other intangible assets:

	June 30,	December 31,	Weighted	September 30,	December 31,	Weighted
	2023	2022	Average	2023	2022	Average
	Unaudited		Remaining Life	Unaudited		Remaining Life
Original amounts:						
Technology	\$ 16,936	\$ 16,936	1.7	\$ 16,936	\$ 16,936	1.5
Brand	376	376	1.9	376	376	1.7
	<u>17,312</u>	<u>17,312</u>		<u>17,312</u>	<u>17,312</u>	
Accumulated amortization:						
Technology	9,375	7,199		10,480	7,199	
Brand	259	197		291	197	
	<u>9,634</u>	<u>7,396</u>		<u>10,771</u>	<u>7,396</u>	
Other intangible assets, net	<u>\$ 7,678</u>	<u>\$ 9,916</u>		<u>\$ 6,541</u>	<u>\$ 9,916</u>	

b. Amortization expenses for the six-month period ended June 30, 2023 and for the year ended December 31, 2022 amounted to \$2,238 and \$4,361, respectively.

b. Amortization expenses for the nine-month period ended September 30, 2023 and for the year ended December 31, 2022 amounted to \$3,375 and \$4,361, respectively.

c. Estimated amortization expense:

For the year ended December 31,

Remainder of 2023	\$ 2,274	\$ 1,137
2024	4,452	4,452
2025	952	952
	<u>\$ 7,678</u>	<u>\$ 6,541</u>

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 9: - STOCKHOLDERS' EQUITY**

- a. In April 2020, the Compensation Committee of the Board of Directors (the "Compensation Committee") approved a monthly grant of shares of the Company's common stock equal to \$18.00 of restricted shares to certain service providers per month, to be granted monthly during the period that the certain consulting agreement remains in effect. During the six-month nine-month period ended June 30, 2023 September 30, 2023, a total of 24,027 39,013 restricted unregistered shares of common stock were issued to certain service providers under pursuant to this approval. During the six-month nine-month period ended June 30, 2023 September 30, 2023, the Company recorded compensation expenses for service providers in the amount of \$87, \$135.

- b. In May 2022 and June 2022, the Compensation Committee authorized the Company to grant warrants to purchase up to 70,000, and 175,000 shares (of which warrants to purchase 87,500 shares have expired) of the Company's common stock which shall vest over 12 months and 24-month periods, respectively, to certain consultants of the Company, with an exercise price of \$6.45 and \$7.20, respectively. During the six-month nine-month period ending June 30, 2023 ended September 30, 2023, the Company recorded a warrant compensation expense for service providers in the amount of \$264.
- c. In December 2022, the Compensation Committee authorized the Company to issue warrants to purchase up to 500,000 shares of common stock, to a certain consultant of the Company which shall vest over a 12-month period, with an exercise price of \$5.00. During the six-month nine-month period ending June 30, 2023 ended September 30, 2023, the Company recorded a warrant compensation expense for the service provider in the amount of \$352, \$531.
- d. During the six-month nine-month period ended June 30, 2023, September 30, 2023, the Company's Compensation Committee approved the grant of 630,600 927,100 restricted shares of the Company's common stock to employees and consultants of which 490,600 537,100 are under the Company's 2020 Plan, Equity Incentive Plan, as amended ("2020 Plan"). Out of the restricted shares granted, 125,000 235,000 restricted shares will vest immediately, 30,000 restricted shares will vest over a period of six months, and the remaining 475,600 662,100 restricted shares will vest over a period between two to three four years commencing on the respective grant dates. The Compensation Committee also approved the grant of options to purchase up to 776,600 833,900 shares of common stock for employees and consultants of the Company, at exercise prices between \$3.92 \$3.69 and \$4.48 per share. 676,600 Stock options to purchase 528,900 shares of the common stock options vests over a three-year period commencing on the respective grant dates, and 100,000 options to purchase 305,000 shares of common stock are performance based, performance-based. The options have a ten-year term and were issued under the 2020 Plan.
- e. During the six-month nine-month period ended June September 30, 2023, certain Series A Convertible Preferred stockholders converted 10 shares of various classes of the Company's Series A Convertible Preferred Stock into 3,582 shares of common stock.
- f. In January 2023 and March 2023, the Compensation Committee approved the grant of a non-qualified stock option awards to purchase 200,000 shares of the Company's common stock, as well as an additional non-qualified performance-based stock option award to purchase an additional 180,000 shares of the Company's common stock outside of the Company's 2020 Plan, pursuant to Nasdaq Listing Rule 5635(c)(4), in connection with the employment of its Senior Vice President of Growth and its Chief Product Officer.
- g. In January 2023, the Compensation Committee approved the grant of warrants to purchase up to 280,000 shares of common stock, with an exercise price of \$5.20, per share to certain consultants. The warrants are exercisable into common stock on or before December 31, 2026. During the six nine months ended June 30, 2023 September 30, 2023, the Company recorded compensation expense for those certain service providers in the amount of \$310, \$480.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 9: - STOCKHOLDERS' EQUITY (Cont.)**

- h. In January 2023, the Compensation Committee approved a reduction in the exercise price of warrants to purchase up to 350,000 shares of common stock issued to certain consultants in the past at exercise prices between \$7.50 to \$30.00 per share, to an exercise price of \$5.20 per share, subject to the performance of additional services. The Company has accounted for the change as a modification and recorded the increase in fair value as compensation expense for those certain service providers in the amount of \$228, \$351.
- i. In January 2023 and April 2023, the Board of Directors approved to accelerate the acceleration of the unvested portion of 42,500 restricted shares of the Company's common stock to a certain employee of the Company. The share acceleration was part of a separation agreement with the employee. The Company has accounted for the acceleration as a type-3 modification and recorded compensation expenses in the amount of \$153.
- j. In April 2023, the Company issued 76,637 shares of common stock to settle an earn-out payment owed in connection with the acquisition of WayForward, PsyInnovations, Inc. (dba wayForward).

- k. On July 11, 2023, out of the pre-funded warrants that were issued in July 2020 and February 2022, 86,985 were exercised on a cashless basis into 86,983 shares of common stock.
- l. On July 25, 2023, the Compensation Committee approved the grant of warrants to purchase up to 40,000 shares of common stock, with an exercise price of \$3.46, per share to a certain consultant, the stock options vests over a three-year period. The warrants are exercisable into common stock on or before December 31, 2026. During the nine months ended September 30, 2023, the Company recorded compensation expenses for this service provider in the amount of \$20.
- m. On October 22, 2021, the Company entered into an At-The-Market Equity Offering Sales Agreement (the "ATM" (the "ATM")), allowing the Company to sell its common stock for aggregate sales proceeds of up to \$50,000 from time to time and at various prices, subject to the conditions and limitations set forth in the sales agreement. If shares of the Company's common stock are sold, there is a three percent (3%) fee paid to the sales agent. For the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, the Company received net proceeds of ~~\$1,410~~ \$1,614 from the sale of ~~355,743~~ 408,043 shares of the Company's common stock. As of ~~June 30, 2023~~ September 30, 2023, there were ~~\$48,181~~ was \$47,971 in remaining funds available under the ATM.
- i.n. On May 1, 2023, the Company entered into securities purchase agreements with accredited investors relating to an offering and the sale of an aggregate of 6,200 shares of newly designated Series B Preferred Stock (the "Series B Preferred Stock"), an aggregate of 7,946 shares of Series B-1 Preferred Stock (the "Series B-1 Preferred Stock"), and an aggregate of 150 shares of Series B-2 Preferred Stock (the "Series B-2 Preferred Stock") at a purchase price of \$1,000 for each share of Preferred Stock, preferred stock. Certain of our executive officers and directors purchased shares of Series B-2 Preferred Stock in the offering. On May 5, 2023, the Company entered into purchase agreements with accredited investors, relating to the offering of 1,106 shares of newly designated Series B-3 Preferred Stock (the "Series B-3 Preferred Stock" and, collectively with the Series B Preferred Stock, the Series B-1 Preferred Stock, and the Series B-2 Preferred Stock, the "Preferred Stock"), at a purchase price of \$1,000 for each share of Preferred Stock. The initial conversion price for the Series B, B-1, B-2, and B-3 Preferred Stock was \$3.334, \$3.334, \$3.370 and \$3.392, respectively, subject to adjustment in the event of stock splits, stock dividends, and similar transactions. As a result of the sale of the Preferred Stock, the aggregate gross proceeds to the Company from the offering offerings were approximately \$15,400 (\$14,807 net of issuance expenses).

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 9: - STOCKHOLDERS' EQUITY (Cont.)**

The Series B Preferred Stock and Series B-3 Preferred Stock will vote together with the common stock as a single class on an as-converted basis on any matter presented to the shareholders of the Company. The Series B-1 Preferred Stock and Series B-2 Preferred Stock do not possess any voting rights with respect to such matters. Upon any liquidation, dissolution or winding-up of the Company, after the satisfaction in full of the debts of the Company and payment of the liquidation preference to the Senior Securities (as defined herein), holders of Preferred Stock shall be entitled to be paid, on a pari passu basis with the payment of any liquidation preference afforded to holders of any Parity Securities (as defined herein), the remaining assets of the Company available for distribution to its stockholders. For these purposes, (i) "Parity Securities" means the common stock, Series B Preferred Stock, Series B-1 Preferred Stock, the Series B-2 Preferred Stock, the Series B-3 Preferred Stock and any other class or series of capital stock of the Company hereinafter created that expressly ranks pari passu with the Series B Preferred Stock, Series B-1 Preferred Stock, the Series B-2 Preferred Stock and/or the Series B-3 Preferred Stock; and (ii) "Senior Securities" shall mean any class or series of capital stock of the Company hereafter created which expressly ranks senior to the Parity Securities.

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**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****U.S. dollars in thousands (except stock and stock data)****NOTE 9: - STOCKHOLDERS' EQUITY (Cont.)**

The Preferred Stock will automatically convert into shares of common stock, subject to certain beneficial ownership limitations, including a non-waivable 19.99% ownership blocker, on the 15-month anniversary of the issuance date. The holders of Preferred Stock will also be entitled dividends payable as follows: (i) a number of shares of common stock equal to five percent (5.0%) of the number of shares of common stock issuable upon conversion of the Preferred Stock then held by such holder for each full quarter anniversary of holding for a total of four (4) quarters from the closing date, and (ii) a number of shares of common stock equal to ten percent (10%) of the number of shares of common stock issuable upon conversion of the Preferred Stock then held by such holder on the fifth full quarter from the closing. The Series B-2 Preferred Stock dividend is **the** subject to receipt of the approval of the Company's shareholders. The Preferred Stock has been accounted for as **an** equity instruments.

**m.** **o**On May 1, 2023, the Company entered into agreements with certain holders of 3,557 of the Company's Series A-1 Preferred Stock pursuant to a subscription agreement dated November 27, 2019, which are convertible to 1,273,498 shares of common stock. In consideration for deferring the conversion of the Series A-1 Convertible Preferred Stock, the Company agreed to issue additional shares of common stock upon the deferred conversion of the Series A-1 Convertible Preferred Stock as follows: 63,676 shares, in the aggregate, if not converted for at least one quarter, 127,350 shares, in the aggregate, if not converted for at least two quarters, 191,026 shares, in the aggregate, if not converted for at least three quarters, 254,700 shares, **in the aggregate**, if not converted for at least four quarters and 382,050 shares, in the aggregate, if not converted for at least five quarters.

The Company has concluded that the Series A-1 preferred shares modification should be accounted **for** as an extinguishment transaction and recorded the increase in fair value as a deemed dividend in the amount of \$984.

**n.** **p**During the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, the Company accounted for the dividend shares of common stock upon the deferred conversion of the Series A-1 Convertible Preferred Stock and the dividend shares earned by Series B Preferred Stock as a deemed dividend in a total amount of **\$707**. **\$1,879**.

**o.** **q**On May 1, 2023, the Company repaid its existing \$25,000 credit facility to the Orbimed Lender with a new \$30,000 credit facility in the LSA, by and between the Company and the Avenue Lenders. On the closing date, and with respect to the Initial Tranche only, the Company agreed to issue each Avenue Lender the Avenue Warrant to purchase up to 292,442 shares of the Company's common stock, at an exercise price of \$3.334 per share, which shall have a term of five years from the issuance date. The Company accounted the Avenue Warrants as equity instruments and recorded it in fair value as of May 1, 2023, using the relative fair value method in the amount of \$1,389.

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[Table of Contents](#)**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)****U.S. dollars in thousands (except stock and stock data)****NOTE 9: - STOCKHOLDERS' EQUITY (Cont.)**

**p.** **r.** Stock plans:

On January 23, 2012, the Company's Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan") was adopted by the Board of Directors of the Company and approved by a majority of the Company's stockholders, under which options to purchase shares of the Company's common stock have been reserved. Under the 2012 Plan, options to purchase shares of common stock may be granted to employees and non-employees of the Company or any affiliate, each option granted can be exercised to one share of common stock. The 2012 Plan has expired.

On October 14, 2020, the Company's stockholders approved the 2020 Equity incentive Plan (the "2020 Plan"). Under the 2020 Plan, options to purchase shares of common stock may be granted to employees and non-employees of the Company or any affiliate, each option granted can be exercised to one share of common stock.

In January 2023, pursuant to the terms of the 2020 Plan as approved by the Company's stockholders, the Company increased the number of shares authorized for issuance under the 2020 Plan by 1,994,346 shares, from 3,868,514 to 5,862,860.

Transactions related to the grant of options to employees, directors, and non-employees under the above plans and non-plan options during the nine-months period ended September 30, 2023, (unaudited) were as follows:

	Number of options	Weighted		
		Weighted average	average remaining	Aggregate
		exercise	contractual	Intrinsic
		price	life	value
Options outstanding at beginning of period	2,124,302	13.38	6.98	121
Options granted	1,213,900	4.33	—	—
Options exercised	(4,800)	—	—	—
Options expired	(221,870)	29.85	—	—
Options forfeited	(267,360)	7.05	—	—
Options outstanding at end of period	2,844,172	8.85	7.46	75
Options vested and expected to vest at end of period	2,313,229	9.18	7.32	75
Exercisable at end of period	1,236,729	12.80	5.40	75

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing stock price on the last day of the third quarter of 2023 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on September 30, 2023. This amount is impacted by the changes in the fair market value of the common stock.

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 9: - STOCKHOLDERS' EQUITY (Cont.)**

In January 2023, pursuant to the terms of the 2020 Plan as approved by the Company's stockholders, the Company increased the number of shares authorized for issuance under the 2020 Plan by 1,994,346 shares, from 3,868,514 to 5,862,860.

Transactions related to the grant of options to employees, directors, and non-employees under the above plans and non-plan options during the six-months period ended June 30, 2023, (unaudited) were as follows:

	Weighted			
	Weighted	average	remaining contractual	Aggregate Intrinsic
	average exercise	life		
Number of options	\$	Years		\$
Options outstanding at beginning of period	2,124,302	13.38	6.98	121
Options granted	1,156,600	4.37	—	—
Options exercised	(4,800)	—	—	—
Options expired	(164,982)	27.96	—	—
Options forfeited	(173,825)	8.31	—	—
Options outstanding at end of period	<u>2,937,295</u>	<u>9.33</u>	<u>7.68</u>	<u>155</u>
Options vested and expected to vest at end of period	<u>2,384,548</u>	<u>9.74</u>	<u>7.55</u>	<u>140</u>
Exercisable at end of period	<u>1,156,150</u>	<u>14.42</u>	<u>5.27</u>	<u>92</u>

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing stock price on the last day of the second quarter of 2023 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on June 30, 2023. This amount is impacted by the changes in the fair market value of the common stock.

Transactions related to the grant of restricted shares to employees, directors, and non-employees under the above plans during the three-month nine-month period ended June 30, 2023 September 30, 2023, (unaudited) were as follows:

	Number of Restricted shares
Restricted shares outstanding at beginning of period year (audited)	2,207,772
Restricted shares granted	525,600 572,100
Restricted shares forfeited	(70,185) (90,471)
Restricted shares outstanding at end of period	<u>2,663,187</u> 2,689,401

As of June 30, 2023 September 30, 2023, the total amount of unrecognized stock-based compensation expense was approximately \$17,166 \$13,286 which will be recognized over a weighted average period of 1.05 0.94 years.

The following table presents the assumptions used to estimate the fair values of the options granted to employees, directors, and non-employees in the period presented:

	Nine months ended	
	September 30,	
	2023	2022
	Unaudited	
Volatility	90.90-92.62 %	92.25-92.60 %
Risk-free interest rate	3.45-4.13 %	2.70-3.01 %
Dividend yield	0 %	0 %
Expected life (years)	5.81-5.88	5.81-5.88

The total compensation cost related to all of the Company's stock-based awards recognized during the nine-month period ended September 30, 2023, and 2022 was comprised as follows:

	Nine months ended	
	September 30,	
	2023	2022
<b>Unaudited</b>		
Cost of revenues	\$ 62	\$ 72
Research and development	3,713	3,215
Sales and marketing	5,549	5,089
General and administrative	5,983	5,522
 Total stock-based compensation expenses	 <u>\$15,307</u>	 <u>\$13,898</u>

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**DARIOHEALTH CORP. AND ITS SUBSIDIARIES**

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**U.S. dollars in thousands (except stock and stock data)**

**NOTE 10: - SELECTED STATEMENTS OF OPERATIONS DATA**

Financial expenses, net:

	Nine months ended	
	September 30,	
	2023	2022
<b>Unaudited</b>		
Bank charges	\$ 88	\$ 59
Foreign currency adjustments expenses, net	39	51
Interest income	(1,398)	(228)
Revaluation of short-term investments	(37)	—
Remeasurement of long-term loan	4,354	1,945
Remeasurement of warrant liability	(386)	(929)
Debt issuance cost	508	724
Remeasurement of financial commitment asset	—	153
 Total Financial expenses, net	 <u>\$ 3,168</u>	 <u>\$ 1,775</u>

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**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

U.S. dollars in thousands (except stock and stock data)

**NOTE 9: - STOCKHOLDERS' EQUITY (Cont.)**

The following table presents the assumptions used to estimate the fair values of the options granted to employees, directors, and non-employees in the period presented:

	Six months ended	
	June 30,	
	2023	2022
Unaudited		
Volatility	92.05-92.62 %	91.42-92.04 %
Risk-free interest rate	3.45-4.13 %	2.89-3.00 %
Dividend yield	0 %	0 %
Expected life (years)	5.81-5.88	5.81-6.00

The total compensation cost related to all of the Company's stock-based awards recognized during the six-month period ended June 30, 2023, and 2022 was comprised as follows:

	Six months ended	
	June 30,	
	2023	2022
Unaudited		
Cost of revenues	\$ 44	\$ 48
Research and development	2,488	2,048
Sales and marketing	3,670	3,132
General and administrative	3,946	3,744
 Total stock-based compensation expenses	 \$10,148	 \$ 8,972

**NOTE 10: 11: - SELECTED STATEMENTS OF OPERATIONS DATA BASIC AND DILUTED NET EARNINGS (LOSS) PER COMMON AND PREFERRED STOCK**

## Financial expenses, net:

We compute net loss per share of common and preferred stock using the two-class method. Basic and diluted net earnings or loss per share is computed using the weighted-average number of shares outstanding during the period. This calculation includes the total weighted average number of the common stock, which includes prefunded warrants.

The total number of potential shares of common stock related to the outstanding options, warrants and preferred shares excluded from the calculations of diluted net loss per share due to their anti-dilutive effect was 12,551,707 and 6,804,530 for the nine months ended September 30, 2023, and 2022, respectively.

The following table sets forth the computation of the Company's basic net loss per common and preferred stock:

	Six months ended	
	June 30,	
	2023	2022

	<b>Unaudited</b>	
Bank charges	\$ 65	\$ 45
Foreign currency adjustments expenses, net	105	138
Interest income	(864)	(21)
Revaluation of short-term investments	(37)	—
Remeasurement of long-term loan	3,456	172
Remeasurement of warrant liability	(246)	(342)
Debt issuance cost	<u>503</u>	<u>724</u>
 Total Financial expenses, net	 <u>\$ 2,982</u>	 <u>\$ 716</u>

	<b>Three months ended</b>					
	<b>September 30,</b>					
	<b>2023</b>					
	<b>Unaudited</b>					
	<b>Common Stock</b>	<b>Preferred A-1</b>	<b>Preferred B</b>	<b>Preferred B-1</b>	<b>Preferred B-2</b>	<b>Preferred B-3</b>
<b>Basic loss per share</b>						
Numerator:						
Allocation of undistributed loss	\$ 14,195,692	\$ 432,853	\$ 916,373	\$ 1,174,436	\$ 21,949	\$ 160,745
 Denominator:						
Number of shares used in per share computation	28,815,604	3,557	6,200	7,946	150	1,106
 Basic loss per share amounts:						
Distributed earnings - deemed dividends	—	64.66	61.10	61.10	60.45	61.97
Undistributed loss - allocated	(0.49)	(121.69)	(147.80)	(147.80)	(146.32)	(145.34)
Basic losses per share	<u>\$ (0.49)</u>	<u>\$ (57.03)</u>	<u>\$ (86.70)</u>	<u>\$ (86.70)</u>	<u>\$ (85.87)</u>	<u>\$ (83.37)</u>
 <b>Nine months ended</b>						
	<b>September 30,</b>					
	<b>2023</b>					
	<b>Unaudited</b>					
	<b>Common Stock</b>	<b>Preferred A-1</b>	<b>Preferred B</b>	<b>Preferred B-1</b>	<b>Preferred B-2</b>	<b>Preferred B-3</b>
<b>Basic earnings (loss) per share</b>						
Numerator:						
Allocation of undistributed loss	\$ 42,859,300	\$ 1,335,551	\$ 1,543,179	\$ 1,977,758	\$ 36,962	\$ 250,711
 Denominator:						
Number of shares used in per share computation	28,195,216	3,557	3,384	4,337	82	559
 Basic earnings (loss) per share amounts:						
Distributed earnings - deemed dividends	—	382.33	179.33	179.57	177.65	182.78
Undistributed loss - allocated	(1.52)	(375.47)	(456.04)	(456.04)	(451.48)	(448.44)
Basic earnings (loss) per share	<u>\$ (1.52)</u>	<u>\$ 6.86</u>	<u>\$ (276.70)</u>	<u>\$ (276.47)</u>	<u>\$ (273.83)</u>	<u>\$ (265.65)</u>

**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

U.S. dollars in thousands (except stock and stock data)

**NOTE 11: - BASIC AND DILUTED NET EARNINGS (LOSS) PER COMMON AND PREFERRED STOCK(Cont.)**

We compute net loss per share of common stock using the two-class method. Basic net loss per share is computed using the weighted-average number of shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares and the effect of potentially dilutive securities outstanding during the period.

The total number of potential shares of common stock related to the outstanding options, warrants and preferred shares excluded from the calculations of diluted net loss per share due to their anti-dilutive effect was 12,195,745 and 7,198,771 for the six months ended June 30, 2023, and 2022, respectively.

The following table sets forth the computation of the Company's basic and diluted net loss per common stock:

	Three months ended		Six months ended	
	June 30,		June 30,	
	2023	2022	2023	2022
<b>Unaudited</b>				
Net loss attributable to common stock shareholders used in computing basic net loss per share	\$ 16,338	\$ 16,607	\$ 28,849	\$ 31,267
Weighted average number of common stock used in computing basic loss per share	28,186,345	22,426,019	27,879,881	21,925,089
Basic net loss per common stock	\$ 0.58	\$ 0.74	\$ 1.03	\$ 1.43

**NOTE 12: - SUBSEQUENT EVENTS**

- a. On July 25, 2023, the Company's Compensation Committee approved the grant of 296,500 restricted shares of the Company's common stock to employees and consultants of the Company of which 46,500 are under the 2020 Plan. Out of the restricted shares granted, 100,000 restricted shares will vest immediately, and 196,500 restricted shares will vest over a period between three to four years commencing on the respective grant dates. The Compensation Committee also approved grant warrants to purchase up to 40,000 shares of the Company's common stock which shall vest over three years to certain consultants of the Company, with an exercise price of \$3.46, and the grant of options to purchase up to 57,300 shares of common stock to employees, at exercise prices between \$3.69 and \$3.97 per share. The stock options vest over a three-year period commencing on the respective grant dates. The options have a ten-year term and were issued under the 2020 Plan.
- b. On July 11, 2023, out of the pre-funded warrants that were issued in July 2020 and February 2022, 86,985 were exercised on a cashless basis into 86,983 shares of common stock.
- c. In July 2023, the Company entered into an amended and restated strategic agreement with Sanofi. In this amendment, the parties adjusted certain pre agreed economic parameters, including revenue share adjustments and to allow the acceleration of certain development milestones agreed upon in the initial agreement.

**Three months ended**

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**September 30,**

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**2022**

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**Unaudited**

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	Common Stock	Preferred A	Preferred A-1	Preferred A-2	Preferred A-3	Preferred A-4
<b><u>Basic loss per share</u></b>						
Numerator:						
Allocation of undistributed Loss	\$ 14,634,828	\$ 516,470	\$ 678,820	\$ 114,013	\$ 133,011	\$ 55,220
Denominator:						
Number of shares used in per share computation	22,973,197	3,283	4,315	765	1,039	510
Basic loss per share amounts:						
Distributed earnings - deemed dividends	—	37.31	58.51	44.22	55.07	55.57
Undistributed loss - allocated	(0.64)	(157.32)	(157.32)	(149.04)	(128.02)	(108.27)
Basic loss per share	\$ (0.64)\$	(120.01)\$	(98.80)\$	(104.82)\$	(72.95)\$	(52.70)
<b>Nine months ended</b>						
<b>September 30,</b>						
<b>2022</b>						
<b>Unaudited</b>						
	Common Stock	Preferred A	Preferred A-1	Preferred A-2	Preferred A-3	Preferred A-4
<b><u>Basic loss per share</u></b>						
Numerator:						
Allocation of undistributed loss	\$ 46,210,877	\$ 1,637,933	\$ 2,152,812	\$ 361,581	\$ 421,832	\$ 175,125
Denominator:						
Number of shares used in per share computation	22,876,397	3,283	4,315	765	1,039	510
Basic loss per share amounts:						
Distributed earnings - deemed dividends	—	135.94	146.97	139.81	163.42	164.91
Undistributed loss - allocated	(2.02)	(498.91)	(498.91)	(472.65)	(406.00)	(343.38)
Basic loss per share	\$ (2.02)\$	(362.97)\$	(351.95)\$	(332.84)\$	(242.58)\$	(178.48)

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**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*Readers are advised to review the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and related notes thereto in our Annual Report on Form 10-K for the year ended December 31, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements". You should review the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

*The following financial data in this narrative are expressed in thousands, except for stock and stock data or as otherwise noted.*

We are revolutionizing how people with chronic conditions manage their health through the innovation of a new category of digital health: Digital Therapeutics as a Service ("DTaaS"). We believe that our innovative approach to digital therapeutics disrupts the traditional provider-centered system of healthcare delivery by offering user-centric care that is continuous, customized supportive of better overall

health. Our solutions combine the power of technologies and behavior science to make better health accessible, affordable, and easy for all by solving for what people need, when and where they want it, with hyper-personalized care that is always connected – to services, devices, and people – and delivered continuously. Our solutions are proven to drive savings for health plans and employers by improving the health of their populations.

We began as a direct-to-consumer digital therapeutics company, solving first for the problem of how to engage users and support behavior change to improve clinical outcomes in diabetes. Beginning in 2020, we enacted a strategic shift to transform the business model by deploying a business-to-business-to-consumer ("B2B2C") approach, leveraging the strengths of our consumer solution platform to enable commercial growth opportunities in traditional health business channels by selling to health plans and employers.

At the same time, we expanded from a single-condition platform to a multi-condition platform, creating a robust suite of solutions to address the five most commonly co-occurring, behaviorally driven, and expensive chronic conditions, which are also representative of some of the most sought-after digital health solutions: diabetes, hypertension, pre-diabetes/weight management, musculoskeletal and behavioral health. After building weight loss and hypertension management into the legacy diabetes platform, we made three acquisitions in order to expand into musculoskeletal (MSK) and behavioral health (BH). In that regard, we acquired Upright, PsyInnovations and Physimax Technology assets to expand into the fields of MSK and BH. Our approach to integrating all solutions into one digital therapeutics platform follows the "best-of-suite" offering design principal which provides the user one place to monitor all identified chronic conditions and to deliver a seamless user experience for commonly co-occurring chronic conditions.

These two shifts led to the rapid expansion of our B2B2C business over the last two years and positioned us for success in commercial markets. We continue to achieve key benchmarks as we rapidly scale our B2B2C model, including more than 100 total signed contracts to date and the shift in our commercial pipeline where more than 50% of the contracts signed in the second half of 2022 are for multi-chronic solutions. We believe we have a unique and defensible position in the market thanks to our unique solution origin in consumer markets.

We continue to generate a significant number of clinical publications. In that regard, we have published 43 real world data studies with total of 10 and 67 generated in 2022 and 2023, respectively, and several more already planned for 2023.

We believe that we are proving the value of our solutions as enterprise business sales continue to grow. With more than 100 signed contracts to date, we have solid evidence on the key differentiators that lead to new business

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opportunities: a consumer-friendly approach that drives engagement; deep integration capabilities; and best-in-class clinical outcomes.

### **Recent Developments**

#### **PIPE Financing**

On May 1, 2023, we entered into securities purchase agreements (each, a "Series B Purchase Agreement") with accredited investors relating to an offering (the "Offering") and the sale of an aggregate of 6,200 shares of newly designated Series B Preferred Stock (the "Series B Preferred Stock"), an aggregate of 7,946 shares of Series B-1 Preferred Stock (the "Series B-1 Preferred Stock"), and an aggregate of 150 shares of Series B-2 Preferred Stock (the "Series B-2 Preferred Stock") at a purchase price of \$1,000 for each share of Preferred Stock. Certain of our executive officers and directors purchased shares of Series B-2 Preferred Stock in the Offering. On May 5, 2023, we entered into purchase agreements (the "Series B-3 Purchase Agreement" and together with the Series B Purchase Agreement, the "Purchase Agreement") with accredited investors, relating to the Offering, to an offering and the sale of an aggregate of 1,106 shares of newly designated Series B-3 Preferred Stock (the "Series B-3 Preferred Stock" and, collectively with the Series B Preferred Stock, the Series B-1 Preferred Stock and the Series B-2 Preferred Stock, the "Preferred Stock"), at a purchase price of \$1,000 for each share of Preferred Stock. As a result of the sale of the Preferred Stock, the aggregate gross proceeds to us from the Offering are approximately \$15.4 million.

On May 1, 2023, we filed the Certificate of Designation of Preferences, Rights and Limitations of the Series B Preferred Stock, the Certificate of Designation of Preferences, Rights and Limitations of the Series B-1 Preferred Stock, and the Certificate of Designation of Preferences, Rights and Limitations of the Series B-2 Preferred Stock with the Secretary of State of the State of Delaware (the "Series B Certificate of Designation," the "Series B-1 Certificate of Designation," and the "Series B-2 Certificate of Designation", respectively). On May 5, 2023, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of the Series B-3 Preferred Stock (the "Series B-3 Certificate of Designation," and together with the Series B Certificate of Designation, the Series B-1 Certificate of Designation, and the Series B-2 Certificate of Designation, the "Certificates of Designation"). Each share of Preferred Stock is convertible at the option of the holder, subject to certain beneficial ownership limitations as set forth in each of the Certificates of Designation, into such number of shares of our common stock equal to the number of Preferred Shares to be converted, multiplied by the stated value of \$1,000 (the "Stated Value"), divided by the conversion price in effect at the time of the conversion (the initial conversion price of the Series B Preferred Stock and Series B-1 Preferred Stock is \$3.334, the initial conversion price of the Series B-2 Preferred Stock is \$3.37, and the initial conversion price of the Series B-3 Preferred Stock is \$3.392) each subject to adjustment in the event of stock splits, stock dividends, and similar transactions.

In addition, the Preferred Stock will automatically convert into shares of common stock, subject to certain beneficial ownership limitations, including a non-waivable 19.99% ownership blocker, on the 15-month anniversary of the issuance date. The holders of Preferred Stock will also be entitled dividends payable as follows: (i) a number of shares of common stock equal to five percent (5.0%) of the number of shares of common stock issuable upon conversion of the Preferred Stock then held by such holder for each full quarter anniversary of holding for a total of four (4) quarters from the Closing Date, and (ii) a number of shares of common stock equal to ten percent (10%) of the number of shares of common stock issuable upon conversion of the Preferred Stock then held by such holder on the fifth full quarter from the closing date.

#### *Loan Facility*

On May 1, 2023, we entered into a Loan and Security Agreement, and Supplement thereto (the "LSA"), by and between the us and our subsidiary, PsyInnovations Inc. ("PsyInnovations"), collectively as the borrowers (the "Borrowers") and Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., collectively as the lenders (the "Avenue Lenders"). The LSA provides for a four-year secured credit facility in an aggregate principal amount of up to \$40 million (the "Loan Facility"), of which \$30 million was made available on the closing date (the "Initial Tranche") and up to \$10 million (the "Discretionary Tranche") may be made available on the later of July 1, 2023 or the date the Avenue Lender approves the issuance of the Discretionary Tranche. On May 1, 2023, the Borrowers closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders.

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As a result of the execution of the LSA and the funding of the Initial Tranche, the Company satisfied its prior Credit Agreement it previously executed with OrbiMed Royalty and Credit Opportunities III, LP ("Orbimed"), on June 9, 2022 and terminated the Credit Agreement with Orbimed.

#### *Employer Contracts*

In May August 2023, the Company announced a new agreement with MedOne Pharmacy Benefit Solutions ("MedOne"), a national leader in modern pharmacy benefits management, to integrate the Company's suite of digital health solutions as a complement to MedOne's digital diabetes solution, the Diabetes Care Path.

In June 2023, the Company we announced two new employer contracts for the Company's full suite expansion of integrated solutions. The new accounts are scheduled to launch in the second half of 2023.

In July 2023, the Company announced a new our agreement with a large regional health plan to deliver highly personalized digital health solutions to more than 160,000 Plan plan members living with hypertension, diabetes. The launch for this large regional health plan is anticipated to be in the first quarter of 2024.

In August 2023, we announced a new agreement with PlanSource, a leading provider of cloud-based benefits administration and engagement technology, to offer integrated digital health solutions to more than five million consumers.

In October 2023, we announced a new strategic partnership with a top five national employee benefits consulting firm to become the preferred digital health and chronic condition solution partner for its national employer clients.

#### *Presentation of New Studies*

In July August 2023, we announced new research presented at the Company ADCES23 Annual Conference held in Houston, Texas. The new research demonstrated our ability to sustainably improve health outcomes for users with diabetes over a two-year period.

In September 2023, we announced a new analysis research published in the Journal of Medical Internet Research (JMIR) demonstrating the impact of coaching and breathing exercises as part of our digital behavioral health program alongside coaching and breathing exercises for members living with depression or anxiety.

In October 2023, we announced new research presented by Sanofi at the Academy of Managed Care Pharmacy's 2023 annual conference Nexus, demonstrating a significant 36% reduction in the cost of care 30-day hospital readmissions for Dario our users compared to non-users living with Type type 2 diabetes. The study used matched claims to show an estimated \$5,077 in medical cost savings for Dario users compared to non-users.

#### *Agreement with Sanofi Launch of Apple iPhone 15 Accessible Smart Blood Glucose Meter*

In July November 2023, we entered into an amended and restated strategic agreement with Sanofi, an innovative global healthcare company. In this amendment, announced the parties adjusted certain pre agreed economic parameters, to better align the common interests launch of the parties in light of the developments in the digital health market after the first year of partnership, including revenue share adjustments that align with both parties' strategic goals. The changes apply to certain customers in exchange a new smart blood sugar meter for additional promotional activities to be performed by Sanofi. The parties also agreed to allow the acceleration of certain development milestones agreed upon in the initial agreement. This multi-year, \$30 million agreement, which is subject to certain contingencies, will help accelerate commercial adoption of our full suite of digital therapeutics and drive the expansion of digital health solutions on our platform. We and Sanofi will collaborate on promoting our multi-condition digital therapeutics solution, significantly increasing our sales reach in the health plan market and selectively in the employer channel. In addition, the agreement calls for us and Sanofi to develop new or enhanced solutions leveraging our platform, and for the parties to generate robust evidence Apple iPhone 15 users to support future commercialization in the health plan channel.

#### *New Programs*

In August 2023, the Company announced a ongoing engagement with new program to deliver tailored behavior change support for individuals using GLP-1s and other anti-obesity drugs, existing members.

#### **Results of Operations**

**Comparison of the three and six nine months ended June 30, 2023 September 30, 2023, and June 30, 2022 September 30, 2022 (dollar amounts in thousands)**

##### *Revenues*

Revenues for the three and six nine months ended June 30, 2023 September 30, 2023, amounted to \$6,152 \$3,518 and \$13,218 \$16,736 respectively, compared to revenues of \$6,183 \$6,605 and \$14,242 \$20,847 during the three and six nine months ended June 30, 2022 September 30, 2022, representing a decrease of 0.5% 46.7% and 7.2% 19.7%, respectively. The decrease in revenues for the three and six months ended June 30, 2023 September 30, 2023, compared to the three and six months ended June 30, 2022 September 30, 2022, resulted mainly from a reduction in revenue relating to data access and development services derived from the Company's strategic partnerships that are included in revenues from providing services. The decrease in revenues for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, resulted mainly from the intended reduction in revenues from consumer hardware sales and a reduction in revenue relating to data access and development services derived from the Company's consumer (B2C) channel, strategic partners that are included in revenues from providing services.

##### *Cost of Revenues*

During the three and nine months ended September 30, 2023, we recorded cost of revenues in the amount of \$2,908 and \$10,884, respectively, compared to costs related to revenues of \$4,805 and \$13,924 during the three and nine

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*Cost of Revenues*

During the three and six months ended June 30, 2023, we recorded cost of revenues in the amount of \$4,078 and \$7,976, respectively, compared to costs related to revenues of \$5,045 and \$9,119 during the three and six months ended June 30, 2022 September 30, 2022, representing a decrease of 19.2% 39.5% and 12.5% 21.8%, respectively. The decrease in cost of revenues in the three and six months ended June 30, 2023 September 30, 2023, compared to the three and six months ended June 30, 2022 September 30, 2022, was mainly due to lower cost of revenues from our services channel due to a postponement of certain projects caused by our strategic partner. The decrease in cost of revenues in the Company's nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, was mainly due to lower cost of revenues from our consumer channel, hardware channel, resulting mainly from an intended reduction in revenues from our consumer hardware channel.

Cost of revenues consist mainly of cost of device production, employees' salaries and related overhead costs, depreciation of production line and related cost of equipment used in production, amortization of technologies, hosting costs, shipping and handling costs and inventory write-downs.

*Gross Profit*

Gross profit for the three and six nine months ended June 30, 2023 September 30, 2023, amounted to \$2,074 (33.7% \$610 (17.3% of revenues) and \$5,242 (39.7% \$5,852 (35% of revenues), respectively, compared to \$1,138 (18.4% \$1,800 (27.3% of revenues) and \$5,123 (36% \$6,923 (33.2% of revenues) during the three and six nine months ended June 30, 2022 September 30, 2022. The decrease in gross profit as a percentage of revenues for the three months ended September 30, 2023, compared to the three months ended September 30, 2022, is due to the decrease in gross profit derived from the sale of services partially offset by an increase in the gross profit generated from consumer hardware. The increase in gross profit as a percentage of revenue revenues for the three and six nine months ended June 30, 2023 September 30, 2023, compared to the three and six nine months ended June 30, 2022 September 30, 2022, is due to the increase in the gross profit generated from consumer hardware revenues partially offset by a decrease in gross profit derived from revenues derived from sales through our commercial channel, services. Gross profit for the three and six nine months ended June 30, 2023 September 30, 2023, excluding amortization of acquired technology were \$3,168 (51.5% \$1,716 (48.8% of revenues) and \$7,417 (56.1% \$9,133 (54.6% of revenues) compared to \$2,232 (36.1% \$2,905 (44% of revenues) and \$7,149 (50.2% \$10,054 (48.2% of revenues) during the three and six nine months ended June 30, 2022 September 30, 2022.

*Research and Development Expenses*

Our research and development expenses increased by \$1,085, \$862, or 26.2% 17.9%, to \$5,222 \$5,665 for the three months ended June 30, 2023 September 30, 2023, compared to \$4,137 \$4,803 for the three months ended June 30, 2022 September 30, 2022, and increased by \$323, \$1,185, or 3.2% 8%, to \$10,387 \$16,052 for the six nine months ended June 30, 2023 September 30, 2023, compared to \$10,064 \$14,867 for the six nine months ended June 30, 2022 September 30, 2022. This The increase in research and development expenses for the three months ended September 30, 2023 compared to the three months ended September 30 2022 was mainly a result of payroll-related a reduction in the allocation of payroll expenses and share-based compensation due related to development services provided under our strategic agreements to the expansion cost of our revenues, partially offset by a reduction in subcontractors and consulting expenses. The increase in research and development activities, expenses for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, was mainly due to an increase in payroll expenses, share-based compensation expenses, a reduction in the allocation of payroll expenses related to development services provided under our strategic agreements to the cost of revenues and other research and development expenses, partially offset by a reduction in subcontractors and consulting expenses. Our research and development expenses, excluding stock-based compensation and depreciation, for the three and six nine months ended June 30, 2023 September 30, 2023, were \$3,904 \$4,417 and \$7,865 \$12,282 compared to \$3,567 \$3,625 and \$7,995 \$11,620 for the three and six nine months ended June 30, 2022 September 30, 2022, an increase of \$337 \$792 and a decrease of \$130 \$6,624, respectively.

Research and development expenses consist mainly of employees' salaries and related overhead costs involved in research and development activities, expenses related to: (i) our solutions including our Dario Smart Diabetes Management Solution, Dario Engage our engagement platform, Dario Move solution and our digital behavioral health solution, (ii) labor contractors and engineering expenses, (iii) depreciation and maintenance fees related to equipment and software tools used in research and development, (iv) clinical trials performed in

the United States to satisfy the FDA product approval requirements and (v) facilities expenses associated with and allocated to research and development activities.

#### *Sales and Marketing Expenses*

Our sales and marketing expenses decreased by ~~\$2,837~~ \$1,208, or ~~30.5%~~ 16%, to ~~\$6,460~~ \$6,363 for the three months ended ~~June 30, 2023~~ September 30, 2023, compared to ~~\$9,297~~ \$7,571 for the three months ended ~~June 30, 2022~~ September 30, 2022, and decreased by ~~\$6,032~~ \$7,240, or ~~32%~~ 27.4%, to ~~\$12,800~~ \$9,163 for the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, compared to ~~\$18,832~~ \$26,403 for the ~~six~~ nine months ended ~~June 30, 2022~~ September 30, 2022. The decrease in sales and marketing expenses for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, was mainly due to decreases in our payroll and related expenses.

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The decrease in sales and marketing expenses for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, was mainly due to the decrease in our digital marketing expenses and payroll and related expenses. Our sales and marketing expenses, excluding stock-based compensation and depreciation, for the three and ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023 were ~~\$4,591~~ \$4,445 and ~~\$9,039~~ \$13,484 compared to ~~\$7,553~~ \$5,570 and ~~\$15,396~~ \$20,966 for the three and ~~six~~ nine months ended ~~June 30, 2022~~ September 30, 2022, a decrease of ~~\$2,962~~ \$1,125 and increase of ~~\$6,356~~ \$7,482 respectively.

Sales and marketing expenses consist mainly of employees' salaries and related overhead costs, online marketing campaigns of our service offering, trade show expenses, customer support expenses and marketing consultants, marketing expenses and subcontractors.

#### *General and Administrative Expenses*

Our general and administrative expenses ~~decreased~~ increased by ~~\$647~~ \$129, or ~~12.8%~~ 3.2%, to ~~\$4,412~~ \$4,128 for the three months ended ~~June 30, 2023~~ September 30, 2023, compared to ~~\$5,059~~ \$3,999 for the three months ended ~~June 30, 2022~~ September 30, 2022, and decreased by ~~\$971~~ \$842, or ~~10.3%~~ 6.3% to ~~\$8,483~~ \$12,611 for

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the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, compared to ~~\$9,454~~ \$13,453 for the ~~six~~ nine months ended ~~June 30, 2022~~ September 30, 2022. This increase in general and administrative expenses for the three months ended September 30, 2023, compared to the three months ended September 30, 2022, was due to an increase in stock-based compensation and legal fees. The decrease in general and administrative expenses for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, was mainly due to a decrease in acquisition and restructuring costs expenses, and other consulting expenses during the ~~three~~ and ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023. Our general and administrative expenses, excluding stock-based compensation, depreciation, acquisition related acquisition-related costs and earn-out remeasurement for the three and ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, were ~~\$2,229~~ \$2,053 and ~~\$4,468~~ \$6,521 compared to ~~\$2,290~~ \$2,178 and ~~4,929~~ \$7,107 for the three and ~~six~~ nine months ended ~~June 30, 2022~~ September 30, 2022, a decrease of ~~\$61~~ \$125 and ~~\$374~~, \$586, respectively.

Our general and administrative expenses consist mainly of employees' salaries and related overhead costs, directors' fees, legal and accounting fees, patent registration, expenses related to investor relations, as well as our office rent and related expenses.

#### *Financial Expenses, net*

Our financial expenses, net for the three months ended **June 30, 2023** **September 30, 2023**, were **\$2,565**, **\$186**, representing an increase **a decrease** of **\$1,893**, **\$873**, compared to financial expenses of **\$672**, **\$1,059** for the three months ended **June 30, 2022** **September 30, 2022**. Our financial expenses, net for the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, were **\$2,982**, **\$3,168**, representing an increase of **\$2,266**, **\$1,393**, compared to financial expenses of **\$716**, **\$1,775** for the **six** **nine** months ended **June 30, 2022** **September 30, 2022**. The decrease in our financial expenses for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, was mainly due to the increase in interest income and an income from the reduction of the revaluation of the long-term loan and the warrant liability relating to the loan provided by Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., collectively as lenders (the "Avenue Lenders"). The increase in our financial expenses for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was mainly due to expenses, related to the Company's refinancing of its existing former \$25,000 credit facility obtained on June 9, 2022 with a new \$30,000 credit facility, interest expense, debt issuance costs and the revaluation of the long-term loan and the warrant liability in relating to the amount of \$3,713 partially offset loan previously provided by interest income OrbiMed Royalty and the revaluation of short-term investments in the amount of \$901. Credit Opportunities III, LP ("Orbimed").

Financial expenses, net primarily consists of credit facility interest expense, interest income from cash balances, the revaluation of short-term investments, loss on early extinguishment of debt, bank charges, lease liability and foreign currency translation differences.

#### Net loss

Net loss **decreased** increased by **\$1,443**, **\$100**, or **8%** **0.6%**, to **\$16,585**, **\$15,732** for the three months ended **June 30, 2023** **September 30, 2023**, compared to a net loss of **\$18,028**, **\$15,632** for the three months ended **June 30, 2022** **September 30, 2022**, and decreased by **\$4,533**, **\$4,434**, or **13.4%** **8.9%**, to **\$29,410**, **\$45,142** for the **six** **nine** months ended **June 30, 2023** **September 30, 2023**, compared to a net loss of **\$33,944**, **\$49,576** for the **six** **nine** months ended **June 30, 2022** **September 30, 2022**.

The decrease in net loss for the **three and six** **nine** months ended **June 30, 2023** **September 30, 2023**, compared to the **three and six** **nine** months ended **June 30, 2022** **September 30, 2022**, was mainly due to the decrease in our operating expenses.

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The factors described above resulted in net loss attributable to **common** stockholders for the **three and six** **nine** months ended **June 30, 2023** **September 30, 2023**, amounted to **\$18,276**, **\$16,904** and **\$31,101**, **\$48,005**, respectively, compared to net loss attributable to **common** stockholders of **\$18,461**, **\$16,126** and **\$34,828**, **\$50,954** for the **three and nine** months ended **September 30, 2022**.

#### Non-GAAP Financial Measures

To supplement our unaudited condensed consolidated financial statements presented in accordance with "U.S. GAAP" within this Quarterly Report on Form 10-Q, management provides certain non-GAAP financial measures ("NGFM") of the Company's financial results, including such amounts captioned: "net loss before interest, taxes, depreciation, and amortization" or "EBITDA", and "Non-GAAP Adjusted Loss", as presented herein below. Importantly, we note the NGFM measures captioned "EBITDA" and "Non-GAAP Adjusted Loss" are not recognized terms under U.S. GAAP, and as such, they are not a substitute for, considered superior to, considered separately from, nor as an alternative to, U.S. GAAP and /or the most directly comparable U.S. GAAP financial measures.

Such NGFM are presented with the intent of providing greater transparency of information used by us in our financial performance analysis and operational decision-making. Additionally, we believe these NGFM provide meaningful information to assist investors, shareholders, and other readers of our unaudited condensed consolidated financial statements, in making comparisons to our historical financial results, and analyzing the underlying financial results of our operations. The NGFM are provided to enhance readers' overall understanding of our current financial results and to provide further information to enhance the comparability of results between the current year period and the prior year period.

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We believe the NGFM provide useful information by isolating certain expenses, gains, and losses, which are not necessarily indicative of our operating financial results and business outlook. In this regard, the presentation of the NGFM herein below, is to help the reader of our unaudited condensed consolidated financial statements to understand the effects of the non-cash impact on our (U.S. GAAP) unaudited condensed consolidated statement of operations of the revaluation of the warrants and the expense related to stock-based compensation, each as discussed herein above.

A reconciliation to the most directly comparable U.S. GAAP measure to NGFM, as discussed above, is as follows:

	Three Months Ended June 30, (in thousands)			Three Months Ended September 30, (in thousands)				
	2023		2022	\$ Change	2023		2022	\$ Change
	<b>Net Loss Reconciliation</b>	Net loss - as reported	\$ (16,585)	\$ (18,028)	\$ 1,443	\$ (15,732)	\$ (15,632)	\$ (100)
<b>Adjustments</b>								
Depreciation expense	94	84	10	99	89	10		
Amortization of acquired technology and brand	1,125	1,125	—	1,137	1,136	1		
Other financial expenses, net	2,565	672	1,893	186	1,059	(873)		
Income tax	—	1	(1)					
EBITDA	(12,801)	(16,146)	3,345	(14,310)	(13,348)	(962)		
Earn-out remeasurement	—	1,391	(1,391)	—	6	(6)		
Stock-based compensation expenses	5,292	3,629	1,663	5,159	4,926	233		
Non-GAAP adjusted loss	\$ (7,509)	\$ (11,126)	\$ 3,617	\$ (9,151)	\$ (8,416)	\$ (735)		
<b>Six Months Ended June 30, (in thousands)</b>								
<b>2023</b>			<b>2022</b>	<b>\$ Change</b>				
<b>Net Loss Reconciliation</b>								
Net loss - as reported	\$ (29,410)	\$ (33,944)	\$ 4,534					
<b>Adjustments</b>								
Depreciation expense	191	154	37					
Amortization of acquired technology and brand	2,238	2,088	150					
Other financial expenses, net	2,982	716	2,266					
Income tax	—	1	(1)					
EBITDA	(23,999)	(30,985)	6,986					
Earn-out remeasurement	—	939	(939)					
Stock-based compensation expenses	10,148	8,972	1,176					
Non-GAAP adjusted loss	\$ (13,851)	\$ (21,074)	\$ 7,223					

	Nine Months Ended September 30,		
	(in thousands)		
	2023	2022	\$ Change
<b>Net Loss Reconciliation</b>			
Net loss - as reported	\$(45,142)	\$(49,576)	\$ 4,434
Adjustments			
Depreciation expense	290	243	47
Amortization of acquired technology and brand	3,375	3,224	151
Other financial expenses, net	3,168	1,775	1,393
Income tax	—	1	(1)
EBITDA	(38,309)	(44,333)	6,024
Earn-out remeasurement	—	945	(945)
Stock-based compensation expenses	15,307	13,898	1,409
Non-GAAP adjusted loss	<u><u>\$(23,002)</u></u>	<u><u>\$(29,490)</u></u>	<u><u>\$ 6,488</u></u>

**Liquidity and Capital Resources (amounts in thousands except for share and share amounts)**

As of **June 30, 2023** **September 30, 2023**, we had approximately **\$52,602** **\$43,878** in cash and cash equivalents compared to **\$49,357** on December 31, 2022.

We have experienced cumulative losses of **\$316,951** **\$333,855** since inception (August 11, 2011) through **June 30, 2023** **September 30, 2023**, and have a stockholders' equity of **\$78,404** **\$68,035** as of **June 30, 2023** **September 30, 2023**. In addition, we have not completed our efforts to establish a stable recurring source of revenues sufficient to cover our operating costs and expect to continue to generate losses for

the foreseeable future. However, we believe that our sources of liquidity and capital resources will be sufficient to meet our business needs for at least the next twelve months.

Since inception, we have financed our operations primarily through private placements and public offerings of our common stock and warrants to purchase shares of our common stock, receiving aggregate net proceeds totaling **\$244,188** **\$244,392** and a credit facility of **\$25,564** as of **June 30, 2023** **September 30, 2023**.

On February 28, 2022, we entered into a securities purchase agreement with institutional investors, pursuant to which we agreed to issue and sell to the investors in a registered direct offering priced at-the-market under Nasdaq rules an aggregate of 4,674,454 shares of our common stock, par value \$0.0001 per share, and pre-funded warrants to purchase an aggregate of 667,559 shares of our common stock. Each share was sold at an offering price of \$7.49 per share, and each pre-funded warrant was sold at an offering price of \$7.4899, for aggregate gross proceeds of approximately \$40 million before deducting the offering expenses. In addition, the investors have executed lock up agreements agreeing to a lock up period of three days.

On October 22, 2021, we entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"), as agent, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to \$50 million from time to time

through Cowen. As of June 30, 2023For the nine months ended September 30, 2023, we sold an aggregate of 429,050 shares of our common stock for aggregate the Company received net proceeds of approximately \$1,670, pursuant to \$1,614 from the sale of 408,043 shares of the Company's common stock. As of September 30, 2023, there was \$47,971 in remaining funds available under the Sales Agreement.

On February 1, 2021, we entered into securities purchase agreements with institutional accredited investors relating to an offering with respect to the sale of an aggregate of 3,278,688 shares of common stock, at a purchase price of \$21.35 per share. The aggregate gross proceeds were approximately \$70,000.

On May 1, 2023, we entered into securities purchase agreements with accredited investors relating to an offering and the sale of an aggregate of 6,200 shares of newly designated Series B Preferred Stock, an aggregate of 7,946 shares of

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Series B-1 Preferred Stock, and an aggregate of 150 shares of Series B-2 Preferred Stock, at a purchase price of \$1,000 for each share of Preferred Stock. Certain of our executive officers and directors purchased shares of Series B-2 Preferred Stock in the offering. On May 5, 2023, we entered into securities purchase agreements with accredited investors, relating to an offering and the sale of an aggregate of 1,106 shares of newly designated Series B-3 Preferred Stock, at a purchase price of \$1,000 for each share of Preferred Stock. As a result of the sale of the Preferred Stock, the aggregate gross proceeds to us from the offering are approximately \$15.4 million.

On May 1, 2023, we entered into a Loan and Security Agreement, and Supplement thereto (the "LSA"), by and between the LSA, with us and our subsidiary, PsyInnovations Inc. ("PsyInnovations"), collectively as the borrowers (the "Borrowers") and the Avenue Lenders. The LSA Lenders, which provides for a four-year secured credit facility in an aggregate principal amount of up to \$40 million, of which \$30 million was made available on the closing date (the "Initial Tranche") and up to \$10 million may be made available on the later of July 1, 2023 or the date the Avenue Lenders approve the issuance of the Discretionary Tranche. On May 1, 2023, we closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders. As a result of the execution of the LSA and the funding of the Initial Tranche, the Company satisfied its prior Credit Agreement it previously executed with Orbimed OrbiMed, on June 9, 2022 and terminated the Credit Agreement with Orbimed.

Management believes that the proceeds from the prior private placements and the Avenue Loan Facility and the funds we may draw down from the Sales Agreement, combined with our cash on hand and short-term investments are sufficient to meet our obligations as they come due for at least a period of twelve months from the date of the issuance of these unaudited condensed consolidated financial statements. As a result, we have resolved to remove the going concern note from our financial statements. There are no assurances, however, that we will be able to obtain an adequate level of financial resources that are required for the long-term development and commercialization of our product offerings.

As such, we have a significant present need for capital. If we are unable to scale up our commercial launch of our products or meet our commercial sales targets (or if we are unable to generate any revenue at all), and if we are unable to obtain additional capital resources in the near term, we may be unable to continue activities absent material alterations in our business plans and our business might fail.

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Additionally, readers are advised that available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding sooner than expected. Should this occur, we will need to seek additional capital earlier than anticipated in order to

fund (1) further development and, if needed (2) our efforts to obtain regulatory clearances or approvals necessary to be able to commercially launch Dario, Dario Engage and Dario Intelligence, (3) expenses which will be required in order to expand manufacturing of our products, (4) sales and marketing efforts and (5) general working capital. Such funding may be unavailable to us on acceptable terms, or at all. Our failure to obtain such funding when needed could create a negative impact on our stock price or could potentially lead to the failure of our company. This would particularly be the case if we are unable to commercially distribute our products and services in the jurisdictions and in the timeframes we expect.

#### **Cash Flows (dollar amounts in thousands)**

The following table sets forth selected cash flow information for the periods indicated:

	June 30,		September 30,	
	2023		2022	
	\$	\$	\$	\$
Cash used in operating activities:	(14,393)	(29,209)	(23,038)	(39,904)
Cash used in investing activities:	(183)	(340)	(464)	(514)
Cash provided by financing activities:	18,049	61,675	18,253	61,675
	<u>3,473</u>	<u>32,126</u>	<u>(5,249)</u>	<u>21,257</u>

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#### *Net cash used in operating activities*

Net cash used in operating activities was ~~\$14,393~~ \$23,038 for the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, a decrease of ~~50.7%~~ ~~42.3%~~ compared to ~~\$29,209~~ \$39,904 used in operations for the same period in 2022. Cash used in operations decreased mainly due to the decrease in our operating expenses, net loss, decrease in trade receivables, inventories, and trade payables.

#### *Net cash used in investing activities*

Net cash used in investing activities was ~~\$183~~ \$464 for the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023 compared to ~~\$340~~ \$514 net cash used in investing activities during the same period in 2022. The decrease is a result of the ~~decline~~ ~~decrease~~ in our intangible assets purchased, and property and equipment purchased in the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, compared to the same period in 2022.

#### *Net cash derived/provided from financing activities*

Net cash derived from financing activities was ~~\$18,049~~ \$18,253 for the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023, compared to \$61,675 net cash provided by financing activities during the same period in 2022. The decrease results from the decrease in the proceeds from the issuance of preferred shares in the ~~six~~ nine months ended ~~June 30, 2023~~ September 30, 2023 compared to the proceeds from the issuance of common stock and prefunded warrants in the ~~six~~ nine months ended ~~June 30, 2022~~ September 30, 2022, and from the reduction in the amounts borrowed in the first nine months of 2023 compared to the first nine months of 2022.

#### **Item 4. Controls and Procedures.**

##### *Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), conducted evaluations of our disclosure controls and procedures. As defined under Sections 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act", the term "disclosure controls and procedures" means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of

the SEC. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and

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communicated to the issuer's management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on their evaluation, the Certifying Officers concluded that, as of **June 30, 2023** **September 30, 2023**, our disclosure controls and procedures were designed at a reasonable assurance level and were therefore effective.

*Changes in Internal Control over Financial Reporting*

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

*Limitations on the Effectiveness of Internal Controls*

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our control have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

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**PART II - OTHER INFORMATION**

**Item 1A. Risk Factors.**

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, which could materially affect our business, financial condition, or future results.

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, except as noted below.

***Currently, our revenues are concentrated with two major customers, Sanofi, and a national health plan, and our revenues may decrease significantly if we were to lose our major customers.***

Due to our limited operating history, we have a limited customer base and have depended on a major customer, Sanofi, for a significant portion of our revenue. On February 8, 2022, we entered into an exclusive preferred partner, co-promotion, development collaboration and license agreement for a term of five (5) years (the "Exclusive Agreement") with Sanofi. Pursuant to the Exclusive Agreement, we will provide a license to access and use certain Company data. As of **June 30, 2023** September 30, 2023, our major customer accounted for **68.8%** **77.5%** of our accounts receivable balance and, for the three- and **six-month** **nine-month** periods ended **June 30, 2023** September 30, 2023, Sanofi accounted for **37.8%** **5.7%** and **40.2%** **32.9%**, respectively, of our revenue. If Sanofi were to terminate the Exclusive Agreement, or if we fail to adequately perform under the Exclusive Agreement, and if we are unable to diversify our customer base, our revenue could decline, and our results of operations could be adversely affected.

***Our principal executive offices and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them.***

Our executive offices and corporate headquarters are located in Israel. In addition, most of our officers are residents of Israel. Accordingly, political, economic and military and security conditions in Israel and the surrounding region may directly affect our business. Any conflicts, political instability, terrorism, cyberattacks or any other hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations. Ongoing and revived hostilities in the Middle East or other Israeli political or economic factors, could harm our operations.

In October 2021, we entered into 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a master services agreement series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a national health plan, which provided for various projects that military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks.

The intensity and duration of Israel's current war against Hamas is difficult to predict, as are such war's economic implications on the Company's business and operations and on Israel's economy in general. These events may be undertaken by us at intertwined with wider macroeconomic indications of a deterioration of Israel's economic standing, which may have a material adverse effect on the direction Company and its ability to effectively conduct some of its operations.

In connection with the national health plan customer. As Israeli security cabinet's declaration of June 30, 2023, the national health plan customer accounted for 11% war against Hamas and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service. Certain of our accounts receivable balance employees and consultants (and their spouses or partners) in Israel have been called, and additional employees (or their spouses or partners) may be called, for service in the three current or future wars or other armed conflicts with Hamas, and six months such persons may be absent for an extended period ended June 30, 2023, they accounted for 4.1% and 7.3% respectively, of our revenue. During this period, these revenues were as time. As a result, our operations in Israel may be disrupted by such absences, which disruption may materially and adversely affect our business, prospects, financial condition and results of a specific project that we were assigned to complete for this particular customer. There is no guarantee that the national health plan customer will continue to assign us projects under the master services agreement in the future and we may not realize any significant revenues, if at all, if we are not operations.

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assigned

Following the attack by Hamas on Israel's southern border, Hezbollah in Lebanon has also launched missile, rocket and shooting attacks against Israeli military sites, troops, and Israeli towns in northern Israel. In response to these attacks, the Israeli army has carried out a number of targeted strikes on sites belonging to Hezbollah in southern Lebanon. It is possible that other terrorist organizations, including Palestinian military organizations in the West Bank, as well as other hostile countries, such projects. If as Iran, will join the hostilities. Such hostilities may include terror and missile attacks. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Our commercial insurance does not cover losses that may

occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we are unable to assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to realize any additional revenues from our master services agreement economic boycotts. Several countries still restrict business with the national health plan customer, State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our revenue, operating results, financial condition or the expansion of our business. A campaign of boycotts, divestment and sanctions has been undertaken against Israel, which could decline, also adversely impact our business.

Prior to the Hamas attack in October 2023, the Israeli government pursued extensive changes to Israel's judicial system. In response to the foregoing developments, individuals, organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed changes may negatively impact the business environment in Israel including due to reluctance of foreign investors to invest or transact business in Israel as well as to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. The risk of such negative developments has increased in light of the recent Hamas attacks and the war against Hamas declared by Israel, regardless of the proposed changes to the judicial system and the related debate. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors.

***The market price of our common stock has been extremely volatile and may continue to be volatile due to numerous circumstances beyond our control.***

The market price of our common stock has fluctuated, and may continue to fluctuate, widely, due to many factors, some of which may be beyond our control. These factors include, without limitation:

- "short squeezes";
- comments by securities analysts or other third parties, including blogs, articles, message boards and social and other media;
- large stockholders exiting their position in our securities or an increase or decrease in the short interest in our securities;
- actual or anticipated fluctuations in our financial and operating results;
- risks and uncertainties associated with the ongoing COVID-19 pandemic;
- changes in foreign currency exchange rates;
- the commencement, enrollment or results of our planned or future clinical trials of our product candidates or those of our competitors;
- the success of competitive drugs or therapies;

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- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- litigation matters, including amounts which may or may not be recoverable pursuant to our officer and director insurance policies, regulatory actions affecting the Company and the outcome thereof;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;

- market conditions in our market sector;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors' general perception of us and our business.

Stock markets in general and our stock price in particular have recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies and our company. For example, the closing sale prices of our Common Stock from January 1, 2023 through October 27, 2023 ranged from a high of \$6.22 per share (on January 17, 2023) to a low of \$1.30 per share (on October 27, 2023). During that time, we have not experienced any material changes in our financial condition or results of operations that would explain such price volatility or trading volume; however, we have sold equity which was dilutive to existing stockholders. These broad market fluctuations may adversely affect the trading price of our securities. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent our stockholders from readily selling their shares of our common stock and may otherwise negatively affect the liquidity of our common stock.

In addition, if the stock price of our common stock continues to trade at its current level, it may imply as a negative indicator of the valuation of our intangible assets and our goodwill, which could be adversely affected, result in an impairment for these assets.

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

During the **second** **third** quarter of 2023, we issued an aggregate of **123,591** **264,986** shares of the Company's common stock to certain of our service providers as compensation in lieu of cash compensation owed to them for services rendered.

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We claimed exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"), for the foregoing transactions under Section 4(a)(2) of the Securities Act.

#### **Item 6. Exhibits.**

No.	Description of Exhibit
10.1*U	<a href="#">Amended and Restated Exclusive Preferred Partner, Co-Promotion, Development Collaboration and License Agreement by and between Sanofi US Services, Inc. and DarioHealth Corp., dated July 10, 2023.</a>
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a).</a>
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a).</a>
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350.</a>
32.2**	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.</a>
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended <b>June 30, 2023</b> <b>September 30, 2023</b> , formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Statements of Changes in Stockholders' Deficiency, (iv) Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

\* Filed herewith.

\*\* Furnished herewith.

U Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material

and (ii) would likely cause competitive harm to the Company if publicly disclosed. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

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**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 hereunto duly authorized.

Date: **August 10, 2023** **November 2, 2023**

**DarioHealth Corp.**

By: **/s/ Erez Raphael**

Name: **Erez Raphael**

Title: **Chief Executive Officer (Principal Executive Officer)**

By: **/s/ Zvi Ben David**

Name: **Zvi Ben David**

Title: **Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer)**

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**Exhibit 10.1**

**AMENDED AND RESTATED**

**EXCLUSIVE PREFERRED PARTNER, CO-PROMOTION, DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT**

**THIS AMENDED AND RESTATED COLLABORATION AGREEMENT** (this "Agreement") is made and entered into as of July 10, 2023 (the "Restatement Date"), by and between Sanofi US Services, Inc., a Delaware corporation, with a place of business located at Head Office 55 Corporate Drive, Bridgewater, NJ 08807, United States ("Sanofi") and Dario Health Corp., a Delaware corporation with a place of business located at 18 West 18th Street, New York 10011, United States ("Dario"). Sanofi and Dario are each referred to individually as a "Party" and collectively as the "Parties".

**WHEREAS**, Dario is a digital therapy technology company which has developed and commercializes a mobile and web-based, customized, user-centric, modular platform, integrating digital therapeutics, coaching, devices, and care providers, currently supporting diabetes, pre-diabetes, hypertension, behavioral health (BH), musculoskeletal (MSK), and obesity;

**WHEREAS**, Sanofi and Dario wish to jointly co-promote Dario's Solution to Targeted Channels in the Territory and for the Therapeutic Areas;

**WHEREAS**, Sanofi and Dario also wish to develop and co-promote new digital therapy applications that combine the Solution with Sanofi know how and proprietary Sanofi assets, and conduct relevant medical studies (prospective and retrospective, medical and health economic) to understand various intermediate, post-intermediate, and long term health outcomes;

**WHEREAS**, the Parties initially entered into a collaboration agreement with respect to the foregoing activities on February 28, 2022 (the "**Initial Agreement**"); and

**WHEREAS**, the Parties now desire to amend and restate the Initial Agreement in its entirety on the terms and subject to the conditions set forth herein.

**NOW THEREFORE**, in consideration of these premises and mutual promises and agreements herein set forth, and other valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

**1. DEFINITIONS.** In this Agreement the following words and phrases have the following meanings:

**1.1** "**Adequate Anonymization Process**" means a process through which Personal Data is subjected to various processing operations resulting in the inability for the data processing owner or any person who will be granted access to such data to relate it to an identified or identifiable natural person without implementing disproportionate efforts. Any Adequate Anonymization Process must at least include actions relating to (i) perturbation of the Personal Data (e.g. through the removal of certain characteristics of the data); (ii) contractual or operational restrictions on the use of the data sets (e.g. through contractual restrictions on the matching, combination or re-identification attempts relating to the data sets) and (iii) technical and organizational security measures designed to ensure the confidentiality of the data sets (e.g. through access rights management). Any

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anonymization process shall only be regarded as an Adequate Anonymization Process on a case by case basis.

**1.2** "**Advanced Discussion List**" means accounts in the Health Plan Channel provided on **Exhibit E**. Accounts may be removed from the Advanced Discussion List upon approval by the JSC.

**1.3** "**Affiliate**" of a Party means any corporation or other business entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party for so long as such Party controls, is controlled by or is under common control with such corporation or other business entity. As used herein, the term "control" means the direct or indirect ownership of 50% or more of the stock having the right to vote for directors thereof or other ownership interest or the ability to otherwise control the management thereof.

**1.4** "**Agreement**" has the meaning set forth in the preamble hereto.

**1.5** "**Amwell**" means American Well Corporation and its Affiliates.

**1.6** "**Anonymized Data**" means Personal Data which has been subjected to an Adequate Anonymization Process ensuring that, at the time of its processing, it cannot be related to an identified or identifiable natural person.

**1.7** "**Applicable Law**" means applicable laws, rules or regulations, including any rules, regulations or other requirements of any applicable federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the activities conducted pursuant to this Agreement, including, but not limited to, applicable Data Protection Laws, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, *et seq.*) and the regulations promulgated thereunder ("FDCA"), the Public Health Service Act (42 U.S.C. 262) ("PHSA") and the regulations promulgated thereunder; the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b), the federal False Claims Act (31 U.S.C. § 3729 *et seq.*), federal, state or provincial licensing, disclosure and reporting requirements, and all state consumer and other privacy and anti-kickback laws, in each case, as amended from time to time.

**1.8** **"Bundled Account"** means any account on the Bundling Discussions List that enters into both (a) a Sanofi Rebate Agreement and (b) a Dario Platform Agreement for the term of such Dario Platform Agreement. A list of Bundled Accounts will be maintained by the JSC.

**1.9** **"Bundled Member Data"** has the meaning set forth in Section 3.3.

**1.10** **"Bundling Discussion List"** means the accounts listed on **Exhibit H**. Accounts may be added or removed from the Bundling Discussion List upon approval by the JSC.

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**1.11** **"Business Day"** means any twenty-four (24) hour day period other than a Saturday, Sunday or other day on which commercial banks in New York, New York are authorized or required by Applicable Law to close.

**1.12** **"Calendar Quarter"** means any of the 3-month periods beginning on January 1, April 1, July 1 or October 1 of any Calendar Year, except that the first Calendar Quarter of the Term will commence on the Effective Date and end on March 31, 2022, and the last Calendar Quarter will end on the last day when all of Dario's post-Term revenue share payment obligations pursuant to Section 7.4.1.2, Section 7.4.2.2 and Section 7.4.3 terminates. For clarity, the end date of the last Calendar Quarter shall not be a date that is later than three (3) years from the Termination Date.

**1.13** **"Calendar Year"** means (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31, 2022, (b) for the last Calendar Year, the period commencing on January 1 of the last year of the Term, and ending on the last day of the Term, and (c) each interim period of 12 months commencing on January 1 and ending on December 31.

**1.14** **"Change of Control"** means, with respect to a Party, from and after the Effective Date: (a) a merger or consolidation in which (i) such Party is a constituent party, or (ii) an Affiliate of such Party that directly or indirectly controls such Party is a constituent party, except in the case of either clause (i) or (ii) any such merger or consolidation involving such Party or such Affiliate in which the shares of capital stock of such entity outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or are exchanged for shares of capital stock which represent, immediately following such merger or consolidation, fifty percent (50%) or more by voting power of the capital stock of (A) the surviving or resulting corporation or (B) a parent corporation of such surviving or resulting corporation, whether direct or indirect; (b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by such Party or an Affiliate of such Party of all or substantially all of the assets of such Party or such Affiliate taken as a whole and whether owned directly or indirectly through Affiliates (except where such sale, lease, transfer, exclusive license or other disposition is to an Affiliate of such Party existing prior to such time); or (c), any "person" or "group", as such terms are defined in Sections 13(d) and 14(d) of the U.S. Securities Exchange Act of 1934, in a single transaction or series of related transactions, becomes the beneficial owner as defined under the U.S. Securities Exchange Act of 1934, directly or indirectly, whether by purchase or acquisition or agreement to act in concert or otherwise, of fifty percent (50%) or more by voting power of the then-outstanding capital stock or other equity interests of such Party or a subsidiary of such Party.

**1.15** **"Claims"** has the meaning set forth in Section 11.1.

**1.16** **"Competing Solution"** has the meaning set forth in Section 6.2.1.

**1.17** **"Confidential Information"** has the meaning set forth in Section 9.1.

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**1.18** **"Contractual Personal Data"** has the meaning set forth in Section 8.6.7.

**1.19** **"Dario Background IP"** means any Intellectual Property rights owned or controlled by Dario which has been licensed or developed, or is later licensed or developed, by or on behalf of Dario outside the scope of this Agreement. For clarity, Dario Background IP includes Intellectual Property rights relating to the Solution.

**1.20** **"Dario Competitor Companies"** means [\*\*].

**1.21** **"Dario Data"** means all data and information controlled by Dario that is not included in Sanofi Data.

**1.22** **"Dario Foreground IP"** means (a) Dario Solution Enhancements, (b) the Intellectual Property rights other than Sanofi Foreground IP that are embodied in, claim, or cover the Enhanced Solution, or any element thereof, and (c) all Intellectual Property conceived, invented, produced, developed, fabricated, authored, generated or reduced to practice by Dario other than pursuant to a Development Plan.

**1.23** **"Dario Member Data"** means all De-Identified personal data of Enrolled Users of the Dario integrated platform (meaning Dario's multi-condition digital therapeutics platform through which Enrolled Users can access solutions for diabetes, hypertension, weight management, MSK and BH) with respect to which Dario has the right to disclose such data to Sanofi pursuant to this Agreement. Dario Member Data excludes data from non-Dario integrated solution services (where "non-integrated" services refer to Dario's stand-alone platforms for MSK and BH).

**1.24** **"Dario Platform Agreement"** means a platform service agreement between Dario and a third party, including any related data processing or business association agreements required in connection therewith, pursuant to which Dario agrees to provide access to such third party's members to the Solution or Enhanced Solutions.

**1.25** **"Data Protection Laws"** means any and all Applicable Laws relating (specifically or generally) to the processing of data relating to individuals including but not limited to (a) all U.S. state and federal privacy and data protection laws, including, to the extent applicable, the Health Insurance Portability and Accountability Act of 1996, (42 U.S.C. § 300gg, 29 U.S.C. § 1181 et seq., and 42 USC 1320d et seq.) and the rules promulgated thereunder ("HIPAA"); (b) the federal Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"); and (c) the General Data Protection Regulation ((EU) 2016/679) ("EU GDPR") and any national implementing law relating thereto.

**1.26** **"Dario Solution Enhancement"** means improvements to the Solution that are necessary to effectuate a Development Plan but are peripheral to the requirement and features described in the Development Plan.

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**1.27** **"De-Identified"** means, with respect to any Personal Data collected or Processed pursuant to this Agreement, which has been de-identified in accordance with Section 164.514(a) of the HIPAA Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

**1.28** **"Derivative Work"** means any work product, study and analysis results, reports, publications and other data, generated by or on behalf of Sanofi using Dario Member Data as source data alone or in combination with other data.

**1.29** **"Development Plan"** means the written plan to develop the Enhanced Solution(s), including the components set forth in Section 2.3.

**1.30** **"Disclosing Party"** has the meaning set forth in Section 9.1.

**1.31** **"Dollars"** or **"\$"** means the legal tender of the United States.

**1.32** **"Effective Date"** means February 28, 2022.

**1.33** **"Employer Channel"** means (1) employers who contract directly with Dario, (2) private self-funded insurance accounts, (3) pharmacy benefit managers accounts, (4) Third Party administrators (e.g. Maestro), (5) employee benefit consultants (e.g. Mercer), and (6) employee benefit digital health brokers (e.g., Vitality and other channel partners). For clarity, Employer Channel shall not include Amwell or any Bundled Account.

**1.34** **"Enhanced Solution(s)"** has the meaning set forth in Section 4.1.

**1.35** **"Enrolled User"** means an eligible (where "eligible" is defined pursuant to Dario's end customer contracts) member who agreed to use the Solution or Enhanced Solution.

**1.36** **"Enrollment Rate"** means the percentage calculated by taking the sum of all Enrolled Users from accounts that have been active for at least six (6) months, across all Targeted Channel accounts, and then dividing such sum by the sum of Total Eligible Lives that have been contiguously eligible for at least six (6) months, across all Targeted Channel accounts.

**1.37** **"Evidence Generation Plan"** has the meaning set forth in Section 4.2.9.

**1.38** **"Excluded Channel"** means the direct-to-consumer (DTC) market.

**1.39** **"Existing Customer"** means a customer who was an Enrolled User prior to, or as of, the Effective Date, as set forth in **Exhibit G**.

**1.40** **"Fair Market Value"** means the monetary consideration that, in an open and unrestricted market place, a prudent and informed buyer would pay to a prudent and informed seller, for the relevant goods or services, each acting with the other and under no compulsion to act. The Fair Market Value of the initial rates and

associated calculation are set forth in **Exhibit A**, and Fair Market Value may be updated from time to time as set forth in **Exhibit A**.

**1.41** **"FDA"** means the United States Food and Drug Administration.

**1.42** **"Fee Report"** has the meaning set forth in Section 7.8.1.

**1.43** **"First Contingent Payment"** has the meaning set forth in Section 7.3.

**1.44** **"Force Majeure Event"** has the meaning set forth in Section 13.3.

**1.45** **"Health Plan Channel"** means (1) public insurance Medicare accounts, (2) public insurance Medicaid accounts, (3) private fully-insured insurance accounts, and (4) At-risk Integrated Delivery Networks Accounts ("**IDN Accounts**"), in each case that provide the Solution and Enhanced Solution to their respective customers, directly or through an intermediary. For clarity, Health Plan Channel shall not include Amwell or any Bundled Account.

**1.46** **"Health Plan Revenue Share Stoppage"** has the meaning set forth in Section 7.4.1.3.

**1.47** **"Intellectual Property"** means: (i) all Patents, copyrights, Trademarks, trade secrets, and all other intellectual property and proprietary rights and goodwill associated with the foregoing; (ii) databases, algorithms, inventions, processes and techniques (including research techniques, algorithms for data analysis and processes for conducting real world evidence data research); (iii) computer software (including source code, object code, firmware, operating systems and specifications); (iv) copies and tangible embodiments of any of the foregoing, in whatever form or medium; and (v) all rights to sue for past, present and future infringement, misappropriation, dilution, misuse or other violation of any of the foregoing, including for injury to goodwill, and to recover all proceeds relating to any of the foregoing, including licenses, royalties, income, payments, claims, damages (including attorneys' payments and expert payments) and proceeds of suit under the laws of any jurisdiction worldwide.

**1.48** **"Introduction"** means Sanofi has identified to Dario a relevant account, Dario has accepted for Sanofi to introduce Dario to this account, and a meeting between Dario and the account occurs. A list of completed Introductions will be maintained by the JSC.

**1.49** **"JSC"** means the Joint Steering Committee.

**1.50** **"Losses"** has the meaning set forth in Section 11.1.

**1.51** **"Market Research"** means the systematic gathering and interpretation of information from or about individuals or organizations using statistical and analytical methods and techniques of the applied social sciences in order for Sanofi or its Affiliates to gain insight or support decision making. "Market Research" includes Syndicated Secondary Market Research and Primary Market

Research but excludes Clinical Study, Retrospective and Prospective Real-World Study.

**1.52** **"Monthly Account Report"** has the meaning set forth in Section 7.8.1.2.

**1.53** **"Net Sales"** means the gross receipts invoiced and recognized by Dario directly from its sales of subscriptions and licenses to the Solution and the Enhanced Solutions to entities other than those on the Advanced Discussion List (and for the avoidance of doubt, excluding sales made prior to the Effective Date, and excluding sales made to Existing Customers), upon meeting Dario's applicable revenue recognition criteria and after deduction of the following amounts, which are actually incurred, allowed, accrued or specifically allocated during such Calendar Year or Calendar Quarter:

- i. royalties or commissions paid to Third Party intermediaries (including channel partners and distributors);
- ii. chargebacks;
- iii. sales taxes and other government duties;
- iv. discounts, including cash, trade and quantity discounts inclusive of free goods, price reduction programs (including co-pay assistance, compulsory refunds, and any other patient payment assistant programs), retroactive price adjustments with respect to licenses or sales of such Solution or Enhanced Solutions; and
- v. amounts repaid or credited by reason of defects, refunds, returns, rebates and billing errors.

**1.54** **"Negotiation Period"** has the meaning set forth in Section 6.3.

**1.55** **"Officials"** has the meaning set forth in Section 8.7.

**1.56** **"Option"** has the meaning set forth in Section 6.3.

**1.57** "**Option Exercise Notice**" has the meaning set forth in Section 6.3.

**1.58** "**Option Notice**" has the meaning set forth in Section 6.3.

**1.59** "**Optioned Activity**" has the meaning set forth in Section 6.3.

**1.60** "**Other Foreground IP**" mean any Intellectual Property conceived, produced, invented, authored, developed, fabricated, generated, or reduced to practice by a Party or by the Parties under this Agreement that is neither Dario Foreground IP nor Sanofi Foreground IP.

**1.61** "**Parties**" has the meaning set forth in the preamble hereto.

**1.62** "**Party**" has the meaning set forth in the preamble hereto.

**1.63** "**Patent**" means national, regional and international (a) issued patents and pending patent applications (including provisional patent applications), (b) patent applications filed either from the foregoing or from an application claiming priority to the foregoing, including all provisional applications, converted provisionals, substitutions, continuations, continuations-in-part, divisions, renewals and continued prosecution applications, and all patents granted thereon, (c) patents-of-addition, revalidations, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, utility models, petty patents, innovation patents and design patents, (e) other forms of government-issued rights substantially similar to any of the foregoing, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing, and (f) United States and foreign counterparts of any of the foregoing.

**1.64** "**Patentable Intellectual Property**" means Intellectual Property that the Parties reasonably believe to be both novel and non-obvious under the Applicable Law.

**1.65** "**Payment**" has the meaning set forth in Section 8.7.

**1.66** "**Payment Schedule**" means the payment schedule set for development costs within a Development Plan, including the associated budget allocation and milestone payments.

**1.67** "**Personal Data**" means any information relating to Enrolled Users which is protected by applicable Data Protection Law. At minimum the Personal Data shall include information relating to an identified person or a person who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, contact details, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. The description of Personal Data, the data flow and processing will be described in the data processing agreement as defined in Section 8 of the Agreement.

**1.68** "**PHI**" means protected health information as defined in 45 C.F.R. § 160.103.

**1.69** "**Primary Market Research (PMR)**" is the process of asking questions directly to customers (health care providers, patients, consumers, payers, etc.) for gathering, analyzing and interpreting information from or about individuals, organizations and/or marketplaces using qualitative and/or quantitative methods. It is defined by the objective of providing insight to address business questions and support decision making.

**1.70** **"Product Complaint"** means any written or oral information received from a complainant that alleges deficiencies related to quality, safety, or performance of the Solution or an Enhanced Solution after it has been released and distributed to the commercial market or used in a Study. Product Complaint shall include

reports of the failure of a product to meet its performance specifications or otherwise perform as intended.

**1.71** **"Promotional Materials"** means any promotional or marketing communications describing the Solution or Enhanced Solution.

**1.72** **"Prospective Real World Evidence Study"** means any research sponsored or organized by SANOFI or its Affiliates, carried out on human subjects for the purpose of developing biological, scientific, or medical knowledge and which requires primary data collection to be conducted. A prospective Real World Evidence Study is not a Clinical Study.

**1.73** **"Qualifying Employer Channel Account"** means any account in the Employer Channel that was contracted pursuant to an Introduction.

**1.74** **"Qualifying Health Plan Account"** means any account in the Health Plan Channel that was contracted pursuant to an Introduction.

**1.75** **"Post-Term Qualifying Health Plan Channel Revenue"** means, on a Calendar Quarter basis, sum of two (2) times the Net Sales of the Solution and the Enhanced Solution from each Qualifying Health Plan Account that exists as of the Termination Date during the remainder of the contract term (excluding renewals) for such Qualifying Health Plan Account, up to the maximum of Net Sales of the Solution and the Enhanced Solution from all accounts in the Health Plan Channel in the applicable Calendar Quarter. For clarity, Post-Term Qualifying Health Plan Channel Revenue for the first Calendar Quarter following the termination of the Agreement will be calculated from the date immediately following the Termination Date to the last day of that Calendar Quarter.

**1.76** **"Receiving Party"** has the meaning set forth in Section 9.1.

**1.77** **"Retrospective Real-World Study"** means any research sponsored or organized by SANOFI or its Affiliates, conducted solely through the reuse of data for the purpose of developing biological, scientific, or medical knowledge and in which there is no interaction with study subjects except to obtain consent. Retrospective Real-World Studies include the analysis of data collected prior to the initiation of the Study and scientific activities based on secondary use of data acquired from Third Parties and previously collected for other purposes.

**1.78** **"Sanofi Background IP"** means any Intellectual Property owned or controlled by Sanofi which has been developed, or is later developed, by Sanofi outside the scope this Agreement.

**1.79** **"Sanofi Data"** means data embodied in results of Sanofi's market access relationships and capabilities, data and analytics capabilities, and market research, and any other information generated by Sanofi under this Agreement.

**1.80** **"Sanofi Excluded Companies"** means [\*\*].

**1.81** **"Sanofi Foreground IP"** means (i) all Intellectual Property conceived, produced, developed, fabricated, generated, or reduced to practice by or on behalf of (but not on behalf of Sanofi by Dario hereunder) Sanofi under this Agreement (including, for the removal of doubt, Derivative Works) and (ii) all Patentable Intellectual Property conceived, produced, developed, fabricated, generated or reduced to practice in connection with the Agreement under a Development Plan. For clarity, Sanofi Foreground IP does not include Dario Background IP.

**1.82** **"Sanofi North America Market Access Diabetes Group"** has the meaning set forth in Section 6.2.1.

**1.83** **"Sanofi Rebate Agreement"** means a rebate agreement between Sanofi and an account listed on the Bundling Discussion List, pursuant to which Sanofi shall provide an incremental rebate (the amount of such rebate to be determined by Sanofi at its sole discretion) on certain Sanofi products in exchange for, and conditioned upon, such account's participation in the Solution or Enhanced Solutions via a Dario Platform Agreement, as further set forth in Section 3.3.

**1.84** **"Second Contingent Payment"** has the meaning set forth in Section 7.3.

**1.85** **"Senior Officers"** shall mean for Sanofi, Olivier Bogillot, its General Manager General Medicines, USA and for Dario, Erez Raphael, its CEO.

**1.86** **"Solution"** means Dario's products and services offered as of the Effective Date, including Dario's devices and accessories that integrate with applications on a user's smartphone, DarioEngage, a chronic condition coaching and integration platform, and Dario Loop, an AI-driven engine which personalizes user experience across a range of factors including timing, tone, channel, content, frequency, and intervention. The Solution includes enhancements, modifications and improvements to the foregoing, whether through development or through acquisition, and excludes Unavailable Products.

**1.87** **"Study"** means, collectively, any Market Research and/or Clinical Study and/or Retrospective and/or Prospective Real-World Study, in each case as conducted by Sanofi.

**1.88** **"Syndicated Secondary Market Research"** or **"Syndicated SMR"** refers to research projects conducted using preexisting aggregated data collected by the entity in charge of conducting the Syndicated SMR and licensed to and/or purchased by multiple subscribers, and not specifically conducted or collected at the request of one client. Secondary data analyses include but are not limited to sales volume or value data, prescription data, promotional volume or spending value data, longitudinal patient data, aggregated or compiled meta-analysis or data.

**1.89** **"Targeted Channel"** means entities within the Health Plan Channel and the Employer Channel that Dario contracts with in order to license or sell (directly or in-directly through resellers, distributors or channel partners) the Solution and

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any Enhanced Solutions. Targeted Channels expressly *exclude* Excluded Channels.

**1.90** **"Term"** has the meaning set forth in Section 12.1.

**1.91** **"Termination Date"** means the date corresponding to the last day of the Term.

**1.92** **"Territory"** means the United States of America.

**1.93** **"Therapeutic Areas"** means (1) diabetes, (2) pre-diabetes, (3) obesity, (4) behavioral health, (5) musculoskeletal conditions only when bundled with diabetes, pre-diabetes, obesity and/or behavioral health, (6) hypertension only when bundled with only when bundled with diabetes, pre-diabetes, obesity or behavioral health, (7) any therapeutic area other than the foregoing (1) through (6) which Dario independently, commercializes and integrates into the Solution, and (8) any therapeutic area other than the foregoing (1) through (6) that is integrated by Dario into the Solution pursuant to Dario's acquisition of a Third Party's business or assets in such therapeutic area.

**1.94** **"Third Party"** means any person or entity other than Sanofi, Dario and their respective Affiliates, officers, directors, employees and agents.

**1.95** **"Tokenization"** means, when applied to data security, the process of substituting a sensitive data element with a non-sensitive equivalent, referred to as a token, that has no extrinsic or exploitable meaning or value. The token is a reference that maps back to the sensitive data through a tokenization system.

**1.96** **"Total Eligible Lives"** means the total number of users eligible (defined pursuant to Dario's end customer contracts) to enroll in a Dario product or service.

**1.97** **"Trademarks"** means, collectively, trademarks, service marks, trade dress, logos, brand names, trade names, corporate names and Internet domain names (in each case, whether or not registered), including all variations, derivations, combinations, applications, registrations, and renewals therefor, and all rights and priorities with respect thereto afforded under the Applicable Law of any jurisdiction worldwide, together with all goodwill associated therewith.

**1.98** **"Transition Payment"** means [\*\*].

**1.99** **"Unavailable Product"** means a digital product or service that is (i) a platform-as-a-service (PaaS); or (ii) a standalone behavior health with optional employee assistance plan (EAP) product or service (e.g. is stand-alone and not combined or bundled with any non-behavioral health product or service). No Enhanced Solution(s) will include an Unavailable Product.

**1.100** **"Year X"** means the corresponding "X" anniversary of the Effective Date. For example, Year 2 means the 12-month period beginning on the first (1<sup>st</sup>)

anniversary of the Effective Date, Year 3 means the 12-month period beginning on the second (2<sup>nd</sup>) anniversary of the Effective Date, and so on.

**1.101** **"Year 2 Additional Development Cost"** has the meaning set forth in Section 7.2.2.

**1.102** **"Year 3 Additional Development Cost"** has the meaning set forth in Section 7.2.3.

**1.103** **"Year 5 Development Cost"** has the meaning set forth in Section 7.2.4.

**2. GOVERNANCE**

**2.1** **Alliance Managers.** Promptly following the Effective Date, each Party will designate an individual to act as the primary point of contact between the Parties (each such individual, an “**Alliance Manager**”) to facilitate the effective exchange of information between the Parties, discuss the Parties’ respective performance under this Agreement, assist with governance activities and serve as the initial point of contact to resolve any disputes between the Parties. The Alliance Managers will jointly be responsible for (a) the preparation and circulation of JSC meeting minutes for approval, (b) facilitate the scheduling and conduct of JSC meetings, (c) launch of the collaboration, (d) ensuring that relevant action items from JSC meetings are carried out or otherwise addressed, and (e) bringing matters to the attention of the relevant JSC subcommittee, as applicable. The Alliance Managers will be permanent guests at the JSC meetings or at any related forums. They will receive all meeting materials, but will not be members of any such committees and will have no voting rights. A Party may replace its designated Alliance Manager at any time by written notice to the other Party.

**2.2** **The Joint Steering Committee.**

**2.2.1** **Formation and Composition.** Within 30 days after the Effective Date, each Party will appoint its initial members of the JSC, which will be composed of two (2), and always an equal number of, appointed representatives of each of Sanofi and Dario.

**2.2.2** **Meetings.** The JSC shall meet on a quarterly basis, with each meeting to take place no later than ten (10) Business Days after the start of each Calendar Quarter, unless otherwise agreed to by the Parties. If possible, the meetings shall be held in person or where appropriate, by video or telephone conference. The location of face-to-face meetings of the JSC shall be subject to mutual agreement by the Parties on a case-by-case basis. The Parties shall determine the form of the meeting, including not but limited to virtual or video conferencing. Except as otherwise set forth herein, decisions shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided, that no such decision/vote shall be valid unless each Party is represented by at least one member’s actual or virtual presence at the meeting at which the vote is taken. Subject to appropriate

confidentiality undertakings where applicable, additional participants may be invited by any member to attend meetings where appropriate. Such additional participants shall not be deemed to be, or have any rights or responsibilities of, a member of the JSC. Subject to the terms of this Agreement, and except as otherwise specifically provided by the terms of this Agreement, including the dispute resolution provisions of Section 2.4, the JSC shall have the final decision-making authority with respect to all matters within the jurisdiction of any of the committees established pursuant to this Agreement which are referred to the JSC for determination or resolution. The JSC shall exercise this authority in good faith and in accordance with this Agreement, all decisions shall have a reasonable basis, and subject to the terms of this Agreement, any such decision shall be binding upon the Parties. Where the JSC is unable to reach consensus regarding a matter before it for decision, such disputes shall be resolved in accordance with the provisions of Section 2.4 hereof.

**2.3** **Responsibilities of the JSC.** Except as otherwise set forth herein, the JSC shall coordinate all co-promotion, development and evidence generation activities of the Parties under this Agreement.

The responsibilities of the JSC shall be exercised consistent with this Agreement and shall include, but shall not be limited to, the following:

- a) To define, approve and update or amend Development Plans, which shall include the following:
  - i. the product requirements that define the unique features as specified by the Parties using an agile development methodology, as described in **Exhibit F**;
  - ii. development milestones to develop the product with corresponding project deliverables, program timelines and success criteria. Milestones shall include, *inter alia*, beta testing, proof of concept and validation and be consistent with the agile development methodology;

- iii. the regulatory strategy (as needed); and
- iv. Cost and Payment Schedule based on the Fair Market Value of the activities to be conducted by Dario pursuant to such Development Plan. For clarity, the amounts due under any Development Plan will reflect the Fair Market Value of the activities under such Development Plan and shall not exceed the amounts listed in Section 7.2.

In the event the Parties cannot agree to add an idea proposed by either Party to the Development Plan, with Dario voting against the addition of the idea to the Development Plan, Sanofi will retain a right of first negotiation as described in Section 6.3 with respect to such idea in the event Dario proceeds with such idea individually.

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- b) determine co-promotion strategy and activities of the Solution;
- c) review financial information provided pursuant to Section 4.2.6 and if any financial information provided suggests that Dario may, within the next six (6) months, not have the resources necessary to perform any activities assigned to Dario under the Development Plan, determine where mitigation strategies are necessary under Section 4.2.6;
- d) determine pricing and marketing strategy for the Enhanced Solution;
- e) determine whether or not a customer or potential customer falls within a Targeted Channel; *provided*, in the event an account falls into both the Health Plan Channel and Employer Channel, the Parties will discuss in good faith how that account will be address financially, and Sanofi may decide whether or not to make the Introduction based on this determination;
- f) determine updates and amendments to Dario Competitor Companies list, Advanced Discussion List, Bundling Discussion List and Sanofi Excluded Companies; *provided*, that if the JSC determines to add an entity to the Bundling Discussion List that is also on the Advanced Discussion List, such entity will be removed from the Advanced Discussion List;
- g) determine each Introduction and maintain a list of all Introductions, Qualifying Employer Channel Accounts and Qualifying Health Plan Accounts;
- h) determine each Bundled Account and maintain a list of all Bundled Accounts;
- i) oversee implementation of the (i) Development Plans, (ii) regulatory strategy, and (iii) co-promotion strategy, of Enhanced Solutions;
- j) adopt and oversee the Evidence Generation Plans described in **Exhibit D**;
- k) discuss and make a good faith effort to resolve issues or disputes presented to it by the Alliance Managers;
- l) determine delivery schedule of Dario Member Data to Sanofi, to be provided no less frequently than every six months; and
- m) additional governance responsibilities as defined herein.

**2.4 Expenses.** Sanofi and Dario expressly acknowledge and agree that each shall be solely responsible for any and all of its costs and expenses incurred in relation to performing, organizing, attending or otherwise participating in the JSC.

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**2.5 Disputes Regarding JSC Matters.** In the event that the JSC is, after a period of thirty (30) Business Days from the date first presented to the JSC in writing, unable to make a decision with respect to any matter before it for decision due to a lack of required unanimity, either Party may submit the matter being considered to the Senior Officers for a joint decision. In such event, the JSC, by written notice to each Party, shall formally request the dispute be resolved by the Senior Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Senior Officers. The Senior Officers shall diligently and in good faith, attempt to resolve the referred dispute expeditiously and, in any event, within thirty (30) days (or such other period of time as mutually agreed by the Senior Officers) of receiving such written notification. In the event the Senior Officers are unable to reach a resolution of any referred dispute after good faith negotiations, then, either Party may, by written notice to the other Party, elect to proceed with dispute resolution procedures to be set forth in Section 13.2. Without limiting the foregoing, the JSC does not have the power to (i) interpret, amend, modify or waive compliance with this Agreement (except that the JSC may modify the Dario Competitor Companies list, the Advanced Discussion List on **Exhibit E**, and the Sanofi Excluded Companies list) or (ii) modify the rights and obligations of the Parties under the Agreement.

### 3. CO-PROMOTION

**3.1 Generally.** During the Term, Sanofi shall bring market access relationships and capabilities, data and analytics capabilities to identify unmet needs, and market intelligence to generate new leads and support selling activities for the Solution and the Enhanced Solutions. Dario shall provide Sanofi with training during the first Calendar Quarter of each Year X regarding the Solution's then-current features, capabilities and value proposition, as well as the clinical and outcomes data supporting the Solution. In addition, Dario shall support, maintain and develop the Solution and Enhanced Solutions, share relevant market and customer insights with Sanofi, and control all selling and post-sale account management activities with respect to the Solution and Enhanced Solutions. The Parties shall manage the ongoing co-promotion activities as described in **Exhibit B**.

**3.2 Introductions.** Sanofi may promote the Solution and Enhanced Solutions by performing Introductions or initiating conversations with the intent of a future Introduction, except that Sanofi will not perform Introductions to companies or divisions of companies on the Advanced Discussion List, as provided in **Exhibit E**.

**3.3 Bundled Accounts.** Sanofi may also promote the Solution and Enhanced Solutions by entering into Sanofi Rebate Agreements. Sanofi will provide prompt notice to Dario following execution of any Sanofi Rebate Agreement with an account, and Dario will provide prompt notice to Sanofi following execution of a Dario Platform Agreement with such account. Each Dario Platform Agreement shall include an obligation that such Bundled Account provide Dario with member data necessary to contact such Bundled Account's

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members regarding enrollment in the Solution or Enhanced Solutions ("Bundled Member Data") promptly following execution of the Dario Platform Agreement, with updated Bundled Member Data to be provided at least every six (6) months thereafter for the term of such Dario Platform Agreement. Dario will provide prompt notice to Sanofi upon any receipt of Bundled Member Data by Dario, and Dario shall promptly begin outreach to the members of such Bundled Account in accordance with the implementation plan agreed between Dario and the Bundled Account, and will promptly notify Sanofi when outreach has begun. Dario will provide prompt notice to Sanofi following expiration or termination of any such Dario Platform Agreement. For purposes of this Section 3.3, "prompt notice" shall be deemed to mean no more than five (5) Business Days. Notwithstanding anything in this Agreement to the contrary, Sanofi shall have final decision-

making authority with respect to the terms of any Sanofi Rebate Agreements, including any decision to terminate such agreements and the terms and conditions of any incremental rebate described in Section 1.83. Subject to the provisions of this Section 3.3, Dario shall have final decision-making authority with respect to the terms of all Dario Platform Agreements, including any decision to terminate such agreements, *provided* that Dario may not terminate a Dario Platform Agreements solely for convenience.

**3.4 Promotional Materials and Communications.** Dario will provide Sanofi with marketing material for the Solution to facilitate Sanofi's creation of Promotional Materials to be used by Sanofi. Dario shall have the right to approve such materials before any use by Sanofi, which approval shall not be unreasonably withheld.

**3.5** Neither Party shall use the other Party's logo or trademark in connection with the co-promotion activities without the other Party's written consent or as otherwise permitted herein; *provided, however*, that if a Party consents to the other Party's use of such Party's logo or trademark within Promotional Materials, then such consent shall not be required for additional or subsequent use of such Promotional Materials so long as such use is consistent with the approved intended use and trademark usage guidelines provided by such Party.

**3.6** The Solution and Enhanced Solutions shall be commercialized exclusively under Dario owned trademarks or the trademarks of Dario's white label customers. Any fees associates with such promotional related activities shall be the responsibility of the spending Party.

#### **4. DEVELOPMENT**

**4.1 General.** The principal objective of the development is to combine Sanofi's insight and relevant expertise in cardiometabolic disorders with Dario's digital therapy technology tools and expertise, in order to develop new products, services, features and concepts directed to the Therapeutic Areas as may be approved by the JSC in a Development Plan (an "Enhanced Solution").

**4.2 Responsibilities.**

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**4.2.1 Initial Development Plan.** The Parties shall mutually approve the initial Development Plan for the first Enhanced Solution through the JSC within 120 days of the Effective Date, which shall include, at a high level, required features and specifications.

**4.2.2 Activities.** The Parties shall conduct development activities as described in **Exhibit C** and as approved in Development Plans. Dario shall use diligent efforts to lead product development activities for the Enhanced Solutions. If required by a Development Plan, Dario shall use commercially reasonable efforts to obtain any and all relevant regulatory authorizations for the Enhanced Solutions, subject to a process and budget as determined by the JSC.

**4.2.3 Ongoing.** Following the Effective Date, Dario shall disclose in good faith to the JSC, in response to its requests from time to time, or when Dario becomes aware of, any Sanofi Foreground Intellectual Property created, generated, invented or developed by or on behalf of Dario under the Development Plan.

**4.2.4 Adverse Events.** Dario shall be responsible for handling all Product Complaints related to the Solution or Enhanced Solutions.

**4.2.5 Annual Reporting and Recordkeeping.** The JSC shall review the Development Plans on a regular basis, and in no event less frequently than once each Calendar Year. Each Party shall maintain complete, current and accurate records of all deliverables created pursuant to a Development Plan for at least 3 years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Such records shall fully and properly reflect all work done and results achieved in the performance of development activities, and to the extent applicable, meet the requirements for any regulatory requirements provided for in the Development Plan. Sanofi shall document all Studies for the Solution and Enhanced Solutions in formal written Study reports, and shall document and conduct all Studies in accordance with Applicable Law and national and international guidelines (e.g., GCP, GLP, and GMP). Each Party shall have the right to review and copy such records maintained by the other Party and to obtain access to the original to the extent necessary for regulatory and patent purposes or for other legal proceedings, at reasonable times and upon at least 30 days' prior notice.

**4.2.6 Financial Reporting.** Dario shall provide to the Alliance Manager all financial disclosures provided to the public markets on the same schedule as required for the public markets.

**4.2.7 Mitigation Strategies.** If any financial information provided to the JSC under Section 4.2.6 demonstrates a reasonable likelihood that Dario may, within the next nine (9) months, not have the resources necessary to perform any activities assigned to Dario under the Development Plan, the JSC will discuss if mitigation strategies are required. If, after such discussion, (a) the JSC agrees that Dario is unable to, or will be unable to, perform such activities in accordance with this Agreement or the Development Plan, (b) Sanofi notifies

Dario that Sanofi reasonably determines that Dario is reasonably unlikely to attract the resources beyond those set forth in the initial Development Plan that are now needed to perform such activities and Dario, ninety (90) days after receiving such notice, has not made material progress on attracting such resources or (c) Dario has materially failed to perform such activities and Sanofi notifies Dario that Sanofi reasonably determines that Dario is unlikely to perform such activities within a reasonable time period established by Sanofi, then Sanofi may, by written notice to Dario, elect to assume and complete some or all of such activities and, within a reasonable period of time following Sanofi's request delivered by notice, Dario shall (i) promptly assist Sanofi with transitioning such activities to Sanofi, including, at Sanofi's request, by promptly performing Dario's technology transfer obligations in accordance with Section 4.2.8 and (ii) promptly assign to Sanofi any or all agreements with approved subcontractors to the extent such agreements relate to such activities and as and to the extent such assignment is permitted pursuant to such agreements. In the event that Sanofi assumes any such activities assigned to Dario under the Development Plan, then the JSC shall amend the Development Plan to account for Sanofi's assumption of such activities. In the event that Sanofi assumes all remaining activities assigned to Dario under the Development Plan with respect to an Enhanced Solution, any payments that would have been payable to Dario with respect thereto shall only be payable if the corresponding milestone events were achieved by Dario prior to the assumption of such activities by Sanofi. If, within ten (10) Business Days of receipt of Sanofi's notice under the foregoing clause (b) or clause (c), Dario notifies Sanofi that Dario disputes any of Sanofi's assertions or conclusions set forth in such notice, then the Parties shall suspend performing the mitigation strategies activities described in (i) and (ii) above and shall submit the disagreement to a mutually acceptable independent and neutral Third Party having experience in capital markets ("Neutral Third Party") for determination as to whether the circumstances set forth in clause (b) or clause (c), as applicable, have occurred. Each Party shall provide the Neutral Third Party with such Party's position and supply supporting documentation within thirty (30) days of appointment of the Neutral Third Party, and the Neutral Third Party shall choose the position of either one Party or the other Party within thirty (30) days thereafter. The Parties shall equally share the costs and expenses of the Neutral Third Party.

**4.2.8 Dario Technology Transfer.** In the event mitigation strategies pursuant to Section 4.2.7 are required, the Parties will meet promptly to coordinate the transfer of technology required to complete the Development Plan.

**4.2.9 Evidence Generation.** Sanofi shall prepare and the JSC shall review and approve or disprove Evidence Generation Plans, whereby Sanofi shall design (including considering Dario's design input and suggestions in good faith), execute, publish and disseminate medical, economic and user engagement Studies to evidence insights from the use of the Solution and the Enhanced Solution (as approved by the JSC, the "Evidence Generation Plans"). If the Parties disagree regarding any aspect of the performance of an Evidence

Generation Plan, Sanofi shall retain the final approval. Dario shall, through the JSC, support Sanofi to identify areas where evidence generation is needed and use commercially reasonable efforts to support Sanofi's evidence generation efforts, including but not limited to cohort construction, running de-ID turnkey software, study design feedback, writing, and evidence dissemination, as described in **Exhibit D**.

**4.2.10 Exclusions.** For the avoidance of doubt, except as expressly provided in this Agreement, and subject to the terms and conditions set forth herein, Dario is not restricted from developing features, functions, applications, products, concepts, products or services outside of the Development Plan for inclusion in the Solution.

## 5. LICENSE GRANTS

**5.1 Licenses Granted to Sanofi.** Subject to the terms and conditions of this Agreement, Dario hereby grants to Sanofi a non-exclusive, sublicensable, royalty-free license to copy and modify the Dario Member Data, during the Term, solely for purposes of creating Derivative Works, including, but not limited to, implementing the Evidence Generation Plan. Dario will provide an initial delivery of Dario Member Data to Sanofi within [\*\*] days of the Effective Date, and will deliver subsequent updates to Dario Member Data to Sanofi as determined by the JSC but at least every [\*\*] thereafter.

**5.1.1 Anonymization; Tokenization or De-Identification.** Dario Member Data licensed to Sanofi will be Anonymized Data, Tokenized or De-identified in a manner consistent with industry practice prior to being transferred or made accessible to Sanofi. The Parties acknowledge and warrant that no direct or indirect access to Personal Data of Enrolled Users will be granted to Sanofi.

**5.1.2** Dario Member Data (including, for the removal of doubt, Dario Member Data) shall constitute Confidential Information of Dario for all purposes hereunder. As a result, pursuant to Section 9, Sanofi may not disclose Dario Member Data to any Third Party during the Term without Dario's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, and Sanofi may not use Dario Member Data in a way that is competitive with Dario, and may not use or disclose Dario Member Data following the Term (except Sanofi may use and disclose Dario Member Data that is included within an approved Evidence Generation Plan).

**5.2 Derivative Works.** Sanofi shall remain free, at all times, to use the Derivative Works, including the results and evidence generated under any Market Research, Prospective or Retrospective Real-World Study, for any lawful purpose, including to comply with mandatory publication of the results of such Studies, in accordance with Applicable Laws, *provided*, however that (i) Sanofi may not share those results and evidence nor use, disclose or leverage Derivative Works in a collaboration with a Dario Competitor Company and (ii) Derivative Works will be solely owned by Sanofi.

**5.3** **Trademark and Content License.** Subject to Section 3.5, Dario hereby grants to Sanofi an irrevocable, royalty-free non-exclusive non-transferable right and license (except in connection with a permitted assignment of this Agreement) to use Dario's trademark and content provided by Dario in the Territory solely to the extent required to fulfill its obligations under this Agreement. All goodwill created by Sanofi's use of Dario trademarks and content, and all right, title and interest in and to such trademarks and content, shall belong solely to Dario, and Sanofi hereby assigns to Dario all such goodwill and rights. Neither Party shall have any right to use any trademark of the other Party in connection with its activities under the except as expressly authorized in writing by the other Party or as otherwise permitted herein.

**5.4** **Licenses Granted to Dario.** Subject to the terms and conditions of this Agreement, Sanofi hereby grants to Dario:

**5.4.1** a limited, non-exclusive, non-transferable license under Sanofi Background IP and Sanofi Foreground IP reasonably related to any Development Plan during the Term and in the Territory for purpose of creating and promoting the Enhanced Solution;

**5.4.2** a limited, non-exclusive, non-transferable and non-sublicensable, perpetual license to use and disclose Derivative Works for business purposes, including for purposes of promoting Dario's products and services, provided however that Dario may not share the results and evidence generated by Sanofi pursuant to the Evidence Generation Plans with any Third Party, nor leverage any Derivative Works in a collaboration with an Excluded Company; and

**5.4.3** a non-exclusive, perpetual, non-transferable, worldwide, license to use Sanofi Foreground IP and Sanofi Background IP that is incorporated into an Enhanced Solution under a Development Plan for the purposes of developing, supporting, maintaining and commercializing such Enhanced Solution.

**5.5** Both Parties are permitted to use unpublished results and unpublished evidence generated by the Evidence Generation Plans for internal business purposes, *provided* that (i) Sanofi may not share the unpublished results and unpublished evidence in a collaboration with a Dario Competitor Company and (ii) Dario may not share the results and evidence in a collaboration with a Sanofi Excluded Company. Sanofi shall be responsible for the content of the Evidence Generation Plan and the costs of the evidence generation activities under the Evidence Generation Plan (as approved by the JSC).

**5.6** **No Implied Licenses.** Except as expressly set forth herein, neither Party shall acquire any license or other Intellectual Property interest, by implication or otherwise, under or to any Trademarks, Patents, know-how, or other Intellectual Property rights controlled by the other Party.

## 6. EXCLUSIVITY AND RIGHT OF FIRST NEGOTIATION

### 6.1 Dario Preferred Partnership.

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**6.1.1** During the Term, Dario will work with Sanofi, in the Territory and within the Therapeutic Areas, as follows:

(a) with Sanofi to co-promote the Solution (except Dario will not promote the Solution to any Sanofi Excluded Companies), and

(i) For clarity, DARIO may sell the Solution or Enhanced Solution to any Sanofi Excluded Company within the Employer Targeted Channel solely for the benefit of such company's own employees.

(b) with Sanofi as its exclusive partner to co-promote the Enhanced Solutions in the Targeted Channels (except that such exclusivity shall not apply to Dario's downstream relationships with its distributors and value added resellers).

**6.1.2** Dario will work exclusively with Sanofi, in the Territory and within the Therapeutic Areas, to develop the Enhanced Solutions.

(a) For clarity, and subject to Section 6.3, Dario reserves the right to develop, market and promote the Solution (i) outside of the Territory and (ii) with any parties other than Sanofi Excluded Companies.

(b) The Enhanced Solutions may not be promoted or commercialized by either Party outside the Territory or in the Excluded Channel absent their mutual written agreement.

## 6.2 Sanofi Preferred Partnership.

**6.2.1** Sanofi's employees forming the North America market access - diabetes group, which are responsible for Health Plan payer account management of Sanofi therapeutic Diabetes products in the Territory (the "**Sanofi North America Market Access Diabetes Group**") will not promote, co-promote, license or sell, in the Therapeutic Areas, through the Targeted Channels and in the Territory, digital products or services made available by or owned or controlled by Dario Competitor Companies that are substantially similar to the Solution in terms of target patient population and functionalities (a "**Competing Solution**").

**6.2.2** For clarity, but without limiting any other provision of this Agreement and subject to the other provisions of this Agreement, the Sanofi North America Market Access Diabetes Group may promote, co-promote, license or sell, in the Therapeutic Areas, through the Targeted Channels and in the Territory, a Competing Solution owned by Sanofi as a result of internal development activities or of a Change of Control (including a Change of Control targeting a Dario Competitor Company).

## 6.3 Right of First Negotiation.

**6.3.1** **Option.** If at any time during the Term, and subject to Section 6.3.2, Dario

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(a) desires to expand the co-promotion of the Solution and/or Enhanced Solutions, as applicable, in geographies beyond the Territory, or

(b) desires to develop, with a Third Party, new applications, that are not Unavailable Products, in any therapeutic area within the Territory other than the Therapeutic Areas, or

(c) when acting in its role at the JSC, votes against the addition of a new feature or function (proposed by either Party) to a Development Plan, and then proceeds to develop such new feature or function with a Third Party,

(each activities described in (a) through (c) is an "**Optioned Activity**") Dario hereby grants Sanofi the option to collaborate with Dario to conduct such Optioned Activity in priority to any Third Party (the "**Option**"). Dario must notify Sanofi in writing prior to beginning negotiations with any Third Party regarding an Optioned Activity ("**Option Notice**"). If Sanofi elects to exercise the Option, it shall deliver a notice in writing to Dario within ten (10) Business Days, unless otherwise agreed by the Parties, after receipt of the Option Notice ("**Option Exercise Notice**"), in which case the Parties shall negotiate in good faith, an agreement governing each Party's responsibilities, rights and obligations in relation to the subject matter of the Option Notice for a period of sixty (60) days, unless otherwise agreed by the Parties, from the date of receipt by Dario of the Option Exercise Notice ("**Negotiation Period**"). Dario is prohibited from negotiating with Third Parties during the Negotiation Period. Dario may perform the Optioned Activity if Sanofi does not deliver its Option Exercise Notice within the foregoing ten (10) Business Day period, unless otherwise agreed by the Parties, or the Parties do not conclude an agreement with respect to the applicable Optioned Activity within the foregoing sixty (60) day period, unless otherwise agreed by the Parties.

**6.3.2** **Exclusions.** The foregoing Option does not apply to:

(1) a Change of Control of Dario or (2) if Dario commercializes the Solution for an Existing Customer within the Territory for the use by such Existing Customer's ex-Territory affiliate, and not as a broader market entry into such ex-Territory or

(3) Dario's acquisition of the business or assets of a Third Party. For clarity, during the Negotiation Period, Dario shall not enter into or, as the case may be, shall cease any discussion or negotiation nor sign any transaction with a Third Party regarding the Optioned Activity that is the subject of the negotiations.

**6.3.3 Disclosure Obligations.** From the date of the Option Notice and through the Negotiation Period, in order to assist Sanofi in the evaluation of the opportunity to expand the co-promotion or development, Sanofi may reasonably request information and data from Dario in order to evaluate the applicable Optioned Activity, in which case Dario will use commercially reasonable efforts to promptly provide any information and documentation that Dario controls or possesses (including, *inter alia*, medical, regulatory, clinical and market access related information and documentation) as Sanofi may

reasonably request, within five (5) Business Days of each written request in order to evaluate the applicable Optioned Activity. The Negotiation Period may be extended by up to fifteen (15) days from Dario's last delivery of such information and documentation in response to Sanofi's request received during the initial thirty (30) day period. Sanofi may reasonably request additional information and data from Dario during the second half of the Negotiation Period, which shall not further toll the Negotiation Period.

## 7. PAYMENTS AND RECORDS

### 7.1 Preferred Partnership Payments.

**7.1.1 Preferred Partner Fees.** Sanofi will pay Dario [\*\*] as consideration for the preferred partnership status. This preferred status payment accrues in full as of the Effective Date, and will be paid in installments by Sanofi as follows:

(i) an upfront payment of [\*\*] upon the first delivery of market access team training, Dario Member Data and marketing materials support, but in no event will this be paid later than 30 days following Sanofi's receipt of the invoice; and

(ii) upon completion of a second market access team training, delivery of supporting marketing materials, Dario Member Data and acceptance thereof by Sanofi (such acceptance not to be unreasonably withheld, conditioned or delayed), at the beginning of Year Two, Dario will issue an invoice to Sanofi for a second lump sum payment of [\*\*]. In no event will this be paid later than 60 days following Sanofi's receipt of the invoice.

**7.2 Enhanced Solution Development Service Payments.** Sanofi will pay Dario the development costs for the Enhanced Solutions as defined in the Payment Schedules of the approved Development Plans. All Development Plans shall be approved for the Calendar Year ahead of the year in which they are kicked off (with the exception of Year 1) unless otherwise agreed by the JSC. The Development Plan(s) for each Calendar Year will include milestone payments that will equal the total development cost payments for such Calendar Year, and the deliverables under each Development Plan shall be deliverable by Dario in the same Calendar Year of the corresponding Development Plan.

No.	Development Milestone Event	Total Development Cost Payments
1	Calendar Year 1 Development Plan	[**]
2	First Calendar Year 2 Development Plan	[**]
3	Second Calendar Year 2 Development Plan	[**]
4	Calendar Year 3 Development Plan	[**]

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5	Calendar Year 4 Development Plan	[**]
6	Calendar Year 5 Development Plan	[**]

**7.2.1** For Calendar Year 1, Sanofi shall pay Dario an initial [\*\*] upon JSC approval of the Calendar Year 1 Development Plan, which shall be approved within 120 days of the Effective Date, and such approval constitutes the first deliverable under such Development Plan. The Calendar Year 1 Development Plan shall be designed such that all deliverables will be completed by the end of Calendar Year 1. When Dario completes all deliverables defined in this first Development plan, Sanofi shall pay Dario the balance of money due in the Development Plan.

**7.2.2** For Calendar Year Two, Sanofi shall pay Dario [\*\*], within 60 days of receipt of an invoice from Dario, upon the approval of the first Calendar Year 2 Development Plan by the JSC. When Dario completes all deliverables defined in the first Calendar year 2 Development Plan, Sanofi shall pay Dario the balance of money due in the first Calendar Year 2 Development Plan. In the event Sanofi and Dario agree to conduct additional development for the Enhanced Solutions in Calendar Year Two that is outside the scope of the first Calendar Year 2 Development Plan, such additional development will be set forth in a second Calendar Year 2 Development Plan. The total development costs payable by Sanofi to Dario under the second Calendar Year 2 Development Plan (the "**Year 2 Additional Development Cost**") will be agreed upon by the Parties in the second Calendar Year 2 Development Plan and be reallocated from the development costs reserved for Calendar Year 5. For the avoidance of doubt, in no event will the Year 2 Additional Development Cost exceed [\*\*]. Sanofi shall pay Dario (a) 50% of the Year 2 Additional Development Cost within 60 days of receipt of an invoice from Dario upon the approval of the second Calendar Year 2 Development Plan by the JSC; and (b) remaining 50% of the Year 2 Additional Development Cost upon Dario's completion of all deliverables defined in the second Calendar year 2 Development Plan.

**7.2.3** The development costs initially allocated for Calendar Year 3 is up to [\*\*] upon JSC approval of any Calendar Year 3 Development Plan(s). Parties may decide to increase the development costs payable by Sanofi to Dario in Calendar Year 3 by reallocating some or all of the then-current development costs reserved for Calendar Year 5 to Calendar Year 3 (the total additional development costs payable in Calendar Year 3, the "**Year 3 Additional Development Cost**"). For avoidance of doubt, in no event will the Year 3 Additional Development Cost exceed the balance remaining after Year 2 Additional Development Cost is deducted from [\*\*]. For each Development

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Plan for Calendar Year 3, Sanofi shall pay Dario (a) 50% of the development cost set forth in such Development Plan within 60 days of receipt of an invoice from Dario upon the approval of such Development Plan by the JSC; and (b) remaining 50% of the development cost set forth in such Development Plan upon Dario's completion of all deliverables defined in such Development Plan.

**7.2.4** Sanofi shall pay Dario [\*\*] upon the JSC's approval of the Development Plan for Calendar Year 4. When Dario completes all deliverables defined in the Development Plan for Calendar Year 4, Sanofi shall pay Dario the balance of [\*\*].

**7.2.5** The maximum total development costs payable by Sanofi to Dario in Calendar Year 5 is the balance remaining after the sum of Year 2 Additional Development Cost and Year 3 Additional Development Cost is deducted from [\*\*] (the "Year 5 Development Cost"). Sanofi shall pay Dario (a) 50% of the Year 5 Development Cost within 60 days of receipt of an invoice from Dario upon the approval of the Calendar Year 5 Development Plan by the JSC; and (b) remaining 50% of the Year 5 Development Cost upon Dario's completion of all deliverables defined in the Calendar year 5 Development Plan.

**7.2.6** In no event shall the foregoing Development Plan milestone payments exceed: (a) [\*\*] in Calendar Year 1; (b) [\*\*] in Year 2 (i.e., all development cost reserved for Calendar Year 5 is reallocated to Calendar Year 2); (c) [\*\*] in Calendar Year 3 (i.e., Year 2 Additional Development Cost is zero and all development cost reserved for Calendar Year 5 is reallocated to Calendar Year 3); (d) [\*\*] in Calendar Year 4; and (e) [\*\*] in Calendar Year 5 (i.e., no development cost reserved for Calendar Year 5 is reallocated to either Calendar Year 2 or Calendar Year 3). No Development milestone payment will be made on a new Development Plan until the previous year's Development Plans are completed. For clarity, the maximum aggregate amount of all development milestone payments under all Development Plans payable by Sanofi pursuant to this Section 7.2 is [\*\*].

### 7.3 Contingent Payments.

**7.3.1** Once Dario has demonstrated to Sanofi that it has achieved a Contingent Milestone for the Solution or Enhanced Solution as specified below then Dario will issue an invoice to Sanofi for the corresponding Contingent Milestone Payment and, subject to the terms and conditions of this Agreement, Sanofi will pay Dario the invoiced amount within 60 days after receipt of such invoice:

Contingent Milestones	Contingent Milestone Payment
Cumulative Net Sales reach [**] USD and the Enrollment Rate surpasses 25% ("First Contingent Payment")	[**]

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Contingent Milestones	Contingent Milestone Payment
Cumulative Net Sales reach one hundred and [**] USD and the Enrollment Rate surpasses 25% ("Second Contingent Payment")	[**]

**7.3.2** Both conditions described in a Contingent Milestone must be satisfied simultaneously for a Contingent Milestone to be met. Each Contingent Milestone Payment in this Section 7.3 is due only once and will be payable only upon the first achievement of the corresponding Contingent Milestone event. For clarity, the maximum aggregate amount of Contingent Milestone payments payable by Sanofi pursuant to this Section 7.3 is [\*\*].

### 7.4 Revenue Share.

#### 7.4.1 Health Plan Channel Accounts.

**7.4.1.1 Revenue Share during Term.** During the Term, in consideration for the Introductions made by Sanofi, and subject to the terms and conditions of this Agreement, Dario will pay to Sanofi [\*\*] of Net Sales of the Solution and the Enhanced Solutions from all accounts within the Health Plan Channel (regardless of Sanofi Introduction to account).

**7.4.1.2 Revenue Share following Termination.** In the event of termination of the Agreement for Sanofi's uncured material breach pursuant to Section 12.2.1, Dario will have no revenue sharing obligations after the Term for any Health Plan Channel account. In the event of termination of the Agreement by Sanofi for convenience pursuant to Section 12.2.5, Dario will pay to Sanofi, on an account-by-account basis, [\*\*] of Net Sales of the Solution and the Enhanced Solution from each Qualifying Health Plan Account that exists as of the Termination Date during the period commencing on the date immediately following the Termination Date and ending on the date that is the earlier of (a) the date of end of contract term for the applicable Qualifying Health Plan Account (excluding renewals) and (b) date that is three (3) years from the Termination Date. In the event of expiration of the Agreement or termination of the Agreement for any reason other than pursuant to Section 12.2.1 or Section 12.2.5, Dario will pay to Sanofi [\*\*] of Post-Term Qualifying Health Plan Channel Revenue during the period commencing on the date immediately following the Termination Date and ending on the date that is the earlier of (a) the date of end of contract term for the last to end Qualifying Health Plan Account.

(excluding renewals) and (b) date that is three (3) years from the Termination Date.

**7.4.1.3 Revenue Share Stoppage.** From the start of Year 3 until Termination Date, if sum of aggregate Net Sales of the Solution and any Enhanced Solution from (a) Qualifying Health Plan Accounts and (b) Bundled Accounts is less than [\*\*] of sum of aggregate Net Sales of the Solution and any Enhanced Solution from (a) all accounts in the Health Plan Channel and (b) Bundled Accounts during any given period of two (2) consecutive Calendar Quarters, excluding accounts (i) signed prior to the Effective Date or (ii) listed in the Advanced Discussion List (the "Stoppage Condition"), then Dario's obligation to pay fees on Net Sales of the Solution and any Enhanced Solution in the Health Plan Channel shall be suspended until sum of aggregate Net Sales of the Solution and any Enhanced Solution from (a) Qualifying Health Plan Accounts and (b) Bundled Accounts exceeds [\*\*] of sum of aggregate Net Sales of the Solution and any Enhanced Solution from (a) all account in the Health Plan Channel and (b) Bundled Accounts during any given period of two (2) consecutive Calendar Quarters, which shall be calculated on rolling six (6) month intervals for the preceding two (2) consecutive Calendar Quarters ("Health Plan Revenue Share Stoppage"). To the extent permitted by Qualifying Health Plan Accounts, Dario will promote enrolment in the Solution and any Enhanced Solution to Sanofi Qualifying Health Plan Accounts with a level of effort at least equal to the level of effort Dario employs to promote enrollment in the Solution and the Enhanced Solutions to any other account in the Health Plan Channel in the Territory.

#### **7.4.2 Employer Channel Accounts.**

**7.4.2.1 Revenue Share during Term.** During the Term, in consideration for the Introductions made by Sanofi and other adequate consideration described herein, and subject to the terms and conditions of this Agreement, Dario will pay to Sanofi [\*\*] of Net Sales of the Solution and the Enhanced Solution from Qualifying Employer Channel Accounts.

**7.4.2.2 Revenue Share following Termination.** In the event of termination of the Agreement for Sanofi's uncured material breach pursuant to Section 12.2.1, Dario will have no revenue sharing obligations after the Term for any Employer Channel account. In the event of expiration of the Agreement or termination of the Agreement for any reason other than pursuant to Section 12.2.1, Dario will pay to Sanofi, on an account-by-account basis, [\*\*] of Net Sales of the Solution and the Enhanced Solution from each Qualifying Employer Channel Account that exists as of the Termination Date during the period commencing on the date immediately following the

Termination Date and ending on the date that is the earlier of (a) the date of end of contract term for the applicable Qualifying Employer Channel Account (excluding renewals) and (b) date that is three (3) years from the Termination Date.

For clarity, Net Sales of the Solution and the Enhanced Solution from Qualifying Employer Channel Account includes any Net Sales from any downstream employer account that purchases or licenses the Solution or the Enhanced Solution directly from a Qualifying Employer Channel Account or directly from Dario pursuant to an Introduction to Dario by a Qualifying Employer Channel Account. Without limiting the generality of the foregoing, Net Sales of the Solution and the Enhanced Solution from the Qualifying Employer Channel Account includes Net Sales from any downstream employer account that contracts: (a) directly with Dario following an introduction to Dario by a pharmacy benefit managers account that was contracted pursuant to an Introduction or (b) directly with a pharmacy benefit managers account that was contracted pursuant to an Introduction.

**7.4.3 Bundled Accounts.** For each Bundled Account, Dario will, during the term of the Dario Platform Agreement with such Bundled Account, pay Sanofi [\*\*] of Net Sales of the Solution and the Enhanced Solutions from such Bundled Account, including any Net Sales from any downstream employer account that purchases or licenses the Solution or the Enhanced Solution directly from such Bundled Account or directly from Dario pursuant to an introduction to Dario by such Bundled Account (i.e., prescription benefit management's employer accounts). For clarity, the term of the Dario Platform Agreement with a Bundled Account and Dario's revenue share obligation for such Bundled Account may exceed the Term of this Agreement. Upon termination or expiration of a Dario Platform Agreement with a Bundled Account during the Term, if Dario renews or enters into a new Dario Platform Agreement with such account during the Term but Sanofi does not enter into a new Sanofi Rebate Agreement to incentivize such new Dario Platform Agreement, such account will cease to be a Bundled Account and will instead be deemed either a Qualifying Health Plan Account or a Qualifying Employer Channel Account (as applicable) and be subject to all obligations for Qualifying Health Plan Account or a Qualifying Employer Channel Account (as applicable), including without limitation, the payment obligations set forth in Sections 7.4.1 and 7.4.2. Dario shall have no obligation to pay Sanofi a revenue share under this Section 7.4.4. following the Term if this Agreement is terminated by Dario for Sanofi's uncured material breach pursuant to Section 12.2.1.

**7.4.4 Amwell.** Dario will, during the Term, pay Sanofi [\*\*] of Net Sales of the Solution and the Enhanced Solutions from Amwell, up to a maximum of [\*\*] of such Net Sales from Amwell per Calendar Year. For clarity, Dario is not obligated to pay Sanofi more than [\*\*] per Calendar Year pursuant to this Section 7.4.4. Upon termination or expiration of this Agreement for any

reason, Dario shall have no obligation to pay Sanofi a revenue share under this Section 7.4.4 following the Term.

**7.5 [Reserved].**

**7.6 Currency; Payment Terms; Exchange Rate.** All payments under this Agreement shall be made in Dollars. Any Net Sales incurred in a currency other than Dollars shall be converted to the Dollar equivalent using the paying Party's then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into Dollars. Each Party will deliver invoices to the other Party for all payments owed under this Agreement except for amounts payable by Dario to Sanofi hereunder. Each Party will make all payments owed within 60 days after the date on which the Party receives an invoice for any owed amount, except where a different timeframe is expressly provided in another Section of this Agreement. All payments to be made by a Party to the other Party under this Agreement shall be made by bank wire transfer in immediately available funds to a bank account designated by written notice from the Party that receives the payment or by other agreed electronic payment method. Conversion of reimbursable costs incurred hereunder that are recorded in local currencies to Dollars by a Party or its Affiliates shall be performed in a manner consistent with its normal practices used to prepare its audited financial statements for internal and external reporting purposes.

**7.6.1 Late Payments.**

**7.6.1.1 Interest on Late Payments.** If a Party does not receive payment of any undisputed sum due to it on or before the due date therefor, then it shall notify the paying Party. The paying Party shall pay interest on any undisputed late payments (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of the lesser of (a) 1% per month, or (b) the maximum rate permitted by Applicable Law.

**7.6.1.2 Right to Offset.** Sanofi will have the right, exercisable thirty (30) days following notice, to offset any amount owed by Dario to Sanofi under this Agreement, which amount or related obligation or alleged breach is reasonably described in such notice and is not contested by Dario in good faith as set forth in a responsive notice sent within thirty (30) days of receipt of Sanofi's notice, including but not limited to in connection with any breach or indemnification obligation by Dario pursuant to Article 11, against any undisputed amounts owed by Sanofi to Dario under this Agreement. Such offsets will be in addition to any other rights or remedies available under this Agreement and Applicable Law.

**7.7 Taxes.**

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**7.7.1 General.** The Party receiving each payment under this Agreement will bear any and all taxes levied on account of any such payment received under this Agreement. In the event that the paying Party is required, under Applicable Law, to withhold any deduction or tax from any payment due to the Party receiving payment under this Agreement, such amount will be deducted from the payment to be made by the paying Party, paid to the proper taxing authority, and the paying Party will notify the Party receiving payment and upon that Party's request promptly provide that Party with copies of any tax certificate or other documentation evidencing such withholding. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

**7.7.2 Value Added Tax.** Notwithstanding anything contained in Section 7.7.1, this Section 7.7.2 will apply with respect to VAT. All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, Sanofi will pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by Dario in respect of those Payments, such VAT to be payable on the later of the due date of the payment of the Payments to which such VAT relates and 60 days after the receipt by Sanofi of the applicable invoice relating to that VAT payment.

**7.8 Payment Reports.**

**7.8.1** Commencing as of the Effective Date, for so long as any revenue share term remains in effect for the Solution or Enhanced Solution(s), Dario will:

**7.8.1.1** with respect to each Calendar Quarter, provide a written report to Sanofi (a "Fee Report"), showing the following information in respect of such Calendar Quarter:

(a) reporting, on an individual account basis, of the Health Plan Channel, applicable Employer Channel accounts, any Bundled Accounts and the Amwell account (including, in each case, member utilization reports showing how many members were billed for each account);

(b) aggregate Net Sales of the Solution and each Enhanced Solution and the revenue share due to Sanofi pursuant to Section 7.4 for such Calendar Quarter;

(c) the withholding taxes, if any, required by law to be deducted in respect of such revenue share due to Sanofi; and

(d) a reasonable level of detail to enable Sanofi to understand how the Net Sales are being calculated from gross sales by channel type, by Solution or Enhanced Solution and the measure of Cumulative Net Sales.

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**7.8.1.2** with respect to each calendar month, provide a written report (a "Monthly Account Report") to Sanofi that sets forth summary reporting of any Bundled Accounts (including, in each case, member utilization reports with respect to such accounts).

**7.8.2** Fee payments and the supporting Fee Reports will be due within sixty (60) days following the end of the Calendar Quarter to which such Fee Report relates, and Monthly Account Reports will be due within fifteen (15) Business Days following the end of the month to which such Monthly Account Report relates. Dario will keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the revenue share payable to Sanofi hereunder to be determined.

## **7.9 Audits.**

**7.9.1** Upon the written request of Sanofi and with at least 30 days' prior written notice, but not more than once in any Calendar Year, Dario will permit an independent certified public accounting firm of internationally recognized standing, selected by Sanofi and reasonably acceptable to Dario, at Sanofi's sole cost and expense, to have access during normal business hours at such location as Dario's financial records are kept to any of the records of Dario as reasonably required to verify the accuracy of any payments or receipts due hereunder. Such accountants may audit only records that are relevant for such audit scope and any financial period during the Term and continuing after expiration or termination until such time as payments for Net Sales are no longer due to Sanofi, and no period may be audited more than once. The accounting firm will disclose to Sanofi only whether the payments or receipts were correct or not, and the specific details concerning any discrepancies and such information will be shared at the same time with Dario. No other information obtained by such accountants will be shared with Sanofi.

**7.9.2** If such accounting firm concludes that any payments were owed but not paid to Sanofi, Dario will make such additional payments within 60 days following the date Sanofi delivers to Dario such accounting firm's written report so concluding. The fees charged by such accounting firm will be paid by Sanofi; except that if the audit discloses that the revenue share fees payable by Dario for the audited period are more than 105% of the payments actually paid for such period, then Dario will pay the reasonable fees and expenses charged by such accounting firm. If such accounting firm concludes that the payments paid were more than what was owed during such period, Sanofi will refund or issue to Dario a credit note for the overpayments within 30 days following the date Sanofi receives such accounting firm's written report so concluding.

**7.9.3 Confidential Financial Information.** The Parties will treat all financial information subject to review under this Article 7 as Confidential Information of such Party as set forth in Article 9, and will cause its accounting firm to retain all such financial information in confidence under terms substantially similar to those set forth in Article 9 and with respect to each inspection, the

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independent accounting firm will be obliged to execute for each Party's benefit a reasonable confidentiality agreement prior to commencing any such inspection.

## 8. REPRESENTATIONS, WARRANTIES AND COVENANTS

**8.1 Mutual Representations and Warranties.** Each Party represents, warrants and covenants to the other that:

- 8.1.1** it has the requisite power and full authority to enter into this Agreement, and such Party's execution, delivery of, actions relating to and performance under this Agreement have been duly authorized by such Party and do not and will not violate or conflict with any charter, by-law, law (including but not limited to applicable privacy legislation), contract, including, but not limited to, agreements with Third Parties, permit or obligation applicable to such Party;
- 8.1.2** such Party is the owner of, or otherwise has all of the rights necessary to use (and, as applicable, permit the other Party to use), all Intellectual Property that it may from time to time make available to the other Party in connection with fulfilling its obligations under this Agreement;
- 8.1.3** such Party shall perform its obligations under this Agreement in accordance with Applicable Law, and has obtained all necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by it in connection with this Agreement;
- 8.1.4** nothing herein is in exchange for any explicit or implicit agreement or understanding that either Party purchase, lease, order, prescribe, or recommend or otherwise arrange for, or provide preferential formulary or other status for, the use of any products of the other Party or its Affiliates;
- 8.1.5** it will perform all obligations and undertakings set forth herein in a good and workmanlike manner and in accordance with generally accepted industry practices;
- 8.1.6** (a) Neither it nor any of its Affiliates has been debarred or is subject to debarment pursuant to Section 306 of the FFDCA or analogous provisions of Applicable Law outside the United States or listed on any excluded list, and (b) neither it nor any of its Affiliates has, to its knowledge, used in any capacity, in connection with the activities to be performed under this Agreement, any individual or entity that has been debarred pursuant to Section 306 of the FFDCA or analogous provisions of Applicable Law outside the United States, or that is the subject of a conviction described in such Section or analogous provisions of Applicable Law outside the United States, or listed on any excluded list; and
- 8.1.7** such Party will maintain throughout the Term all permits, licenses, registrations and other forms of authorizations and approvals from any Governmental Authority, necessary or required to be obtained or maintained

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by such Party in order for such Party to execute and deliver this Agreement and to perform its obligations hereunder in a manner which complies with all Applicable Law.

**8.2** Each Party acknowledges that no other consideration has been provided by such Party or its Affiliates in connection with this Agreement to the other Party, and that nothing herein is in exchange for any explicit or implicit agreement or understanding that the other Party purchase, lease, order, prescribe, or recommend or otherwise arrange for, or provide preferential status for, the use of any products of such Party or its Affiliates.

**8.3** In the event either Party receives any communication from a regulatory or other governmental authority, whether verbally or in writing, regarding Dario's or Sanofi's co-promotion of the Solution or Enhanced Solutions, including, without limitation, warning letters, untitled letters or other notices or inquiries, such Party will immediately notify the other Party in writing of such communication and will provide copies of all follow up correspondence from the regulatory or governmental authority as relates to the co-promotion issue (with appropriate redaction of any commercial Confidential Information not relating to the co-promotion). In addition, the Party receiving such inquiry or communication agrees to provide the other Party an opportunity to review and comment on the receiving Party's proposed response to the regulatory or governmental authority, but only as relates to co-promotion matters.

**8.4** Such Party will perform this Agreement in accordance with Applicable Law.

**8.5** **Dario Representations and Warranties.** Dario represents, warrants and covenants to Sanofi that:

**8.5.1** it has and will maintain all regulatory clearances, approvals, licenses, and other permits necessary for development and marketing of the Solution (including any future versions thereof);

**8.5.2** there are no ongoing or pending warning letters, enforcement letters, inspections, 483s, investigations, or other action from FDA or other authority relating to the Solution, and Dario is not aware of information that could give rise to such actions;

**8.5.3** the Solution and Enhanced Solutions is, was and will be developed, investigated, manufactured, labeled, promoted, marketed, etc. by Dario in accordance with all Applicable Laws; and

**8.5.4** the Solution and Enhanced Solutions will be developed using industry practice and in accordance with all Applicable Laws and regulations, including, but not limited to applicable privacy legislation.

**8.6** **Data Protection.** The Parties will process Personal Data pursuant to the Agreement, in accordance with applicable Data Protection Law. Insofar, the

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Parties undertake to seek and obtain any authorization and/or approval prior to any processing of Personal Data.

**8.6.1** Dario herewith represents and warrants that the Enrolled Users have received prior information notice and have given their consent.

**8.6.2** Dario herewith represents and warrants that no direct or indirect access to Personal Data will be granted to Sanofi.

**8.6.3** Dario herewith represents and warrants that the Personal Data will be provided to Sanofi's duly authorized Third Parties will be qualified as De-Identified Data, Anonymized Data and/or subject to prior Tokenization. Dario undertakes not to disclose or otherwise make available to Sanofi any Personal Data, De-Identified and/or subject to Tokenization to Sanofi or give access to Sanofi to any code allowing identification of Enrolled Users.

**8.6.4** Dario undertakes to provide Sanofi with all cooperation and assistance reasonably expected to enable it to comply with all applicable obligations to pursuant Study to the extent set forth in the Evidence Generation Plan.

**8.6.5** Further, Sanofi herewith represents and warrants that it will not undertake any actions to determine the personality or personal data of Enrolled Users, or to get access to any code allowing identification of Enrolled Users.

**8.6.6** For the sole purpose of carrying out the Agreement, the Parties will process Personal Data. Therefore, such processing shall be governed by a data processing agreement (DPA) that sets out the terms and conditions of the processing activities. The Parties agree to execute this specific agreement within twenty (20) days of the Effective Date. The DPA will form a part of the Agreement.

**8.6.7** Each Party will process personal data relating to the other Party and its staff (such as the name, professional contact details, position and role in connection with this Agreement; jointly referred to as the "**Contractual Personal Data**") to manage this Agreement and to comply with any applicable Data Protection Law requirements.

**8.6.8** In this regard, the Parties will be deemed as independent controllers and will be responsible for their own processing of Contractual Personal Data, which shall be carried out in compliance with applicable laws. In particular, the Contractual Personal Data will be kept as long as the contractual rights and duties arising from the Agreement and applicable regulatory rights and duties could be enforced by or against a Party. Only for the above-mentioned purposes, each Party may store the Contractual Personal Data in centralized databases and disclose them to its Affiliates or Third Parties in other countries. Each Party's staff shall communicate any requests in relation to this Section to the Data Protection Officer of the Party concerned.

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**8.7** **Payments and Commitments.** In performing the activities contemplated by this Agreement, neither Party shall make any payment, either directly or indirectly, of money or other assets (hereinafter collectively referred as a "**Payment**"), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "**Officials**") where such Payment would constitute violation of Applicable Law. In addition, neither Party shall make any Payment either directly or indirectly to Officials if such Payment is for the purpose of unlawfully influencing decisions or actions with respect to the subject matter of this Agreement. No employee of either Party or their Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of terms of this Section 8.7.

**8.8** **Import/Export Controls.** The Parties agree that no material or information relating to this Agreement will be exported, re-exported, transferred or disclosed contrary to the Applicable Law and regulations of the United States, or to any country, entity or other Party that is ineligible to receive such items under any Applicable Law, including all applicable U.S. Commerce and Treasury law and regulations.

**8.9** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY, AND EACH PARTY HEREBY SPECIFICALLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, REGARDING ITS PERFORMANCE UNDER AND ARRANGEMENTS CONTEMPLATED BY THIS AGREEMENT, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT AND IMPLIED WARRANTIES ARISING FROM COURSE OF DEALING OR COURSE OF PERFORMANCE.

**9. CONFIDENTIALITY**

**9.1 Confidential Information.** Each Party (the "Receiving Party") acknowledges and agrees that it will have access to Confidential Information of the other Party (the "Disclosing Party") in connection with the performance of its obligations hereunder. For purposes of this Agreement, "Confidential Information" shall mean all confidential or proprietary information, property, or material of the Disclosing Party and any derivatives, portions, or copies thereof, disclosed or made available by or on behalf of the Disclosing Party to the Receiving Party in connection with this Agreement. Other than as provided in Section 9.3, the Receiving Party shall keep all Confidential Information in strict confidence and shall not, without the Disclosing Party's prior consent, disclose, publish, disseminate or otherwise make available, directly or indirectly, any item of the Disclosing Party's Confidential Information to anyone at any time during or for seven (7) years after the expiration or earlier termination of this Agreement, or for such longer time period that any such information constitutes a trade secret.

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of the Disclosing Party or is PHI governed by Applicable Law. The Receiving Party shall use the Disclosing Party's Confidential Information only in connection with the performance of its obligations or exercise of its rights under this Agreement.

**9.2 Exceptions.** Notwithstanding the foregoing, Confidential Information shall not include information which the Receiving Party can prove: (i) is or becomes publicly known through no wrongful act of the Receiving Party or any Affiliate of the Receiving Party; (ii) is rightfully received by the Receiving Party from a Third Party without restriction on disclosure; (iii) is independently developed by the Receiving Party or any of its Affiliates without access to or use of the Disclosing Party's Confidential Information; or (iv) is approved by the Disclosing Party for unrestricted publication.

**9.3 Permitted Disclosures.** Except with respect to PHI, the use and disclosure of which shall be governed by Applicable Law, notwithstanding the obligations set forth above, each Party may disclose Confidential Information of the other Party to any of its employees, agents, attorneys, financial advisors or consultants who need to receive the Confidential Information in order for the Receiving Party to perform its responsibilities and obligations related to this Agreement or to exercise a right granted under this Agreement, provided that each Party shall ensure that, prior to disclosing the Confidential Information, each person or entity to whom the Confidential Information is to be disclosed is made aware that such Confidential Information is confidential to the Disclosing Party, and agrees to adhere to terms of confidentiality that are no less burdensome than those set forth in this Section 9. If the Receiving Party is required to disclose the Disclosing Party's Confidential Information pursuant to any judicial or administrative process or order or requirement under Applicable Law, the Receiving Party shall, as soon as practicable and prior to any such disclosure, give the Disclosing Party sufficient notice and reasonable assistance to contest such requirement or order. The Receiving Party agrees to cooperate fully with the Disclosing Party in seeking any protective order at the Disclosing Party's request and expense. If the Receiving Party is required to disclose the Disclosing Party's Confidential Information pursuant to such process, the Receiving Party shall only disclose such Confidential Information that is required by such process.

**9.4 Nondisclosure of Terms.** Each Party agrees that it will not disclose the terms of this Agreement to any Third Party without the prior consent of the other Party, to the extent the terms of this Agreement have not been publicly disclosed by prior agreement of the Parties or as otherwise permitted herein. If either Party is required to disclose the terms of this Agreement in submissions to the U.S. Securities and Exchange Commission or other equivalent governmental authority, it will (a) consult with the other Party as to which information to redact from the copy of this Agreement that will be disclosed; and (b) to the extent permitted under Applicable Law, redact all sensitive, material and non-public information, from such copy.

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**9.5** **Retained Rights.** As between the Parties, each Party shall retain ownership of its Confidential Information made available to the other Party in the course of fulfilling its obligations under this Agreement. Nothing in this Agreement is intended to transfer ownership of either Party's Confidential Information to the other Party.

**9.6** Upon written request or expiration or termination of this Agreement, a Party shall either return to the other Party or destroy Confidential Information of the other Party (including hard and electronic copies thereof); provided, however, that a Party is not required to destroy electronic copies of the Confidential Information stored in its electronic archive systems, and may retain one (1) copy of such Confidential Information for purpose of complying with its obligations under this Agreement or under Applicable Law, but shall not otherwise use or rely on such Confidential Information.

## 10. INTELLECTUAL PROPERTY

**10.1** **Disclosure of Inventions.** Dario will disclose to Sanofi any patentable components of the Enhanced Solutions promptly after becoming aware thereof.

**10.2** **Ownership of Intellectual Property.**

**10.2.1** **Foreground IP.** Subject to the licenses granted in Article 5, as between the Parties:

**10.2.1.1** Dario shall own all right, title and interest in and to any Dario Foreground IP and Dario Data;

**10.2.1.2** Sanofi will own all right, title and interest in and to any Sanofi Foreground IP and Sanofi Data;

**10.2.1.3** Ownership of Other Foreground IP will be determined according to the Applicable Law.

**10.2.2** Subject to the licenses granted in Article 5, Sanofi will retain ownership of the Sanofi Background IP and Dario will retain ownership of the Dario Background IP.

## 11. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

**11.1** **Indemnity.**

**11.1.1** Each Party shall indemnify, defend and hold harmless the other Party, its Affiliates, and its and their respective directors, officers, shareholders, members, managers and employees ("Indemnified Parties") from and against any and all Third Party claims, actions, causes of action, demands, or suit brought against any of the Indemnified Parties (collectively "Claims"), and all related liabilities, losses, damages, judgments, costs and expenses, including reasonable attorneys' fees, costs and interest (collectively, "Losses"), to the

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extent arising out of or relating to: (i) any gross negligence or willful misconduct of the indemnifying Party in connection with this Agreement, or (ii) breach or alleged breach by the indemnifying Party of its obligations set forth in this Agreement.

**11.1.2** Additionally, Dario shall indemnify, defend and hold harmless Sanofi, its Affiliates, and its and their respective directors, officers, shareholders, members, managers and employees from and against any and all Third Party Claims and related Losses arising out of or relating to such Third Party's allegation that (i) the Solution or an Enhanced Solution infringes or misappropriates or violates such Third Party's rights (including but not limited to Intellectual Property rights), or (ii) such Third Party suffered personal injury or property damage caused by such Third Party's use of the Solution or an Enhanced Solution, *provided, however*, that neither Party shall have any obligation under Section 11.1 to indemnify the other Party for such Claims or Losses to the extent that i) the other Party is required to indemnify for such Claims, ii) in the case of Dario as the indemnifying Party, Claims relate solely to the Sanofi Data or Sanofi Background IP as provided to Dario as stand-alone items, and not Claims resulting from the incorporation or integration of such Sanofi Data or Sanofi Background IP into the Enhanced Solution or otherwise used under a Development Plan, iii) in the case of Sanofi as the indemnifying Party, the Claims relate to Dario Data, Dario Member Data or Dario Background IP.

**11.2** **Limitation of Liability.** NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY AND WITH THE EXCEPTION OF A BREACH OF SECTION 9 OR SECTION 10, A PARTY'S GROSS NEGLIGENCE, FRAUD OR INTENTIONAL OR WILLFUL MISCONDUCT, (i) NEITHER PARTY HERETO SHALL BE LIABLE HEREUNDER FOR ANY CONSEQUENTIAL, PUNITIVE, INDIRECT, INCIDENTAL OR SPECIAL DAMAGES OR LOST PROFITS UNLESS SUCH DAMAGES OR LOST PROFITS ARE PAYABLE TO A THIRD PARTY IN CONNECTION WITH SUCH PARTY'S INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 11.1; AND (ii) EXCEPT WITH REGARD TO THEIR INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 11.1, ABOVE, EACH PARTY'S TOTAL, AGGREGATE LIABILITY TO THE OTHER PARTY FOR ANY CLAIM HEREUNDER SHALL NOT EXCEED TWO TIMES (2X) THE AMOUNTS PAID BY SANOFI TO DARIO UNDER SECTION 7.1, SECTION 7.2 AND SECTION 7.3 DURING THE TWELVE (12) MONTHS IMMEDIATELY PRECEDING THE CAUSE OF ACTION. Amounts accrued and payable by one Party to the other hereunder are not limited by Section 11.2(ii).

**11.3** **Notice of Claim.** Each Party's agreement to indemnify, defend and hold the other harmless from a Claim pursuant to Section 11.1 is conditioned on the indemnified Party:

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**11.3.1** providing prompt written notice to the indemnifying Party of the Claim (provided that failure to promptly notify shall not relieve the indemnifying Party of its obligation to defend the Claim except to the extent that such failure materially prejudices the indemnifying Party's ability to defend the Claim);

**11.3.2** permitting the indemnifying Party to assume full control of and responsibility for the defense of such Claim;

**11.3.3** reasonably assisting the indemnifying Party, at the indemnifying Party's reasonable expense and written request, in investigation of, preparation for and defense of any such Claim; and not compromising or settling such Claim without the indemnifying Party's prior written approval. The indemnifying Party shall not settle any Claim in any manner that does not provide for the full and complete release of the indemnified Party without such indemnified Party's prior written approval, which approval shall not be unreasonably withheld, conditioned or delayed. The indemnified Party may participate in the defense of the Claim with its own counsel at its own expense.

**11.4** **Insurance Requirements.** During the Term of the Agreement, each Party shall maintain adequate insurance or self-insurance to reasonably cover its obligations hereunder.

## **12. TERM AND TERMINATION**

**12.1** **Term.** This Agreement will remain in effect for five (5) years from the Effective Date, with a right of renewal for a subsequent five (5) year term upon mutual written agreement by Parties, unless terminated in accordance with Section 12.2 (the "Term"). The Parties shall start discussions regarding a potential renewal no later than twelve (12) months prior to the expiration date of the initial Term, but the Parties have no obligation to renew this Agreement.

## 12.2 **Termination.**

**12.2.1 Termination by Either Party for Material Breach.** If either Party believes that the other is in material breach of this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party. Following notification by a Party of a material breach by the other Party, which breach is not cured within thirty (30) days of receipt of the notice of such breach (or such longer time as may be agreed by the Parties in writing), the non-breaching Party may terminate this Agreement in its entirety upon notice to the other Party. If a Party disputes an invoiced amount in good faith and notifies the invoicing Party of the good faith dispute within the original time for payment, accompanying such notice with an explanation of the dispute and providing supporting documentation, then such Party may withhold the disputed amount (but shall pay the undisputed amount), and such withholding is not considered a material breach. In this event, the Parties will meet promptly to discuss the dispute, and will work in good faith to resolve the dispute as quickly as possible.

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**12.2.2 Termination by Either Party for Force Majeure.** If the event of Force Majeure continues for a period of more than one hundred eighty (180) days, then the Party not claiming the benefit of Force Majeure may terminate this Agreement upon giving the other Party thirty (30) days' written notice of its intention so to do, but such notice shall not take effect if the Party claiming the benefit of Force Majeure gives notice within that period that the cause has ceased to prevent its performance of this Agreement.

**12.2.3 Termination by Either Party for Insolvency.** In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within 90 days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not charged within 60 days of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon writing notice to such Party.

**12.2.4 Termination by Dario for Failure to Meet Net Sales Requirements.** Dario will have the right, but not the obligation, to terminate this Agreement if beginning at the end of Year 3, sum of annual Net Sales of the Solution and Enhanced Solution arising from (a) Qualifying Health Plan Accounts and (b) Bundled Accounts is less than 35% of corresponding sum of annual Net Sales of the Solution and Enhanced Solution arising from (a) all accounts in the Health Plan Channel, excluding Qualifying Health Plan Accounts (i) signed prior to the Effective Date or (ii) listed in the Advanced Discussion List and (b) Bundled Accounts; provided that for purposes of this calculation, Qualifying Health Plan Accounts whose subscription terms are, as of the Termination Date, within their first 6 months will be included assuming that the revenues from such Qualifying Health Plan Accounts would be equivalent to the revenue of a similarly sized account using the average of the Dario book of business for health plans, and following the first 6 months, the calculation shall be based on actual revenues.

**12.2.5 Termination for Convenience.** Starting at Year 3, and for the remainder of the Term, including any extensions, Sanofi will have the right to terminate the Agreement for convenience upon sixty (60) days' notice to Dario. If Sanofi exercises this termination for convenience, Sanofi will pay Dario the Transition Payment within sixty (60) days of the Termination Date.

**12.2.5.1** In the event Sanofi provides notice of termination for convenience and Sanofi wishes to continue the development of Development Plan approved by the JSC prior to Sanofi's termination notice, Sanofi will provide Dario with notice of that

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wish at the time of termination notice and Dario will, within 15 Business Days of receipt of such notice either

(1) reject such request and invoice Sanofi for the Transition Payment and for any development costs incurred under the current Development Plan through the termination notice date (if any). Dario will stop all development activities on the current Development Plan no later than the date Dario rejects such request, or

(2) forfeit the Transition Payment, continue the development activities as set forth in the Development Plan, and pay the applicable future revenue share with respect to the Enhanced Solutions that are the subject of such Development Plan as set forth in Section 7.4.

**12.2.6 Termination by Sanofi for Dario Failure to Complete a Development Plan.** If Dario is more than 9 months late in completing any Development Plan, then Sanofi will have the right, but not the obligation, to terminate the Agreement in its entirety or to terminate any further Development related activities, upon 30 days' prior written notice. If Sanofi elects not to terminate, Dario will agree to good faith negotiations regarding mitigation strategies as set forth in Section 4.2.6.

**12.2.7 Termination by Sanofi for Change of Control of Dario.** Dario will notify Sanofi in writing no later than three (3) Business Days after the execution of any agreement pursuant to which Dario would, upon consummation of the underlying transactions, undergo a Change of Control of Dario, in which case Sanofi will be entitled, upon 30 days' notice, to terminate this Agreement in its entirety upon written notice to Dario no more than 60 days after receipt of such notice, if such Change of Control is the consequence of acquisition of Dario by any of the Sanofi Excluded Companies that offers any product that is substantially similar to an Enhanced Solution. If Sanofi elects not to terminate, Dario will ensure assumption of the Agreement by the acquirer, including the continuation of the licensing rights and royalties as granted to Sanofi under the Agreement.

**12.3 Effect of Termination.** In the event this Agreement expires or is terminated:

**12.3.1** The Parties shall cooperate with each other in good faith to wind down each Party's performance obligations hereunder and no further activities shall be performed other than as expressly agreed by the Parties in writing including the transfer to Sanofi of Sanofi Foreground IP.

**12.3.2** Dario shall remain obligated to make any payments that have accrued prior to the Termination Date.

**12.3.3** Dario shall continue to pay to Sanofi the post-Term revenue share amounts for the applicable time periods as set forth in Sections 7.4.1.2, 7.4.2.2, and 7.4.3.

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**12.3.4** The Health Plan Revenue Share Stoppage will no longer apply to any of Dario's revenue share payment obligations under Section 7.4.1.2.

**12.3.5** In the event of termination due to Dario's failure to complete a Development Plan under Section 12.2.6 or due to termination for convenience under Section 12.2.5, the Parties will work together to calculate, as of the date of termination, based on the amount of Development Plan milestone payments made by Sanofi to Dario under Section 7.2 and the Fair Market Value of the deliverables that Dario completed and delivered pursuant to the Development Plan, whether Dario will repay any Fair Market Value for deliverables not yet delivered, or whether Sanofi will pay Dario for any Fair Market Value for deliverables delivered, as applicable.

**12.3.6** Dario's reporting obligations to Sanofi under Section 7.8 will continue for the applicable post-Term revenue share periods set forth in Sections 7.4.1.2, 7.4.2.2 and 7.4.3.

**12.3.7** In the event of termination due to Dario's insolvency pursuant to Section 12.2.3, Dario shall immediately proceed with a technology transfer pursuant to Section 4.2.7 of all Dario Foreground IP necessary to complete the approved Development Plans.

**12.3.8** In the event of Sanofi termination for convenience under Section 12.2.5, where additional development activities will be completed under an already approved Development Plan in accordance with Section 12.2.5.1, the JSC duties set forth in Section 2.3 will be limited to decisions relating to the existing pre-approved Development Plan.

**12.4 Survival.** Expiration or termination of this Agreement will not affect any rights or obligations that have accrued before expiration or termination, including outstanding payment obligations. The following provisions shall survive and apply after expiration or termination of this Agreement: Sections 5.4.2, 5.4.3, 5.5, 5.6, 7.4.1.2, 7.4.1.3, 7.4.2.2, 7.4.3, 7.8, 7.9, 8.9, 9, 10, 11.1, 11.2, 11.3, 12.3, 12.4 and 13.

### **13. MISCELLANEOUS**

**13.1 Notices.** Any notice required to be given hereunder shall be in writing and shall be deemed to have been given: (a) when received, if delivered in person; (b) on the third Business Day following the mailing thereof, if mailed by certified first class mail, postage prepaid, return receipt requested; (c) when received, if delivered by overnight commercial courier service; or (d) on the Business Day sent by electronic mail, provided, however, in the case of electronic mail, the sender arranges for the recipient to acknowledge receipt by return electronic mail, in any such case to the addresses specified below, and sends a physical copy of the notice by one of the other above methods following electronic mail delivery;

If to Dario:

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DarioHealth Corp.  
18 W 18th Street  
New York, NY 10011  
Attention: President  
Email: rick@dariohealth.com

If to Sanofi:

Sanofi  
55 Corporate Drive  
Bridgewater, NJ 08807  
Attention: Latoya Bascom  
Email: Latoya.Bascom@sanofi.com

With a copy to:

Arnold & Porter  
250 West 55th Street  
New York, New York 10019  
Attention: Joshua Blank, Esq  
Email: Joshua.Bank@arnoldporter.com

### **13.2 Governing Law; Jurisdiction; Venue and Service.**

**13.2.1 Governing Law.** This Agreement will be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

**13.2.2 Jurisdiction.** The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of any New York State court sitting in the borough of Manhattan in the City of New York or any federal court sitting in the borough of Manhattan in the City of New York for any action arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals and enforcements of awards therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial in any such action.

**13.2.3 Venue.** Subject to Section 13.2.2 the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action arising out of or relating to this Agreement in the courts of the State of New York and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action brought in any such court has been brought in an inconvenient forum.

**13.3 Force Majeure.** Except with respect to payment obligations, neither Party shall be liable for any failure to perform or any delays in performance, and neither Party shall be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent, and for as long as such failure or delay is due to any causes that are beyond its reasonable control and not due to its negligent or wrongful acts or omissions, including such causes as acts of God, fire, flood, severe storm, earthquake, pandemic, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, or other similar causes ("Force Majeure Event"). In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly inform the other Party of the Force Majeure Event and the expected delay, and shall use reasonable efforts to avoid or minimize the delay. The Party affected by the other Party's delay may elect to suspend performance and extend the time for performance for the duration of the Force Majeure Event.

**13.4 Use of Names; Publicity.** Except to the extent reasonably necessary in furtherance of the co-promotional activities contemplated herein, neither Party shall, without the prior written approval of the other Party: (i) advertise or otherwise publicize the existence or terms of this Agreement or any other aspect of the relationship between the Parties or (ii) use the other Party's name or any trade name, trademark or service mark belonging to such Party in press releases or in any form of advertising.

**13.5 Relationship of the Parties.** It is expressly agreed that Dario, on the one hand, and Sanofi, on the other hand, will be independent contractors and that the relationship between the Parties will not constitute a partnership, joint venture or agency. Neither Dario, on the one hand, nor Sanofi, on the other hand, will have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party will be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment will be for the account and expense of such first Party.

**13.6 No Third-Party Beneficiaries.** This Agreement issued shall not benefit, or create any right or cause of action in or on behalf of, any person or entity other than Sanofi or Dario (including their respective Affiliates, subsidiaries and assignees).

**13.7 Successors.** This Agreement will bind and inure to the benefit of the successors and permitted assigns of each Party.

**13.8 Assignments.** Neither Party shall have the right to assign this Agreement or any of its rights or obligations hereunder without prior written consent of the other Party, provided, however, that an assignment may occur without such consent in conjunction with a Change of Control of the assigning Party. This Agreement

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shall inure to the benefit of and be binding upon each Party, its successors and permitted assigns.

**13.9 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Sanofi or Dario are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property expressly licensed to it hereunder and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

**13.10 No Waiver.** Failure to exert a right under this Agreement does not constitute a waiver of that right or remedy. No waiver of any right or remedy is effective unless in writing and signed by the Party who waives the right or remedy.

**13.11 Construction.** The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. The term "including" or "includes" as used in this Agreement means including without limiting the generality of any description preceding such term. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party. References to any Exhibit, schedule, attachment, or other document are to that Exhibit, schedule, attachment, agreement or other document as this document is modified from time to time. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.

**13.12 Severability.** If any provision of this Agreement is determined to be illegal or unenforceable, that provision will be severed from the Agreement and the remainder will remain valid, legal, and enforceable, provided that the surviving portion materially comports with the original intent of the Parties.

**13.13 Amendments.** All amendments and modifications of this Agreement (including any Exhibit hereto) will require the consent of each Party to be deemed effective.

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**13.14 Entire Agreement.** This Agreement and its Exhibits (and associated attachments) entered into pursuant to this Agreement represent the entire understanding between the Parties relating to the collaboration. This Agreement supersedes all previous agreements between the Parties (oral and written) relating to the collaboration described herein, except for any obligations that, by their terms, survive termination or expiration. To the extent of any conflict between this Agreement and any Exhibit attached hereto, the terms of this Agreement shall prevail.

**13.15** **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed to be an original, and all of which shall together constitute one and the same agreement. The exchange of copies of this Agreement and of signature pages by facsimile or other electronic transmission shall constitute effective execution and delivery of this Agreement as to the Parties and may be used in lieu of the original Agreement for all purposes.

*Signature page follows*

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**IN WITNESS WHEREOF**, the Parties hereto have executed this Agreement effective as of the Restatement Date.

**SANOFI US SERVICES, INC.**

By: /s/ Olivier Bogillot  
Name: Olivier Bogillot  
Title: Head of U.S. General Medicines  
Date: July 18, 2023

**DARIO HEALTH CORP.**

By: /s/ Richard Anderson  
Name: Richard Anderson  
Title: President  
Date: July 18, 2023

[Signature Page to Collaboration Agreement]

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**EXHIBIT A**

**Development Plan Fair Market Value**

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**EXHIBIT B**

**Ongoing Relationship between the Parties for Co-Promotion**

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**EXHIBIT C**

**Responsibilities for Development**

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**Exhibit D**

**Responsibilities for Evidence Generation**

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**EXHIBIT E**

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**EXHIBIT F**

**Agile Methodology**

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**EXHIBIT G****Existing Customers**

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**EXHIBIT H**

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**Exhibit 31.1**

**CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a)  
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Erez Raphael, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DarioHealth Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: **August 10, 2023** **November 2, 2023**

*/s/ Erez Raphael*

Erez Raphael

Chief Executive Officer

(Principal Executive Officer)

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**Exhibit 31.2**

**CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a)  
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Zvi Ben David, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DarioHealth Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: **August 10, 2023** **November 2, 2023**

*/s/ Zvi Ben David*

Zvi Ben David

Chief Financial Officer, Secretary and Treasurer  
(Principal Financial Officer)

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**Exhibit 32.1**

**DARIOHEALTH CORP.**  
**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with the quarterly report of DarioHealth Corp., or the Company, on Form 10-Q for the period ended **June 30, 2023** **September 30, 2023**, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Erez Raphael, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ Erez Raphael*

Erez Raphael

Chief Executive Officer  
(Principal Executive Officer)

**August 10, November 2, 2023**

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**Exhibit 32.2**

**DARIOHEALTH CORP.**  
**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with the quarterly report of DarioHealth Corp., or the Company, on Form 10-Q for the period ended **June 30, 2023** **September 30, 2023**, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Zvi Ben David, Chief Financial Officer, Secretary and Treasurer, certify,

pursuant to 18 U.S.C. Section 1350, that to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Zvi Ben David

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Zvi Ben David

Chief Financial Officer, Secretary and Treasurer  
(Principal Financial Officer)

August 10, November 2, 2023

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