

REFINITIV

# DELTA REPORT

## 10-Q

IDYA - IDEAYA BIOSCIENCES, INC.

10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	2275
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 CHANGES	232
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 DELETIONS	1749
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 ADDITIONS	294
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, June 30, 2024

OR

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

For the transition period from to

Commission File Number: 001-38915

IDEAYA Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

47-4268251

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

7000 Shoreline Court, Suite 350

South San Francisco, California

(Address of principal executive offices)

94080

(Zip Code)

(650) 443-6209

(telephone number, including area code)

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

Title of each class		Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share		IDYA	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 May 3, 2024 August 2, 2024, the registrant had 75,686,628 84,481,494 shares of common stock, \$0.0001 par value per share, outstanding.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical facts contained in this Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report on Form 10-Q entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- the scope, progress, results and costs of developing our product candidates or any other future product candidates, and conducting preclinical studies and clinical trials, including our darovasertib Phase 1/2 clinical trials, IDE397 Phase 1/2 clinical trials, IDE161 Phase 1 clinical trial and our the GSK101 (IDE705) clinical trial, as well as the potential clinical utility and tolerability of our product candidates;
- our clinical and regulatory development plans;
- the scope, progress, results and costs related to the research and development of our precision medicine target and biomarker discovery platform, including costs related to the development of our proprietary libraries and database of tumor genetic information and specific cancer-target dependency networks;
- our expectations about the impact of macroeconomic developments, such as health epidemics or pandemics, macro-economic uncertainties, social unrest, geopolitical hostilities, natural disasters or other catastrophic events, on our business, and operations, including clinical trials, manufacturing suppliers and collaborators, and on our results of operations and financial condition;
- the availability of companion diagnostics for biomarkers associated with our product candidates and any future product candidates, or the cost of coordinating and/or collaborating with certain diagnostic companies for the manufacture and supply of companion diagnostics;
- the timing of and costs involved in obtaining and maintaining regulatory approval (or certification in certain foreign jurisdictions) for any current or future product candidates and companion diagnostics, and any related restrictions, limitations, and/or warnings in the label of approved product candidate;
- our expectations regarding the potential market size and size of the potential patient populations for darovasertib, IDE397, IDE161, our other product candidates and any future product candidates, if approved for commercial use;
- the timing and amount of any option exercised, milestone, royalty or other payments we may or may not receive pursuant to any current future collaboration or license agreement, including under the Collaboration, Option and License Agreement with an affiliate of GSK plc, GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO. 4), Limited LIMITED ("GSK");
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including our Collaboration, Option and License Agreement with GSK, our Clinical Supply and Collaboration Agreement with Gilead Sciences, Inc., our Clinical Trial Collaboration and Supply Agreement with MSD International Business GmbH, our Clinical

Trial Collaboration and Supply Agreements with Pfizer Inc., our Clinical Trial Collaboration and Supply Agreement with Amgen Inc., our License Agreement with Novartis and our Option and License Agreement with Cancer Research Technologies Ltd. ("CRT"), and the University of Manchester;

- the timing of commencement of future nonclinical studies and clinical trials and research and development programs;
- our ability to acquire, discover, develop and advance product candidates into, and successfully complete, clinical trials;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and expectations;
- our intentions with respect to the commercialization of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology platforms, including additional indications for which we may pursue;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;
- our potential involvement in lawsuits in connection with enforcing our intellectual property rights;
- our potential involvement in third party interference, opposition, derivation or similar proceedings with respect to our patent rights and our challenges to our patent rights and patent infringement claims;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing therapies and procedures, procedures, as well as the competitive position of our product candidates.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not occur or be achieved, and actual results could differ materially from those projected in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

**IDEAYA Biosciences, Inc.**  
**Form 10-Q for Quarterly Period Ended March 31, 2024 June 30, 2024**

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## PART I—FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS (UNAUDITED).

## IDEAYA Biosciences, Inc.

## Condensed Balance Sheets

*(in thousands, except share and per share amounts)**(Unaudited)*

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
<b>Assets</b>				
Current assets				
Cash and cash equivalents	\$ 108,345	\$ 157,018	\$ 183,049	\$ 157,018
Short-term marketable securities	590,427	368,096	518,609	368,096
Accounts receivable	15	18	1	18
Prepaid expenses and other current assets	10,566	7,500	11,520	7,500
Total current assets	709,353	532,632	713,179	532,632
Restricted cash	757	757	911	757
Long-term marketable securities	242,636	107,492	251,071	107,492
Property and equipment, net	6,909	6,164	7,122	6,164
Right-of-use assets	1,780	2,246	1,305	2,246
Other non-current assets	92	25	75	25
Total assets	\$ 961,527	\$ 649,316	\$ 973,663	\$ 649,316

<b>Liabilities and Stockholders' Equity</b>				
Current liabilities				
Accounts payable	\$ 6,290	\$ 6,598	\$ 15,886	\$ 6,598
Accrued liabilities	17,519	18,756	24,250	18,756
Operating lease liabilities, current	1,151	1,747	606	1,747
Total current liabilities	24,960	27,101	40,742	27,101
Long-term operating lease liabilities	1,256	1,125	1,263	1,125
Total liabilities	26,216	28,226	42,005	28,226
Commitments and contingencies (Note 6)				
Stockholders' equity				
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—		
Common stock, \$0.0001 par value, 300,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 74,764,628 and 65,039,369 shares issued and outstanding as of March 31, 2024 and December 31, 2023	7	7		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—		
Common stock, \$0.0001 par value, 300,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 76,090,834 and 65,039,369 shares issued and outstanding as of June 30, 2024 and December 31, 2023	8	7		
Additional paid-in capital	1,324,163	968,885	1,373,774	968,885
Accumulated other comprehensive (loss) income	(923)	562	(1,416)	562
Accumulated deficit	(387,936)	(348,364)	(440,708)	(348,364)
Total stockholders' equity	935,311	621,090	931,658	621,090
Total liabilities and stockholders' equity	\$ 961,527	\$ 649,316	\$ 973,663	\$ 649,316

*The accompanying notes are an integral part of these condensed financial statements.*

**Condensed Statements of Operations and Comprehensive Loss**  
*(in thousands, except share and per share amounts)*  
**(Unaudited)**

	Three Months Ended			
	March 31,			
	2024		2023	
Collaboration revenue	\$	—	\$	7,880
Total revenue		—		7,880
Operating expenses				
Research and development		42,805		27,859
General and administrative		8,212		6,300
Total operating expenses		51,017		34,159
Loss from operations		(51,017)		(26,279)
Other income				
Interest income and other income, net		11,445		2,639
Net loss	\$	(39,572)	\$	(23,640)
Unrealized (losses) gains on marketable securities		(1,485)		1,466
Comprehensive loss	\$	(41,057)	\$	(22,174)
Net loss per common share, basic and diluted	\$	(0.53)	\$	(0.49)
Weighted-average common shares outstanding, basic and diluted		75,108,484		48,370,074

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
Collaboration revenue	\$ —	\$ 3,544	\$ —	\$ 11,424
Total revenue	—	3,544	—	11,424
Operating expenses				
Research and development	54,533	29,178	97,338	57,037
General and administrative	10,394	7,075	18,606	13,375
Total operating expenses	64,927	36,253	115,944	70,412
Loss from operations	(64,927)	(32,709)	(115,944)	(58,988)
Other income				
Interest income and other income, net	12,155	4,783	23,600	7,422
Net loss	\$ (52,772)	\$ (27,926)	\$ (92,344)	\$ (51,566)
Unrealized (losses) gains on marketable securities	(493)	226	(1,978)	1,692
Comprehensive loss	\$ (53,265)	\$ (27,700)	\$ (94,322)	\$ (49,874)
Net loss per common share, basic and diluted	\$ (0.68)	\$ (0.50)	\$ (1.21)	\$ (0.99)
Weighted-average common shares outstanding, basic and diluted	77,962,730	56,251,130	76,535,607	52,332,373



The accompanying notes are an integral part of these condensed financial statements.

**IDEAYA Biosciences, Inc.**  
**Condensed Statements of Stockholders' Stockholders' Equity**  
*(in thousands, except share amounts)*  
**(Unaudited)**

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulate</u>	<u>Other</u>	<u>Accumulat</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Income</u>	<u>Comprehen</u>	<u>ed</u>	<u>Stockholde</u>
			<u>Capital</u>	<u>(Loss)</u>	<u>sive</u>	<u>Deficit</u>	<u>rs'</u>
							<u>Equity</u>
<b>Balances as of December 31, 2023</b>	65,039,369	\$ 7	\$ 968,885	\$ 562	\$ (348,364)	\$	\$ 621,090
Issuance of common stock related to at-the-market offering program, net of issuance costs	9,260,382	—	343,505				343,505
Issuance of common stock upon exercise of stock options	464,877	—	5,461				5,461
Stock-based compensation			6,312				6,312
Other comprehensive loss				(1,485)			(1,485)
Net loss						(39,572)	(39,572)
<b>Balances as of March 31, 2024</b>	<u>74,764,628</u>	<u>\$ 7</u>	<u>\$ 1,324,163</u>	<u>\$ (923)</u>	<u>\$ (387,936)</u>	<u>\$</u>	<u>\$ 935,311</u>
<b>Balances as of December 31, 2022</b>	48,193,179	\$ 5	\$ 587,724	\$ (2,871)	\$ (235,403)	\$	\$ 349,455
Issuance of common stock related to at-the-market offering program, net of issuance costs	142,160		2,504				2,504
Issuance of common stock upon exercise of stock options	55,055		366				366
Stock-based compensation			3,659				3,659
Other comprehensive income				1,466			1,466
Net loss						(23,640)	(23,640)
<b>Balances as of March 31, 2023</b>	<u>48,390,394</u>	<u>\$ 5</u>	<u>\$ 594,253</u>	<u>\$ (1,405)</u>	<u>\$ (259,043)</u>	<u>\$</u>	<u>\$ 333,810</u>
				<u>Accumulate</u>			
				<u>d</u>			
			<u>Additional</u>	<u>Other</u>			<u>Total</u>

	Common Stock		Paid-In	Comprehen	Accumulat	Stockholde
	Shares	Amount	Capital	sive Income (Loss)	ed Deficit	rs' Equity
<b>Balances as of March 31, 2024</b>	74,764,628	\$ 7	\$ 1,324,163	\$ (923)	\$ (387,936)	\$ 935,311
Issuance of common stock related to at-the-market offering program, net of issuance costs	922,000	1	36,449	—	—	36,450
Issuance of common stock upon exercise of stock options	375,163	—	2,647	—	—	2,647
Employee stock purchase plan (ESPP) purchase	29,043	—	781	—	—	781
Stock-based compensation	—	—	9,734	—	—	9,734
Other comprehensive loss	—	—	—	(493)	—	(493)
Net loss	—	—	—	—	(52,772)	(52,772)
<b>Balances as of June 30, 2024</b>	<u>76,090,834</u>	<u>\$ 8</u>	<u>\$ 1,373,774</u>	<u>\$ (1,416)</u>	<u>\$ (440,708)</u>	<u>\$ 931,658</u>
<b>Balances as of March 31, 2023</b>	48,390,394	\$ 5	\$ 594,253	\$ (1,405)	\$ (259,043)	\$ 333,810
Issuance of common stock upon follow-on public offering, net of issuance costs	8,858,121	\$ 1	\$ 153,589	—	—	\$ 153,590
Issuance of common stock related to at-the-market offering program, net of issuance costs	10,124	—	(78)	—	—	(78)
Issuance of pre-funded warrants to purchase common stock	—	—	35,132	—	—	35,132
Issuance of common stock upon exercise of stock options	139,535	—	1,487	—	—	1,487
Employee stock purchase plan (ESPP) purchase	42,154	—	637	—	—	637
Stock-based compensation	—	—	4,731	—	—	4,731
Other comprehensive income	—	—	—	226	—	226
Net loss	—	—	—	—	(27,926)	(27,926)
<b>Balances as of June 30, 2023</b>	<u>57,440,328</u>	<u>\$ 6</u>	<u>\$ 789,751</u>	<u>\$ (1,179)</u>	<u>\$ (286,969)</u>	<u>\$ 501,609</u>

The accompanying notes are an integral part of these condensed financial statements.

**IDEAYA Biosciences, Inc.**

**Condensed Statements of Stockholders' Equity**  
**(in thousands, except share amounts)**  
**(Unaudited)**

Accumulate

	Common Stock		Additional	Other	Accumulated	Total
	Shares	Amount	Paid-In	Comprehensive Income (Loss)	Deficit	Stockholders' Equity
<b>Balances as of December 31, 2023</b>	65,039,369	\$ 7	\$ 968,885	\$ 562	\$ (348,364)	\$ 621,090
Issuance of common stock related to at-the-market offering program, net of issuance costs	10,182,382	1	379,954	—	—	379,955
Issuance of common stock upon exercise of stock options	840,040	—	8,108	—	—	8,108
Employee stock purchase plan (ESPP) purchase	29,043	—	781	—	—	781
Stock-based compensation	—	—	16,046	—	—	16,046
Other comprehensive loss	—	—	—	(1,978)	—	(1,978)
Net loss	—	—	—	—	(92,344)	(92,344)
<b>Balances as of June 30, 2024</b>	<u>76,090,834</u>	<u>\$ 8</u>	<u>\$ 1,373,774</u>	<u>\$ (1,416)</u>	<u>\$ (440,708)</u>	<u>\$ 931,658</u>
<b>Balances as of December 31, 2022</b>	48,193,179	\$ 5	\$ 587,724	\$ (2,871)	\$ (235,403)	\$ 349,455
Issuance of common stock upon follow-on public offering, net of issuance costs	8,858,121	1	153,589	—	—	153,590
Issuance of common stock related to at-the-market offering program, net of issuance costs	152,284	—	2,425	—	—	2,425
Issuance of pre-funded warrants to purchase common stock	—	—	35,132	—	—	35,132
Issuance of common stock upon exercise of stock options	194,590	—	1,854	—	—	1,854
Employee stock purchase plan (ESPP) purchase	42,154	—	637	—	—	637
Stock-based compensation	—	—	8,390	—	—	8,390
Other comprehensive income	—	—	—	1,692	—	1,692
Net loss	—	—	—	—	(51,566)	(51,566)
<b>Balances as of June 30, 2023</b>	<u>57,440,328</u>	<u>\$ 6</u>	<u>\$ 789,751</u>	<u>\$ (1,179)</u>	<u>\$ (286,969)</u>	<u>\$ 501,609</u>

*The accompanying notes are an integral part of these condensed financial statements.*

**Condensed Statements of Cash Flows**  
(in thousands)  
(Unaudited)

	Three Months Ended March		Six Months Ended June	
	31,		30,	
	2024	2023	2024	2023
<b>Cash flows from operating activities</b>				
Net loss	\$ (39,572)	\$ (23,640)	\$ (92,344)	\$ (51,566)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	616	588	1,238	1,207
Net amortization (accretion) of premiums (discounts) on marketable securities	(6,314)	(1,557)	(12,954)	(4,111)
Stock-based compensation	6,312	3,659	16,046	8,390
Amortization of right-of-use assets	466	372	941	751
Changes in assets and liabilities				
Accounts receivable	3	(257)	17	51
Prepaid expenses and other assets	(3,133)	1,373	(3,504)	(2,508)
Accounts payable	(453)	(12)	9,243	1,589
Accrued and other liabilities	(1,273)	(419)	5,625	(3,260)
Contract liabilities	—	(7,498)	—	(10,935)
Lease liabilities	(465)	(451)	(1,003)	(910)
Net cash used in operating activities	(43,813)	(27,842)	(76,695)	(61,302)
<b>Cash flows from investing activities</b>				
Purchases of property and equipment, net	(1,325)	(43)	(2,298)	(927)
Purchases of marketable securities	(475,781)	(72,296)	(640,544)	(292,543)
Maturities of marketable securities	123,135	95,860	357,428	195,610
Net cash (used in) provided by investing activities	(353,971)	23,521		
Net cash used in investing activities	(285,414)	(97,860)		
<b>Cash flows from financing activities</b>				
Proceeds from issuance of common stock upon public offering, net of issuance costs	—	153,840		
Proceeds from issuance of common stock related to at-the-market offering program, net of issuance costs	343,650	2,560	379,971	2,526
Proceeds from issuance of pre-funded warrants to purchase common stock, net of issuance costs	—	35,132		
Proceeds from ESPP purchase	781	637		
Proceeds from exercise of common stock options	5,461	366	7,542	1,854
Net cash provided by financing activities	349,111	2,926	388,294	193,989
Net decrease in cash, cash equivalents and restricted cash	(48,673)	(1,395)		
Net increase in cash, cash equivalents and restricted cash	26,185	34,827		
<b>Cash, cash equivalents and restricted cash</b>				

Cash, cash equivalents and restricted cash, at beginning of period	157,775	68,738	157,775	68,738
Cash, cash equivalents and restricted cash, at end of period	<u>\$ 109,102</u>	<u>\$ 67,343</u>	<u>\$ 183,960</u>	<u>\$ 103,565</u>
Reconciliation of cash, cash equivalents and restricted cash				
Cash and cash equivalents	\$ 108,345	\$ 67,237	\$ 183,049	\$ 102,843
Restricted cash	757	106	911	722
Cash, cash equivalents and restricted cash	<u>\$ 109,102</u>	<u>\$ 67,343</u>	<u>\$ 183,960</u>	<u>\$ 103,565</u>
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid for interest	\$ 12	\$ 13	\$ 22	\$ 26
<b>Supplemental non-cash investing and financing activities:</b>				
Purchases of property and equipment in accounts payable and accrued liabilities	\$ 183	\$ 746	\$ 45	\$ 600
Accrued ATM costs	\$ 145	\$ 56		
Unpaid offering costs	—	351		
Unpaid at-the-market offering program costs	\$ 16	\$ —		

*The accompanying notes are an integral part of these condensed financial statements.*

**IDEAYA Biosciences, Inc.**  
**Notes to Condensed Financial Statements (Unaudited)**

**1. Organization**

**Description of the Business**

IDEAYA Biosciences, Inc. (the “Company”) is a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. The Company is headquartered in South San Francisco, California and was incorporated in the State of Delaware in June 2015. To date, the Company has been primarily engaged in business planning, research, development, recruiting and raising capital.

**Follow-On Offering**

On April 27, 2023, the Company completed an underwritten public follow-on offering. The offering consisted of 8,858,121 shares of the Company's common stock, par value \$0.0001 per share (“common stock”), at an offering price to the public of \$18.50 per share, including

1,418,920 shares of common stock upon the exercise in full of the overallotment option by the underwriters, as well as pre-funded warrants to purchase 2,020,270 shares of common stock at a public offering price of \$18.4999 per underlying share, in each case before underwriting discounts and commissions. Pursuant to the offering, the Company received aggregate gross proceeds of approximately \$201.3 million, before deducting underwriting discounts and commissions and other offering expenses, resulting in net proceeds of approximately \$188.7 million, after deducting underwriting discounts and commissions and other offering expenses.

On October 27, 2023, the Company completed an underwritten public follow-on offering. The offering consisted of 5,797,872 shares of common stock at an offering price to the public of \$23.50 per share, including 797,872 shares of common stock upon the exercise in full of the overallotment option by the underwriters, as well as pre-funded warrants to purchase 319,150 shares of common stock at a public offering price of \$23.4999 per underlying share, in each case before underwriting discounts and commissions. Pursuant to the offering, the Company received aggregate gross proceeds of approximately \$143.7 million, before deducting underwriting discounts and commissions and other offering expenses, resulting in net proceeds of approximately \$134.6 million, after deducting underwriting discounts and commissions and other offering expenses.

### At-the-Market Offering

On June 26, 2023, the Company filed a new Registration Statement on Form S-3 (File No. 333- 272936) under the Securities Act as an automatic shelf registration statement as a "well-known seasoned issuer", as defined in Rule 405 under the Securities Act. On June 26, 2023, the Company also entered into a new Open Market Sales Agreement, or June 2023 Sales Agreement, with Jefferies LLC ("Jefferies") relating to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of common stock having aggregate gross proceeds of up to \$250.0 million through Jefferies as sales agent.

During the reporting period for the quarter ended March 31, 2024, the Company sold an aggregate of 6,115,516 shares of common stock for aggregate net proceeds of \$215.9 million at a weighted average sales price of approximately \$36.39 per share under the at-the-market offering pursuant to the June 2023 Sales Agreement with Jefferies as sales agent.

On January 19, 2024, the Company entered into a new Open Market Sales Agreement, or January 2024 Sales Agreement, with Jefferies relating to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of common stock having aggregate gross proceeds of up to \$350.0 million through Jefferies as sales agent.

During the reporting period for three months ended June 30, 2024, pursuant to the quarter ended March 31, 2024, January 2024 Sales Agreement, the Company sold an aggregate of 3,144,866 922,000 shares of common stock through at-the-market offerings for aggregate net proceeds of \$127.6 36.5 million, after deducting underwriting discounts and commissions and other offering expenses, at a weighted average sales price of approximately \$41.53 40.40 per share under the at-the-market offering pursuant to the January 2024 Sales Agreement with Jefferies as sales agent.

share. As of March 31, 2024 June 30, 2024, approximately \$219.4 182.1 million of common stock remained available to be sold under the at-the-market facility associated with pursuant to the January 2024 Sales Agreement.

The Company may cancel its at-the-market program at any time upon written notice, pursuant to its terms.

## **Liquidity**

The Company has incurred significant losses and negative cash flows from operations in all periods since inception and had an accumulated deficit of \$387.9 440.7 million as of March 31, 2024 June 30, 2024.

The Company has financed its operations primarily through the sale and issuance of common stock and the upfront payment and certain milestone payments received from GSK.

To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue from commercial products since inception. Management expects operating losses to continue and increase for the foreseeable future, as the Company progresses clinical development activities for its lead product candidates. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed under Risks and Uncertainties in Note 2. While the Company has been able to raise multiple rounds of financing, there can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

As of March 31, 2024 June 30, 2024, the Company had cash, cash equivalents and marketable securities of \$941.4 952.7 million. Management believes that the Company's current cash, cash equivalents and marketable securities will be sufficient to fund its planned operations for at least 12 months from the date of the issuance of these financial statements.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

These condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim reporting.

Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Accordingly, the unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on February 20, 2024.

### ***Unaudited Condensed Financial Statements***

The accompanying financial information for the three and six months ended March 31, 2024 June 30, 2024 and March 31, 2023 June 30, 2023 are unaudited. The unaudited condensed financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present

fairly the Company's financial position as of **March 31, 2024** **June 30, 2024** and its results of operations for the three and six months ended **March 31, 2024** **June 30, 2024** and **March 31, 2023** **June 30, 2023** and cash flows for the **three** **six** months ended **March 31, 2024** **June 30, 2024** and **March 31, 2023** **June 30, 2023**. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other periods.

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

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Such estimates include useful lives of property and equipment, determination of the discount rate for operating leases, accruals for research and development activities, revenue recognition, stock-based

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compensation, and income taxes. On an ongoing basis, management reviews these estimates and assumptions. Changes in facts and circumstances may alter such estimates and actual results could differ from those estimates.

### ***Risks and Uncertainties***

The Company operates in a dynamic and highly competitive industry and is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, contract manufacturers, contract research organizations and collaboration partners, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies and clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting. The Company believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends

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in new technologies and industry standards; results of clinical trials and collaboration activities; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company based on



intellectual property, patent, product, regulatory, or other factors; and the Company's ability to attract and retain employees necessary to support its growth.

Products developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that the products will receive the necessary approvals, or that any approved products will be commercially viable. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval, it could have a materially adverse impact on the Company. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company may require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs which would materially and adversely affect its business, financial condition and operations.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. Substantially all the Company's cash, is cash equivalents and marketable securities are held by two three financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company's investment policy addresses credit ratings, diversification, and maturity dates.

The Company invests its cash equivalents and marketable securities in money market funds, U.S. government securities, commercial paper, and corporate bonds. The Company limits its credit risk associated with cash equivalents and marketable securities by placing them with banks and institutions it believes are creditworthy and in highly rated investments and, by policy, limits the amount of credit exposure with any one commercial issuer. The Company has not experienced any credit losses on its deposits of cash, cash equivalents or marketable securities.

### ***Summary of Significant Accounting Policies***

There have been no material changes in the accounting policies from those disclosed in the financial statements and the related notes included in the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2024.

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### ***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") under its accounting standard codifications ("ASC") or other standard setting bodies and adopted by the Company as of the specified effective date, unless otherwise discussed below.

*New Accounting Pronouncements, Not yet ~~Adopted~~: Adopted*

On October 2023, the FASB issued ASU 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative, which modifies the disclosure or presentation requirements related to variety of FASB Accounting Standard Codification topics. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K is effective. If by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the associated amendment will be removed from the

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Codification and will not become effective for any entities. The Company is currently evaluating the effect of adopting this ASU. On December 14, 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which amends the guidance in ASC 740, Income Taxes. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Entities are permitted to early adopt the standard "for annual financial statements that have not yet been issued or made available for issuance." Adoption is either prospectively or retrospectively; the Company will adopt this ASU on a prospective basis. The Company is currently evaluating the impact of the ASU but does not expect any material impacts upon adoption.

### 3. Fair Value Measurement and Marketable Securities

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

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As of March 31, 2024 June 30, 2024, financial assets measured and recognized at fair value are as follows (in thousands):

		March 31, 2024				June 30, 2024			
		Gross		Gross		Gross		Gross	
		Amortized	Unrealized	Unrealized	Estimated	Amortized	Unrealized	Unrealized	Estimated
		Cost	Gains	Losses	Fair Value	Cost	Gains	Losses	Fair Value
<b>Assets</b>									
U.S. government securities <sup>(1)</sup>	Level 2	\$ 519,487	\$ 71	\$ (542)	\$ 519,016	\$ 505,634	\$ 58	\$ (813)	\$ 504,879
Corporate bonds	Level 2	151,971	44	(396)	151,619	162,797	10	(583)	162,224
Commercial paper <sup>(2) (1)</sup>	Level 2	232,426	—	(98)	232,328	213,224	—	(87)	213,137
Marketable securities		903,884	115	(1,036)	902,963	881,655	68	(1,483)	880,240
Money market funds <sup>(3) (2)</sup>	Level 1	37,953			37,953	63,890	—	—	63,890
Total fair value of assets		\$ 941,837	\$ 115	\$ (1,036)	\$ 940,916	\$ 945,545	\$ 68	\$ (1,483)	\$ 944,130

(1) \$10.9 million was included in cash and cash equivalents on the condensed balance sheets due to securities with purchase dates within 90 days of maturity dates.

(2) \$59.0 million was included in cash and cash equivalents on the condensed balance sheets due to securities with purchase dates within 90 of maturity dates.

(3) Included in cash and cash equivalents on the condensed balance sheets.

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As of December 31, 2023, financial assets measured and recognized at fair value are as follows (in thousands):

		December 31, 2023			
		Amortized	Gross	Gross	Estimated
		Cost	Unrealized	Unrealized	Fair Value
			Gains	Losses	
<b>Assets</b>					
U.S. government securities <sup>(1)</sup>	Level 2	\$ 412,679	\$ 591	\$ (135)	\$ 413,135
Corporate bonds	Level 2	53,983	197	(32)	54,148
Commercial paper <sup>(2)</sup>	Level 2	126,601	—	(58)	126,543
Marketable securities		593,263	788	(225)	593,826
Money market funds <sup>(3)</sup>	Level 1	38,300	—	—	38,300
Total fair value of assets		\$ 631,563	\$ 788	\$ (225)	\$ 632,126

- (1) \$37.8 million was included in cash and cash equivalents on the condensed balance sheets due to securities with purchase dates within 90 days of maturity dates.
- (2) \$80.4 million was included in cash and cash equivalents on the condensed balance sheets due to securities with purchase dates within 90 days of maturity dates.
- (3) Included in cash and cash equivalents on the condensed balance sheets.

As of March 31, 2024, June 30, 2024 and December 31, 2023, all marketable securities had a remaining maturity of less than three two years. There were no financial liabilities measured and recognized at fair value as of March 31, 2024, June 30, 2024 and December 31, 2023.

The Company considers available evidence in evaluating potential other-than-temporary impairments of its marketable securities, including the duration and extent to which fair value is less than cost, and the Company's ability and intent to hold the investment. As of March 31, 2024, June 30, 2024 and December 31, 2023, the Company held certain securities in an unrealized loss position. These unrealized losses were considered to be temporary as the Company expects to recover the entire amortized cost basis on the securities in unrealized loss positions based on the creditworthiness of the underlying issuer, and the Company neither intends to sell these securities nor considers it more likely than not that the Company would be required to sell any such security before its anticipated recovery. As a result, the Company did not consider any of these investments to be other-than-temporarily impaired at March 31, 2024, June 30, 2024 and December 31, 2023.

#### 4. Balance Sheet Components

##### Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	Useful Life (In Years)	March 31, 2024	December 31, 2023	Useful Life (In Years)	June 30, 2024	December 31, 2023
Laboratory equipment	5	\$ 11,636	\$ 11,455	5	\$ 11,624	\$ 11,455
Computer equipment	3	261	261	3	261	261
Software	3	231	231	3	231	231
Leasehold improvements	Shorter of useful life or lease term	4,115	3,321	Shorter of useful life or lease term	4,476	3,321
Furniture and fixtures	5	832	507	5	1,317	507
Total property and equipment		17,075	15,775		17,909	15,775
Less: Accumulated depreciation and amortization		(10,166)	(9,611)		(10,787)	(9,611)
Property and equipment, net		\$ 6,909	\$ 6,164		\$ 7,122	\$ 6,164

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Depreciation and amortization expense was \$0.6 million and \$0.6 million for the three months ended March 31, 2024, June 30, 2024 and March 31, 2023, June 30, 2023, respectively, and \$1.2 million and \$1.2 million for the six months ended June 30, 2024 and June 30, 2023, respectively.

##### Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Accrued research and development expenses	\$ 12,220	\$ 10,676	\$ 17,372	\$ 10,676
Accrued salaries and benefits	4,260	6,974	5,407	6,974
Legal and professional fees	856	959	1,454	959
Other	183	147	17	147
Accrued liabilities	\$ 17,519	\$ 18,756	\$ 24,250	\$ 18,756

## 5. Operating Leases

The Company leases its laboratory and office facilities at 7000 Shoreline Court, South San Francisco for approximately 29,000 square feet with an expiration date in September 2024.

In November 2023, the Company entered into a lease agreement for approximately 5,700 square feet of space at 11710 El Camino Real, San Diego, California for corporate office space. The lease term commenced in December 2023 and expires in March 2028. The Company has an option to renew the lease for 3 years.

In June 2023, the Company entered into a lease agreement for approximately 44,000 square feet of space at 5000 Shoreline Court, South San Francisco, California. The lease term is expected to commence in the third quarter of 2024 and the lease term is one hundred twenty months. The Company has an option to extend the lease term for a total of two consecutive five-year periods.

In November 2023, May 2024, the Company entered into a amended its 5000 Shoreline Court facility lease agreement for to expand the size of the original premises by adding approximately 5,700 11,321 rentable square feet of space at 11710 El Camino Real, San Diego, California for corporate office additional space. The lease term has not yet commenced in December 2023 and expires in March 2028. The Company has an option to renew the lease for 3 years as of June 30, 2024.

Future minimum lease payments under operating leases included on the Company's condensed balance sheet are as follows:

As of March 31, 2024	Operating Leases	
As of June 30, 2024	Operating Leases	
2024	\$ 1,381	\$ 801
2025	386	386
2026	398	398
2027	410	410
2028	106	106
Total future minimum lease payments	2,681	2,101
Less: imputed interest	(274)	(232)
Total operating lease liabilities	\$ 2,407	\$ 1,869

The following table summarizes other information about the Company's operating leases:

As of		As of	
March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023

Remaining Lease Term	2.3	2.4	2.6	2.4
Discount Rate	8.3 %	8.0 %	8.6 %	8.0 %

Operating lease costs were \$0.5 million and \$0.4 million for the quarters three and six months ended March 31, 2024 June 30, 2024 and March 31, 2023, respectively. \$0.4 million and \$0.8 million for the three and six months ended June 30, 2023.

Variable lease costs were \$0.4 million and \$0.8 million for the quarters three and six months ended March 31, 2024 June 30, 2024 and March 31, 2023 \$0.4 million and \$0.7 million for the three and six months ended June 30, 2023. Variable lease costs represent additional costs incurred, related to administration, maintenance and property tax costs incurred, which are billed based on both usage and as a percentage of the Company's share of total square footage.

During the quarters six months ended March 31, 2024 June 30, 2024 and March 31, 2023 June 30, 2023, cash paid for amounts included in the measurement of lease liabilities and included within cash used in operating activities in the statement of cash flows was \$0.5 million. million and \$1.0 million, respectively.

## 6. Commitments and Contingencies

### Contingencies

From time to time, the Company may be involved in litigation related to claims that arise in the ordinary course of its business activities. The Company accrues for these matters when it is probable that future expenditures will be made and these expenditures can be reasonably estimated. As of March 31, 2024 June 30, 2024, the Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's financial position, results of operations or cash flows.

### Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business with vendors, clinical trial sites and other parties. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. Accordingly, the Company has not recorded a liability related to such indemnification agreements as of March 31, 2024 June 30, 2024.

## 7. Income Taxes

For the three and six months ended March 31, 2024 June 30, 2024 and March 31, 2023 June 30, 2023, the Company did not record a federal or state income tax provision due to its recurring net losses. In addition, the Company has taken a full valuation allowance against its net deferred

tax assets as the Company believes it is not more likely than not that the benefit will be realized.

The Company is under audit in California for tax years 2020-2021.

## 8. Common Stock

As of **March 31, 2024** **June 30, 2024** and December 31, 2023, the Company's certificate of incorporation authorized the Company to issue 300,000,000 shares of common stock at a par value of \$0.0001 per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Company's board of directors. As of **March 31, 2024** **June 30, 2024** and December 31, 2023, no dividends have been declared to date.

On April 27, 2023, the Company completed an underwritten public follow-on offering. The offering consisted of 8,858,121 shares of common stock at an offering price to the public of \$18.50 per share, including 1,418,920 shares of common stock upon the exercise in full of the overallotment option by the underwriters, as well as pre-funded warrants to purchase 2,020,270 shares of common stock at a public offering price of \$18.4999 per underlying share, in each case before underwriting discounts and commissions. Pursuant to the offering, the Company received aggregate gross proceeds of approximately \$201.3 million, before deducting underwriting discounts and commissions and other offering expenses, resulting in net proceeds of approximately \$188.7 million, after deducting underwriting discounts and commissions and other offering expenses.

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On October 27, 2023, the Company completed an underwritten public follow-on offering. The offering consisted of 5,797,872 shares of common stock at an offering price to the public of \$23.50 per share, including 797,872 shares of common stock upon the exercise in full of the overallotment option by the underwriters, as well as pre-funded warrants to purchase 319,150 shares of common stock at a public offering price of \$23.4999 per underlying share, in

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each case before underwriting discounts and commissions. Pursuant to the offering, the Company received aggregate gross proceeds of approximately \$143.7 million, before deducting underwriting discounts and commissions and other offering expenses, resulting in net proceeds of approximately \$134.6 million, after deducting underwriting discounts and commissions and other offering expenses.



As of **March 31, 2024** **June 30, 2024**, the following aggregate warrants to purchase shares of the Company's common stock were issued and outstanding:

Issue Date	Expiration Date	Exercise Price per Share	Number of Shares subject to Outstanding Warrants
April 27, 2023	None	\$.0001	2,020,270
October 27, 2023	None	\$.0001	319,150

The warrants are classified as a component of Stockholders' Equity within Additional Paid-in-Capital. The warrants are classified as equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, are indexed to the Company's common stock and meet the equity classification criteria. The warrants will not expire until they are fully exercised. As of **March 31, 2024** **June 30, 2024**, no shares underlying the warrants had been exercised.

The Company had reserved common stock for future issuance as follows:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Outstanding options under the 2015, 2019 and 2023 Plans	7,874,924	6,269,975	7,834,639	6,269,975
Shares available for grant under the 2019 Plan	1,638,170	964,622	1,507,092	964,622
Shares available for grant under the 2023 Inducement Plan	382,500	524,300	1,178,700	524,300
Shares available under the Employee Stock Purchase Plan	1,968,367	1,317,974	1,939,324	1,317,974
Pre-funded warrants issued and outstanding	2,339,420	2,339,420	2,339,420	2,339,420
Total	14,203,381	11,416,291	14,799,175	11,416,291

## 9. Stock-Based Compensation

### 2023 Inducement Plan

On February 24, 2023, the Company adopted the IDEAYA Biosciences, Inc. 2023 Employment Inducement Award Plan (the "2023 Inducement Plan"), pursuant to which the Company reserved 1,000,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The 2023 Inducement Plan was approved by the Company's board of directors without stockholder approval in accordance with such rule. Options granted under the 2023 Inducement Plan have a term of 10 years and generally vest over a 4-year period with 1-year cliff vesting.

On June 25, 2024, the Company amended the 2023 Employment Inducement Award Plan, increasing the number of shares available for issuance by 1,000,000.

As of **March 31, 2024** **June 30, 2024**, the number of shares available for issuance under the 2023 Inducement Plan was **382,500** **1,178,700**.

### 2019 Incentive Award Plan

In May 2019, the Company's board of directors adopted and the Company's stockholders approved the 2019 Incentive Award Plan (the "2019 Plan"), under which the Company may grant cash and equity-based incentive awards to the Company's employees, consultants and directors.

Following the effectiveness of the 2019 Plan, the Company will not make any further grants under the 2015 Equity Incentive Plan (the “2015 Plan”). However, the

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2015 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2015 Plan that are forfeited or lapse unexercised and which following the effective date of the 2019 Plan are not issued under the 2015 Plan will be available for issuance under the 2019 Plan.

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Options granted under the 2019 Plan may be either incentive stock options (“ISOs”) or nonqualified stock options (“NSOs”). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees, directors and consultants.

The 2019 Plan is subject to an annual increase on the first day of each year beginning in 2020 and ending in 2029, equal to the lesser of 4% of the shares outstanding on the last day of the immediately preceding fiscal year, and such smaller number of shares as determined by the Company's board of directors. Options granted under the 2019 Plan have a term of 10 years (or five years if granted to a 10% stockholder) and generally vest over a 4-year period with 1-year cliff vesting.

As of **March 31, 2024** **June 30, 2024**, the number of shares available for issuance under the 2019 Plan was **1,638,170** **1,507,092**.

#### **2015 Equity Incentive Plan**

In 2015, the Company established its 2015 Plan which provides for the granting of stock options to employees, directors and consultants of the Company. Options granted under the 2015 Plan may be either ISOs or NSOs.

#### **2019 Employee Stock Purchase Plan**

In May 2019, the Company's board of directors adopted and the Company's stockholders approved the 2019 Employee Stock Purchase Plan (the “ESPP”). The ESPP provides eligible employees with the opportunity to acquire an ownership interest in the Company through periodic payroll deductions up to 15% of eligible compensation. The offering period is determined by the Company in its discretion but may not exceed 27 months. The per-share purchase price on the applicable exercise date for an offering period is equal to the lesser of 85% of the fair market value of the common stock at either the first business day or last business day of the offering period, provided that no more than 4,000 shares of common stock may be purchased by any one employee during each offering period.

The ESPP is intended to constitute an “employee stock purchase plan” under Section 423(b) of the Internal Revenue Code of 1986, as amended. A total of 195,000 shares of common stock were initially reserved for issuance under the ESPP, subject to an annual increase on January 1 of each year, beginning on January 1, 2020, equal to the lesser of 1% of the shares outstanding on the last day of the immediately preceding fiscal year and such smaller number of shares as may be determined by the Company's board of directors, provided, however, that no more than 2,500,000 shares may be issued under the ESPP.

As of **March 31, 2024** **June 30, 2024**, the number of shares available for issuance under the ESPP was **1,968,367** **1,939,324**. For the **quarters** **six months** ended **March 31, 2024** **June 30, 2024** and **2023**, **June 30, 2023**, the Company recorded \$**0.1** **0.3** million and \$**0.2** million, **respectively**, of compensation expense related to employee participation in the ESPP.

### Stock-Based Compensation Expense

Total stock-based compensation expense recorded related to awards granted to employees and non-employees was as follows (in thousands):

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Research and development	\$ 3,784	\$ 2,087	\$ 5,900	\$ 2,705	\$ 9,683	\$ 4,792
General and administrative	2,528	1,572	3,834	2,026	6,363	3,598
Total stock-based compensation expense	\$ 6,312	\$ 3,659	\$ 9,734	\$ 4,731	\$ 16,046	\$ 8,390

### Stock Options

Activity under the Company's 2015 and 2019 Plans and 2023 Inducement Plan is set forth below:

	Outstanding Options				Outstanding Options			
	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Millions)	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Millions)
<b>Balance, January 1, 2024</b>	6,269,975	\$ 15.53	7.82	\$ 128.49	6,269,975	\$ 15.53	7.82	\$ 128.49
Options granted	2,195,438	\$ 45.91			2,602,838	\$ 44.41		
Options exercised	(464,877)	\$ 11.75			(840,040)	\$ 9.65		
Options canceled	(125,612)	\$ 19.29			(198,134)	\$ 22.59		

<b>Balance, March 31, 2024</b>	7,874,924	\$	24.18	8.36	\$	157.56
<b>Exercisable as of March 31, 2024</b>	2,807,378	\$	13.34	6.84	\$	84.70
<b>Vested and expected to vest as of March 31, 2024</b>	7,874,924	\$	24.18	8.36	\$	157.56
<b>Balance, June 30, 2024</b>	7,834,639	\$	25.60	7.91	\$	96.02
<b>Exercisable as of June 30, 2024</b>	2,884,505	\$	15.12	6.65	\$	56.35
<b>Vested and expected to vest as of June 30, 2024</b>	7,834,639	\$	25.60	7.91	\$	96.02

The weighted-average grant-date fair value of options granted during the **three** ~~six~~ months ended **March 31, 2024** **June 30, 2024** and **March 31, 2023** **June 30, 2023** was **\$33.00** ~~31.85~~ and **\$12.57** ~~13.34~~ per share, respectively. The aggregate intrinsic value of options exercised for the **three** ~~six~~ months ended **March 31, 2024** **June 30, 2024** and **March 31, 2023** **June 30, 2023** was **\$14.5** ~~27.0~~ million and **\$0.6** ~~1.9~~ million, respectively. Intrinsic values are calculated as the difference between the exercise price of the underlying options and the fair value of the common stock on the date of exercise.

As of **March 31, 2024** **June 30, 2024** and December 31, 2023, total unrecognized stock-based compensation expense for stock options was **\$105.8** ~~105.2~~ million and \$41.1 million, respectively, which is expected to be recognized over a weighted-average period of **2.92** ~~2.82~~ years and 2.59 years, respectively.

### Black-Scholes Assumptions

The fair values of options were calculated using the assumptions set forth below:

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Expected term	6.08 years	6.08 years	5.5 years - 6.1 years	6.1 years	5.5 years - 6.1 years	6.1 years
Expected volatility	80.2% - 81.3%	85.4% - 85.9%	78.8% - 79.8%	85.2% - 86.4%	78.8% - 81.3%	85.2%-86.9%
Risk-free interest rate	4.0% - 4.3%	3.6% - 4.1%	4.3% - 4.7%	3.6% - 4.1%	4.0% - 4.7%	3.6%-4.1%
Dividend yield	0%	0%	0%	0%	0%	0%

**Expected term.** The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the options' vesting terms, contractual terms and industry peers, as the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

**Expected Volatility.** The expected volatility is based on the Company's historical stock price volatility. The historical stock price volatility is calculated based on a period of time commensurate with the expected term assumption for each grant.

**Risk-Free Interest Rate.** The risk-free rate assumption is based on U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

*Expected Dividend Rate.* The Company has not paid and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

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The Company accounts for forfeitures as they occur.

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#### ***Fair Value of Common Stock***

The fair value of the Company's common stock is determined based on the market price on the date of grant.

#### **10.10. Significant Agreements**

##### ***GSK Collaboration, Option and License Agreement***

In June 2020, the Company entered into the Collaboration, Option and License Agreement (the "GSK Collaboration Agreement"), with an affiliate of GSK plc, GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO. 4), Limited LIMITED ("GSK"), pursuant to which the Company and GSK have entered into a collaboration for its synthetic lethality programs targeting MAT2A, Pol Theta and Werner Helicase. On July 27, 2020, ("the Effective Date"), the Company and GSK received Hart-Scott-Rodino Antitrust Improvements Act clearance, or HSR Clearance, and the GSK Collaboration Agreement became effective.

Pursuant to the GSK Collaboration Agreement, GSK paid the Company \$100.0 million on July 31, 2020. As of March 31, 2024 June 30, 2024, GSK has made aggregate payments in the amount of \$13.0 million for the achievement of certain development and regulatory milestones with respect to Pol Theta and WRN products.

##### ***GSK Collaboration - MAT2A Program***

Under the MAT2A program, the Company led research and development through early clinical development stage, and GSK had an exclusive option to obtain an exclusive license to continue development of and commercialize MAT2A products arising out of the MAT2A program, or the Option. The Company delivered an Option data package resulting from its conduct of a dose escalation portion of a MAT2A Phase 1 monotherapy clinical trial pursuant to the GSK Collaboration Agreement, following which the Option was exercisable within a specified time period. In August 2022, the Company received notice from GSK waiving its rights to exercise its Option, or the MAT2A Option Waiver, pursuant to the GSK Collaboration Agreement. As such, the Company retains and fully owns all right, title and interest in and to IDE397 and the MAT2A

program, including all worldwide commercial rights thereto. The Company will be responsible for the costs of further research and clinical development activities that the Company conduct for the MAT2A program following the MAT2A Option Waiver.

#### *GSK Collaboration - Pol Theta Program*

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize Pol Theta products arising out of the Pol Theta program. The Company and GSK collaborated on preclinical research for the Pol Theta program, and GSK is leading clinical development for the Pol Theta program. GSK is responsible for all research and development costs for the Pol Theta program. The Company will be eligible to receive total development and regulatory milestones of up to \$485.0 million, with respect to each Pol Theta product, including as applicable, for multiple Pol Theta products that target certain alternative protein domains or are based on alternative modalities. Additionally, the Company will be eligible to receive up to \$475.0 million of commercial milestones with respect to each Pol Theta product. The Company is also entitled to receive tiered royalties on global net sales of Pol Theta products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double-digit percentages, subject to certain customary reductions. In June 2022, the Company announced the nomination of a Pol Theta Helicase Inhibitor development candidate, or DC, and in August 2022, announced the achievement of an initial preclinical development milestone in connection with ongoing IND-enabling studies to support evaluation of Pol Theta Helicase Inhibitor DC, triggering a \$3.0 million milestone payment, which the Company received in October 2022. An IND was submitted and was cleared by the FDA in August 2023 to enable clinical evaluation in combination with niraparib, triggering a \$7.0 million milestone payment. The Company has the potential to achieve an additional \$10.0 million development milestone upon initiation of Phase 1 clinical dose expansion, as well as potential further aggregate late-stage development and regulatory milestones of up to \$465.0 million.

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#### *GSK Collaboration - Werner Helicase Program*

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize WRN products arising out of the WRN program. The Company and GSK are collaborating on ongoing preclinical research for the WRN program, and GSK will lead clinical development for the WRN program, with IDEAYA responsible for 20% and GSK responsible for 80% of such global research and development costs. The cost-sharing percentages will be adjusted based on the actual ratio of U.S. to global profits for WRN products, as measured three and six years after global commercial launch thereof.

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The Company will be eligible to receive total development milestones of up to \$485.0 million, with respect to each WRN product, including as applicable, for multiple WRN products that are based on alternative modalities. Additionally, the Company will be eligible to receive up to \$475.0 million of commercial milestones with respect to each WRN product. The Company will be entitled to receive 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of WRN products by GSK, its affiliates and their sublicensees ranging from high single digit to sub-teen double-digit percentages, subject to certain customary reductions. The Company will have a right to opt-out of the 50% U.S. net profit share and corresponding research and development cost share for the WRN program, and would be eligible to receive tiered royalties on U.S. net sales of WRN products by GSK, its affiliates and their sublicensees at the same royalty rates as for global non-U.S. net sales thereafter, with economic adjustments based on the stage of the WRN program at the time of opt-out.

In October 2023, the Company earned a \$3.0 million milestone from GSK in connection with IND-enabling studies for the Werner Helicase Inhibitor DC.

The Company has the potential to earn up to an additional \$17 million aggregate milestone payments through early Phase 1 clinical studies, including \$7.0 million upon IND clearance. The Company is also eligible to receive additional future aggregate total development milestones of up to \$465.0 million.

#### *GSK Collaboration - General*

Under the terms of the GSK Collaboration Agreement, subject to certain exceptions, the Company and GSK will not, directly or through third parties, develop or commercialize other products whose primary and intended mechanism of action is the modulation of WRN or Pol Theta for an agreed upon period of time. The Company and GSK have formed a joint steering committee, joint development committees, and joint commercialization committees responsible for coordinating all activities under the GSK Collaboration Agreement. Ownership of intellectual property developed under the GSK Collaboration Agreement is allocated between or shared by the parties depending on development and subject matter.

GSK's royalty obligations continue with respect to each country and each product until the later of (i) the date on which such product is no longer covered by certain intellectual property rights in such country and (ii) the 10th anniversary of the first commercial sale of such product in such country.

Each party has the right to sublicense its rights under the GSK Collaboration Agreement subject to certain conditions.

The GSK Collaboration Agreement will continue in effect on a product-by-product and country-by-country basis until the expiration of the obligation to make payments under the GSK Collaboration Agreement with respect to such product in each country, unless earlier terminated by either party pursuant to its terms. Either party may terminate the GSK Collaboration Agreement for the other party's insolvency or certain uncured breaches. The Company may terminate the GSK Collaboration Agreement if GSK or any of its sublicensees or affiliates challenge certain patents of the Company. GSK may terminate the GSK Collaboration Agreement in its entirety or on a target-by-target basis upon 90-day notice to the Company.

#### *Novartis License Agreement*

In September 2018, the Company entered into a license agreement with Novartis to develop and commercialize Novartis' LXS196 (also known as IDE196), a Phase 1 PKC inhibitor, for the treatment of cancers having GNAQ and GNA11 mutations. The Company renamed Novartis' LXS196 oncology as IDE196, and which has a non-proprietary name of darovasertib. Under the license agreement, Novartis granted to us a worldwide, exclusive, sublicensable license to research, develop, manufacture, and commercialize certain defined compounds and

products, including IDE196 and certain other PKC inhibitors as well as companion diagnostic products, collectively referred to as the licensed products, for any purpose.

The Company paid Novartis an upfront payment of \$2.5 million and issued 263,615 shares of its Series B redeemable convertible preferred stock concurrently with the execution of the license agreement. Subject to completion of certain clinical and regulatory development milestones, the Company agreed to make milestone

payments in the aggregate of up to \$9.0 million, and subject to achievement of certain commercial sales milestones, the Company agreed to make milestone payments in the aggregate of up to \$20.0 million. The Company also agreed to pay mid to high single-digit tiered royalty payments based on annual worldwide net sales of licensed products, payable on a licensed product-by-licensed product and country by country basis until the latest of the expiration of the last to expire exclusively licensed patent, the expiration of regulatory exclusivity, and the ten year anniversary of the first commercial sale of such product in such country. The royalty payments are subject to reductions for lack of patent coverage, loss of market exclusivity, and payment obligations for third-party licenses.

#### ***Pfizer Clinical Trial Collaboration and Supply Agreements***

In March 2020, the Company entered into a clinical trial collaboration and supply agreement with Pfizer, Inc., or the Pfizer Agreement, as amended in September 2020, April 2021, September 2021 and May 2023. Pursuant to the Pfizer Agreement, Pfizer supplies the Company with their MEK inhibitor, binimetinib, and their cMET inhibitor, crizotinib, to evaluate combinations of darovasertib independently with each of the Pfizer compounds, in patients with tumors harboring activating GNAQ or GNA11 mutations. Under the Pfizer Agreement, the Company is the sponsor of the combination studies and will provide darovasertib and pay for the costs of the combination studies. Pfizer will provide binimetinib and crizotinib for use in the clinical trial at no cost to the Company. The Pfizer Agreement provides that the Company and Pfizer will jointly own clinical data generated from the clinical trial and will also jointly own inventions, if any, relating to the combined use of darovasertib and binimetinib, or independently, to the combined use of darovasertib and crizotinib. The Company and Pfizer have formed a joint development committee responsible for coordinating all regulatory and other activities under the agreement.

In March 2022, the Company and Pfizer entered into a second clinical trial collaboration and supply agreement, or the Second Pfizer Agreement, pursuant to which the Company is evaluating darovasertib and crizotinib as a combination therapy in MUM in a planned Phase 2/3 potential registration-enabling clinical trial. Pursuant to the Second Pfizer Agreement, the Company is the sponsor of the combination trial and the Company will provide darovasertib and pay for the costs of the combination trial; Pfizer will provide crizotinib for the planned combination trial at no cost to us for up to an agreed-upon number of MUM patients. The Company and Pfizer will jointly own clinical data from the planned combination trial and all inventions relating to the combined use of darovasertib and crizotinib. The Company and Pfizer have formed a joint development committee responsible for coordinating all regulatory and other activities under the Second Pfizer Agreement.

Separately, in March 2022, the Company and Pfizer also entered into a third clinical trial collaboration and supply agreement, or the Third Pfizer Agreement, pursuant to which the Company may, subject to preclinical validation and FDA feedback and guidance, evaluate darovasertib and crizotinib, as a combination therapy in cMET-driven tumors such as NSCLC and/or HCC in a Phase 1 clinical trial. Pursuant to the Third Pfizer



Agreement, the Company is the sponsor of the planned combination trial, and the Company will provide darovasertib and pay for the costs of the combination trial; Pfizer will provide crizotinib for the planned combination trial at no cost to us.

In May 2023, the Company continued **our** relationship with Pfizer by entering into Amendment No. 4 to the Pfizer Agreement relating to the supply of crizotinib in support of this Phase 2 clinical trial, pursuant to which Pfizer will continue to provide us with an additional defined quantity of crizotinib at no cost.

The Company also expanded its relationship with Pfizer in May 2023 under an Amendment No. 1 to the Second Pfizer Agreement to support the Phase 2/3 registrational trial to evaluate darovasertib and crizotinib as a combination therapy in MUM. Under the as-amended Second Pfizer Agreement, Pfizer will provide the Company with a first defined quantity of crizotinib at no cost, as well as an additional second defined quantity of crizotinib at a lump-sum cost. Under Amendment No. 1 to the Second Pfizer Agreement, the Company and Pfizer also terminated the Third Pfizer Agreement.

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#### ***Cancer Research UK and University of Manchester Exclusive Option and License Agreement***

In January 2022, the Company exercised its option for an exclusive worldwide license covering a broad class of PARG inhibitors from Cancer Research Technology Ltd. ("**CRT**") and the University of Manchester, and in connection therewith, paid a one-time option exercise fee of £250,000. The Company will be obligated to make payments to CRT aggregating up to a total of £19.5 million upon the achievement of specific development and regulatory approval events for development of a PARG inhibitor in oncologic diseases. The Company will also pay

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low single-digit tiered royalties, and potentially also sales-based milestones, to CRT based on net sales of licensed products. In addition, in the event the Company sublicenses the intellectual property, it will also be obligated to pay CRT a specified percentage of any sublicense revenue. In April 2023, the Company incurred an obligation to pay milestone payments in an aggregate amount of £750,000 to CRT based upon the achievement of certain milestones relating to first and second tumor histologies in connection with the Phase 1 portion of the Phase 1/2 clinical trial in oncologic diseases.

The Company will be obligated to make additional payments to CRT aggregating up to £18.75 million upon the achievement of specific development and regulatory approval events for development of a PARG inhibitor in oncologic diseases, including an aggregate of up to £1.5 million and up to £2.25 for the achievement of certain Phase 2 and Phase 3 development milestones, respectively, in each case as relating to first and second tumor histologies.

### ***Amgen Clinical Trial Collaboration and Supply Agreement***

In July 2022, the Company entered into a clinical trial collaboration and supply agreement with Amgen Inc., or the Amgen CTCSA, to clinically evaluate IDE397 in combination with AMG 193, the Amgen investigational MTA-cooperative PRMT5 inhibitor, in patients having MTAP-null solid tumors, in a Phase 1/2 clinical trial. Under the mutually non-exclusive Amgen CTCSA, the Company will provide IDE397 drug supply to Amgen, who will be the sponsor of the Phase 1 clinical combination trial evaluating IDE397 and AMG 193. Each party will pay for fifty percent (50%) of the external third-party costs of the combination study. Each party will be responsible for its own internal costs and expenses in support of the combination study. The Company and Amgen will jointly oversee clinical development of the combination therapy through a Joint Oversight Committee responsible for coordinating all regulatory and other activities under the Amgen CTCSA. The parties will jointly own collaboration data and combination-related intellectual property, if any, arising from the combination clinical trial. The Company and Amgen each retain commercial rights to its respective compounds, including with respect to use as a monotherapy agent or combination agent.

### ***Gilead Clinical Study Collaboration and Supply Agreement***

In November 2023, the Company entered into a clinical study collaboration and supply agreement with Gilead Sciences, Inc., or the Gilead CSCSA, to clinically evaluate IDE397 in combination with Trodelvy (sacituzumab-govitecan-hziy), a Trop-2 directed ADC, in patients having MTAP-deletion **bladder urothelial** cancer, in a Phase 1 clinical trial. Under the mutually non-exclusive Gilead CSCSA, the Company will receive Trodelvy drug supply from Gilead and will sponsor the Phase 1 clinical combination trial evaluating IDE397 and Trodelvy. Gilead will bear internal or external costs incurred in connection with its supply of Trodelvy. The Company will bear all internal and external costs and expenses associated with the conduct of the combination study. The Company and Gilead will jointly oversee clinical development of the combination therapy through a Joint Steering Committee responsible for coordinating all regulatory and other activities under the Gilead CSCSA. The Company and Gilead each retain commercial rights to its respective compounds, including with respect to use as a monotherapy agent or combination agent.

### ***Merck Clinical Trial Collaboration and Supply Agreement***

In March 2024, the Company entered Clinical Trial Collaboration and Supply Agreement, or the Merck CTCSA, with MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, or Merck. The Company is planning to evaluate IDE161 in a combination study with **KEYTRUDA® KEYTRUDA®** (pembrolizumab), Merck's

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anti-PD-1 therapy, in patients with MSI-high and MSS endometrial cancer. Pursuant to the Merck CTCSA, the Company is the sponsor of the combination study and the Company will provide the IDE161 compound and pay for the costs of the combination study. Merck will provide KEYTRUDA at no cost to the Company. The Company and Merck will jointly own clinical data from the combination. Each party retains commercial rights to its respective compounds, including with respect to use as a monotherapy or combination agent.

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## 11. Revenue Recognition

The Company recognizes revenue in accordance with ASC 606 for the GSK Collaboration Agreement (see Note 10, Significant Agreements).

### *Disaggregation of Revenue*

The Company recognized no revenue for the quarter three months ended March 31, 2024 June 30, 2024 and \$7.9 3.5 million for the quarter three months ended March 31, 2023 June 30, 2023. The \$7.9 3.5 million revenue for the quarter ended March 31, 2023 consisted June 30, 2023 primarily related to the WRN program.

The Company recognized no revenue for the six months ended June 30, 2024 and \$11.4 million for the six months ended June 30, 2023, consisting of \$7.6 11.0 million, \$0.2 million and \$0.1 0.2 million related to the WRN, MAT2A & Pol Theta and MAT2A programs, respectively.

The Company completed all performance obligations related to the upfront payment under the GSK Collaboration Agreement as of December 31, 2023. Future collaboration revenue recognized under the GSK Collaboration Agreement will be related to future milestone payments as they are earned.

### *Contract Balances*

As of March 31, 2024 June 30, 2024 and December 31, 2023, the Company had no accounts receivable and no contract liabilities related to the GSK Collaboration Agreement.

The Company has identified the following six performance obligations associated with the GSK Collaboration Agreement:

- (i) Preclinical and Phase 1 Monotherapy clinical research and development services under the MAT2A program ("MAT2A R&D Services")
- (ii) Preclinical research services and the related license to IDEAYA-owned technology under the Pol Theta program ("Pol Theta R&D Services")
- (iii) Preclinical research services and the related license to IDEAYA-owned technology under the WRN program ("WRN R&D Services")
- (iv) Material right associated with the option to license IDEAYA-owned technology under the MAT2A program ("Option")
- (v) Material right associated with the option to license to IDEAYA-owned technology under the MAT2A program to the extent necessary for preclinical activities in preparation for the MAT2A Combination Trial ("Preclinical MAT2A License")
- (vi) Material right associated with the supply of MAT2A product for the MAT2A Combination Trial ("MAT2A Supply")

The Company recognizes revenue related to amounts allocated to the MAT2A R&D services as the underlying services are performed over the period through the delivery of the Option data package, which is generated from its conduct of the dose escalation portion of the MAT2A Phase 1 monotherapy clinical trial. The Company uses its internal research and development capability and also engages third-party clinical research organizations, or CROs, for which the Company acts as a principal. The Company has delivered the Option data package to GSK. Accordingly, the performance obligation related to the MAT2A R&D services has been fulfilled.

With respect to the Pol Theta and WRN programs, the Company identified two promises: (1) granting of the license to develop and commercialize Pol Theta and WRN products, respectively, and (2) the preclinical research services. The Company has determined that these two promises are not distinct within the context of the contract.

For the Pol Theta product, the Company achieved and earned a \$7.0 million payment for a milestone in August 2023 based on acceptance of the IND by the FDA, payment. An earlier preclinical development \$3.0 million milestone

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payment from GSK was achieved in August 2022 in connection with ongoing IND-enabling studies to support evaluation of GSK101. The Company has the potential to receive an additional \$10.0 million milestone payment upon initiation of Phase 1 clinical dose expansion.

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For the WRN product, the Company achieved and earned a \$3.0 million payment for a milestone in October 2023 in connection with IND-enabling studies for the Werner Helicase Inhibitor DC. The Company is, in collaboration with GSK, targeting an IND submission in 2024 to enable first-in-human clinical evaluation of its Werner Helicase Inhibitor DC in high MSI tumors.

The Company recognized revenue related to amounts allocated to the Pol Theta R&D Services and WRN R&D Services as the underlying services are performed over the period through the completion of the Pol Theta and WRN preclinical research programs, respectively. Within 90 days from the end of each calendar quarter, GSK reimbursed the Pol Theta program costs incurred by the Company. Within 75 days from the end of each calendar quarter, the Company and GSK determined the amounts of WRN program costs incurred by both parties and the net amount owed by GSK to the Company or by the Company to GSK, which was paid within 75 days from such determination by a reimbursing party. The Company used its internal research capability and may also engage third-party clinical research organizations, or CROs, in transferring the Pol Theta R&D services and WRN R&D services, for which the Company acts as a principal. The Company completed Pol Theta R&D services during December 2022. Accordingly, the performance obligation related to the Pol Theta R&D services has been fulfilled. The Company completed WRN R&D services during December 2023. Accordingly, the performance obligation related to the WRN R&D services has been fulfilled.

As of March 31, 2024 Since December 31, 2023, there are have been no remaining performance obligations related to the WRN, Pol Theta and MAT2A program, programs.

*Significant judgments*

In applying ASC 606 to the GSK Collaboration Agreement, the Company made the following judgments that significantly affect the timing and amount of revenue recognition:

(i) Determination of the transaction price, including whether any variable consideration is included at inception of the contract

The transaction price is the amount of consideration that the Company expects to be entitled to in exchange for transferring promised goods or services to the customer. The transaction price must be determined at inception of a contract and may include amounts of variable consideration. However, there is a constraint on inclusion of variable consideration in the transaction price, if there is uncertainty at inception of the contract as to whether such consideration will be recognized in the future.

The decision as to whether or not it is probable that a significant reversal of revenue will occur in the future, depends on the likelihood and magnitude of the reversal and is highly susceptible to factors outside the Company's influence (for example, the Company cannot determine the outcome of clinical trials; the Company cannot determine if or when the counterparty will initiate or complete clinical trials; and the Company cannot determine if or when an regulatory agency provides any approval). In addition, the uncertainty is not expected to be resolved for a long period and finally, the Company has limited experience in the field. Therefore, at inception of the GSK Collaboration Agreement, development and regulatory milestones were fully constrained and were not included in the transaction price based on the factors noted above.

The Company constrains estimates of other variable consideration, such as reimbursable program costs, to amounts that are not expected to result in a significant revenue reversal in the future. The Company re-evaluates the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

## 12. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Numerator:						
Net loss attributable to common stockholders	\$ (39,572)	\$ (23,640)	\$ (52,772)	\$ (27,926)	\$ (92,344)	\$ (51,566)
Denominator:						
Weighted-average common shares outstanding, basic and diluted <sup>(1)</sup>	75,108,484	48,370,074	77,962,730	56,251,130	76,535,607	52,332,373
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.53)	\$ (0.49)	\$ (0.68)	\$ (0.50)	\$ (1.21)	\$ (0.99)

(1) The shares underlying the pre-funded warrants to purchase shares of the Company's common stock have been included in the calculation of the weighted-average number of shares outstanding, basic and diluted, for the three and six months ended March 31, 2024 June 30, 2024.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	As of March 31,		As of June 30,	
	2024	2023	2024	2023
Options to purchase common stock	7,874,924	6,874,959	7,834,639	7,138,527
Total	7,874,924	6,874,959	7,834,639	7,138,527

13. Subsequent Events

Subsequent to March 31, 2024, from April 1, 2024 through April 24, 2024

On July 11, 2024, the Company sold completed an aggregate underwritten public follow-on offering. The offering consisted of 922,000 8,355,714 shares of common stock for at an offering price to the public of \$35.00 per share, including 1,127,142 shares of common stock upon the exercise in full of the overallotment option by the underwriters, as well as pre-funded warrants to purchase 285,715 shares of common stock at a public offering price of \$34.9999 per underlying share, in each case before underwriting discounts and commissions. Pursuant to the offering, the Company received aggregate gross proceeds of approximately \$37.2 302.4 million, at a weighted average sales price of approximately \$40.40 per share under the at-the-market before deducting underwriting discounts and commissions and other offering pursuant to the January 2024 Sales Agreement with Jefferies as sales agent, generating expenses, resulting in net proceeds of approximately \$36.5 283.8 million, after deducting underwriting discounts and commissions and other estimated offering expense. As expenses.

On July 30, 2024, the Company entered into an option and license agreement for a potential first-in-class B7H3/PTK7 topoisomerase-I-inhibitor-payload BsADC program with Biocytogen Pharmaceuticals (Beijing) Co., Ltd. ("Biocytogen"). The agreement grants IDEAYA an option for an exclusive worldwide license from Biocytogen for a potential first-in-class B7H3/PTK7 topoisomerase-I-inhibitor-payload BsADC program (the "Option"). Under the terms of April 24, 2024, approximately the agreement, IDEAYA will pay Biocytogen an upfront fee and, upon IDEAYA's potential exercise of the Option, an exercise fee totaling up to \$182.1 6.5 million. The Option is exercisable by the Company within a specified time period after the Company obtains all data and results from certain non-GLP toxicology studies specified in the Agreement, which the Company will conduct at its own cost. Subject to the Company's exercise of the Option, Biocytogen will be eligible to receive an option exercise fee, development and regulatory milestone payments and commercial milestone payments, as well as low to mid single-digit royalties on net sales. Total potential milestone payments equal an aggregate of \$400.0 million, including development and regulatory milestone payments of common stock remained available up to be sold under the ATM facility. \$100.0 million.

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described, in or implied, by these forward-looking statements. Please also see the section of this Quarterly Report on Form 10-Q titled "Forward-Looking Statements."*

## Overview

We are a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. Our approach integrates small molecule drug discovery with extensive capabilities in identifying and validating translational biomarkers to develop targeted therapies for select patient populations that are most likely to benefit from these targeted therapies. Our small molecule drug discovery expertise includes discovery and development of small molecule therapeutics. We are applying these capabilities to develop a robust pipeline in precision medicine oncology.

Our clinical pipeline includes four potential first-in-class clinical-stage product candidates – darovasertib (PKC), IDE397 (MAT2A), IDE161 (PARG) and GSK101 (Pol Theta Helicase). We own or control all commercial rights of the three most-advanced of these product candidates: darovasertib, IDE397, and IDE161. We are also advancing our Werner Helicase program for which a development candidate has been selected in collaboration with GlaxoSmithKline, or GSK and, subject to investigational new drug-, or IND-, enabling studies, are targeting an IND in 2024. In July 2024, we entered into an Option and License Agreement with Biocytogen Pharmaceuticals (Beijing) Co., Ltd., or Biocytogen, pursuant to which Biocytogen granted to us an option for an exclusive worldwide license to develop and commercialize products in connection with a potential first-in-class B7H3/PTK7 topo-I-payload bispecific antibody drug conjugate program. We also have multiple earlier-stage preclinical programs. We have established selective, value-accretive collaborations with leading pharmaceutical companies to support our clinical development activities.

### **Darovasertib – PKC Inhibitor Clinical Candidate in Uveal Melanoma and GNAQ/11 Melanomas**

Darovasertib (IDE196) is our most advanced clinical-stage product candidate, which we in-licensed from Novartis. Darovasertib is a potent, selective small molecule inhibitor of protein kinase C, or PKC, which we are developing for genetically-defined cancers having GNAQ or GNA11 gene mutations. PKC is a protein kinase that functions downstream of the GTPases GNAQ and GNA11.

We have achieved double-digit triple-digit patient enrollment and have opened multiple clinical sites, including international sites, in our potential registration-enabling Phase 2/3 clinical trial, designated as IDE196-002. The purpose of the clinical trial is to evaluate darovasertib in combination with crizotinib, Pfizer's investigational cMET inhibitor, in patients having metastatic uveal melanoma, or MUM, with human leukocyte antigen-, or HLA-A\*02:01 negative, or HLA-A2(-), serotype, as part of a second Clinical Trial Collaboration and Supply Agreement, or Second Pfizer agreement, with Pfizer. We are targeting clinical program update(s) in 2024.

We are planning to enroll additional HLA-A\*02:01 positive, or HLA-A2(+), patients as an independent clinical strategy to address HLA-A2(+) MUM patients, in our ongoing Phase 2 clinical trial, designated as IDE196-001. We are further evaluating darovasertib in combination with crizotinib in the Phase 2 expansion arm of IDE196-001 in patients with GNAQ/11 melanomas, including metastatic cutaneous melanoma. We separately initiated and have achieved double-digit patient enrollment in our Phase 2 clinical trial, designated as IDE196-009, evaluating darovasertib as single-agent neoadjuvant and adjuvant therapy in patients having primary uveal melanoma, or UM, with ongoing enrollment and multiple clinical sites open. A clinical efficacy update on over 30 patients and an We have scheduled a Type C meeting with the U.S. Food and Drug Administration, or FDA, regulatory guidance to discuss a potential registrational trial in the neoadjuvant UM setting in the third quarter of 2024 and are targeting a clinical efficacy update are both targeted in over 30 patients in the second half of 2024.

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We are also supporting evaluation of darovasertib as single-agent neoadjuvant and adjuvant therapy in primary UM in an ongoing investigator-sponsored clinical trial, or IST, captioned as "Neoadjuvant / Adjuvant trial of Darovasertib in Ocular Melanoma", or NADOM, led by St. Vincent's Hospital in Sydney with the participation of Alfred Health and the Royal Victorian Eye and Ear Hospital in Melbourne. The In June 2024, we announced interim results clinical data from the ongoing investigator-sponsored Phase 2 trial have

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been accepted for of darovasertib as neoadjuvant/adjuvant treatment in UM, which was included in an oral presentation at the upcoming 2024 American Society of Clinical Oncology, or ASCO, annual meeting 2024 Annual Meeting, and preliminary clinical data from our Phase 2 trial of darovasertib for neoadjuvant UM.

#### *ASCO Clinical Data from Investigator-Sponsored Phase 2 Trial*

In our ongoing investigator-sponsored Phase 2 trial of darovasertib as neoadjuvant/adjuvant treatment in June 2024, UM, 15 patients planned for enucleation with localized UM were treated twice daily with a 300 mg dose of darovasertib in the Phase 2 investigator-sponsored clinical trial as of May 14, 2024. An initial safety cohort of three patients was treated for one month, and the remaining 12 patients were treated in an expansion cohort for up to six months with darovasertib as neoadjuvant treatment prior to their primary intervention (enucleation, plaque brachytherapy or external beam radiotherapy, or EBRT) across three Australian centers. As of May 14, 2024, 13 patients had completed neoadjuvant darovasertib treatment, 11 patients received adjuvant darovasertib treatment after primary treatment of UM, with five patients completing the planned six months of therapy. As of May 14, 2024, 75% (nine out of 12 enucleation patients) had confirmed preservation of the eye, by conversion from planned enucleation to plaque brachytherapy or EBRT, and approximately 67% (eight out of 12 enucleation patients) observed greater than 30% tumor shrinkage (maximum tumor volume change) after six months. Median tumor shrinkage (maximum tumor volume change) in the 12 enucleation patients was approximately 47% after six months. The darovasertib monotherapy neoadjuvant treatment had a manageable adverse event, or AE, profile with no drug-related serious adverse events, or SAEs, observed in the investigator-sponsored Phase 2 trial. Drug-related AEs in the trial were predominantly Grade 1 or Grade 2 and 20% of patients reported at least one drug-related Grade 3 AE.

#### *Company-Sponsored Phase 2 Trial*

As of July 31, 2024, our Phase 2 company-sponsored darovasertib neoadjuvant UM trial has activated 20 sites globally and enrolled over 50 patients. As of May 24, 2024, eight patients (six enucleation and two plaque eligible) had received darovasertib neoadjuvant treatment for four months or more and observed median tumor shrinkage (maximum change in tumor height, base and volume) of approximately 40% in tumor height, 25% in tumor base and 72% in tumor volume and the majority of the six enucleation patients had reported preservation of the eye, by conversion from planned enucleation to plaque brachytherapy or EBRT. In the eight patients that had been treated with neoadjuvant



darovasertib for four months or more as of May 24, 2024, darovasertib had a manageable AE profile with no drug-related SAEs observed in the company-sponsored Phase 2 trial. Drug-related AEs were predominantly Grade 1 or Grade 2 and approximately 13% of patients reported at least one drug-related Grade 3 AE.

We are pursuing a clinical strategy for darovasertib to broadly address uveal melanoma, alternatively referred to as ocular melanoma, in both primary and metastatic settings. Greater than 90% of uveal melanoma patients have tumors harboring GNAQ or GNA11 mutations. There are no FDA approved FDA-approved systemic therapies for primary UM, as either neoadjuvant or adjuvant therapies. There are likewise no FDA approved FDA-approved therapies for patients having MUM with HLA-A\*02:01 negative, or HLA-A2(-), serotype. These primary UM patients and HLA-A2(-) MUM patients collectively represent approximately 85% of all ocular melanoma patients. We have a separate, independent clinical strategy to address HLA-A\*02:01 positive, or HLA-A2(+), MUM patients.

The potentially addressable patient population for MUM is estimated to include an annual incidence of approximately 4,500 patients across the United States, or U.S., and Europe, with an estimated total prevalence of approximately 14,000 patients in the U.S. and Europe. (Neo)Adjuvant UM represents a significant expansion opportunity for darovasertib – with a potential annual incidence of approximately 8,700 patients aggregate in U.S. and Europe and with an estimated total prevalence of approximately 100,000 patients in the U.S. and Europe.

We own or control all commercial rights in our darovasertib program in uveal melanoma, including in MUM and in primary UM, subject to certain economic obligations pursuant to our exclusive, worldwide license to darovasertib with Novartis.

#### *Darovasertib – Potential Registration-Enabling Clinical Trial in First-Line HLA-A2(-) MUM*

The protocol of the Phase 2/3 clinical trial design incorporates guidance and feedback following our Type C meeting with the FDA in March 2023. This protocol includes an integrated Phase 2/3 open-label study-in-study design in first-line MUM patients with an HLA-A2(-) serotype. The clinical trial design employs a Phase 2 portion with median progression free survival, or PFS, as a primary endpoint for potential accelerated approval. Patients enrolled in Phase 2 will continue on treatment within the same study and will be considered, together with additional enrolled patients, to evaluate overall survival, or OS, as the primary endpoint of the Phase 3 portion of the clinical trial to support a potential confirmational approval.

In the Phase 2 portion of the clinical trial, approximately 230 patients will be randomized on a 2:1 basis for treatment with the darovasertib and crizotinib combination in the treatment arm or investigators choice in the control arm, selected from (a) a combination of ipilimumab (ipi) and nivolumab (nivo), (b) PD1-targeted monotherapy or (c) dacarbazine. The treatment arm of the Phase 2 portion of the clinical trial includes a nested study to confirm the move forward combination dose for the integrated Phase 2/3 clinical trial – including cohorts at the Phase 2 expansion doses of (i) darovasertib 300 mg BID + crizotinib 200 mg BID and (ii) darovasertib 200 mg BID + crizotinib 200 mg BID. Under the nested study design, patients enrolled in the cohort at the move forward dose will be included within the Phase 2/3 registrational clinical trial. The Phase 2 portion of the clinical trial contemplates an efficacy and safety data set of approximately 200 patients randomized 2:1 with the treatment arm at the move forward dose to support a potential accelerated approval based on median PFS by blinded independent central review, or BICR, as a primary endpoint. Accelerated approval is intended to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need based on a demonstration of effectiveness on a surrogate endpoint.

Patients enrolled in Phase 2 at the selected dose would continue on treatment and be included in the Phase 3 study analysis, supplemented by enrollment of approximately 120 additional patients into the Phase 3 portion of the clinical trial, with 2:1 randomization on the same basis as the

Phase 2 portion. Efficacy data from the Phase 3 could support potential approval using median OS as a primary endpoint. In May 2023, we expanded our relationship with Pfizer to support the Phase 2/3 registrational trial to evaluate darovasertib and crizotinib as a combination therapy in MUM by entering into Amendment No. 1 to the Second Pfizer Agreement. Under the as-amended Second Pfizer Agreement, Pfizer will provide us with a first defined quantity of crizotinib at no cost, as well as an additional second defined quantity of crizotinib at a lump-sum cost. We anticipate that the supply of crizotinib under the Second Pfizer Agreement, as amended, will be sufficient to support the planned Phase 2 and Phase 3 portions of the Phase 2/3 potentially registrational clinical trial.

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In parallel, we are continuing to evaluate darovasertib in our ongoing Phase 2 clinical trial, designated as IDE196-001, as a combination therapy with crizotinib in MUM patients. We are the sponsor of this Phase 2 clinical trial and are collaborating with Pfizer on this Phase 2 clinical trial pursuant to the Pfizer Agreement.

#### *Prevalence of HLA-A\*02:01 Negative Serotype in MUM*

Data from darovasertib clinical trials in MUM demonstrate that approximately 70% of MUM patients with known HLA-A\*02:01, or HLA-A2 status were HLA-A2(-). As reported at ESMO 2023, the HLA-A2 status was known in subsets of patients enrolled in clinical trials evaluating darovasertib. Prevalence of HLA-A2(+) and HLA-A2(-) in MUM patients was determined from a first data set of n=149 MUM patients treated with darovasertib as monotherapy or in a combination arm of a clinical trial, and separately in a second data set of n=118 MUM patients treated with the darovasertib and crizotinib combination. These data include 102 of 149 (68%) of patients in the all-treatment subset and 81 of 118 (69%) patients in the darovasertib and crizotinib combination treatment subset.

#### *Darovasertib – Strategy for HLA-A\*02:01 Positive MUM*

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Based on clinical data from the Phase 2 clinical trial evaluating darovasertib and crizotinib in MUM as reported at ESMO 2023, and based on the darovasertib mechanism of action, we anticipate darovasertib will have clinical activity independent of HLA-A2 status in GNAQ11-mutation cancers.

We are planning to enroll additional HLA-A\*02:01 positive, or HLA-A2(+), patients as an independent clinical strategy to address HLA-A2(+) MUM patients, in our ongoing Phase 2 clinical trial, designated as IDE196-001. This strategy demonstrates our commitment to fully address the high unmet medical need in MUM. Such clinical trial data from darovasertib and crizotinib combination treatment in HLA-A2(+) MUM could support publication and potential inclusion in NCCN Clinical Practice Guidelines in Oncology.

#### *Darovasertib – Orphan Drug Designation in UM and Fast Track Designation in MUM*

In April 2022, the FDA designated darovasertib as an Orphan Drug in UM, including primary and metastatic disease under 21 C.F.R Part 316. Under an Orphan Drug designation, darovasertib may be entitled to certain tax credits for qualifying clinical trial expenses, exemption from certain user fees and, subject to FDA approval of a New Drug Application, or NDA, for darovasertib in UM, eligibility for seven years of statutory marketing exclusivity. As an FDA-designated Orphan Drug, darovasertib may also be excluded from certain mandatory price negotiation provisions of the 2022 Inflation Reduction Act, if approved.

In November 2022, the FDA granted Fast Track designation to our development program investigating darovasertib in combination with crizotinib in adult patients being treated for MUM. The Fast Track designation makes our darovasertib and crizotinib development program eligible for various expedited regulatory review processes, including generally more frequent FDA interactions, such as meetings and written communications, potential eligibility for rolling review of a future NDA and potential accelerated approval and priority review of an NDA.

#### *Darovasertib - Neoadjuvant and Adjuvant Therapy in Uveal Melanoma (UM)*

We are clinically evaluating the potential for darovasertib as neoadjuvant or adjuvant therapy, or both, also referred to as (neo)adjuvant therapy, in primary, non-metastatic UM patients. We previously reported preliminary clinical data in the neoadjuvant setting showing evidence of anti-tumor activity that we believe supports further clinical evaluation of darovasertib to determine its potential as a neoadjuvant therapy to either save the eye by avoiding enucleation, or to reduce the tumor thickness in the eye, enabling treatment with less radiation to preserve vision, and as an adjuvant therapy, to potentially extend relapse free survival.

We have initiated and achieved double-digit patient enrollment in our company-sponsored Phase 2 clinical trial designated as IDE196-009, with ongoing enrollment and multiple clinical sites open. The purpose of the clinical trial is to evaluate single-agent darovasertib as neoadjuvant treatment of primary UM prior to primary interventional treatment of enucleation or radiation therapy and also as adjuvant therapy following the primary treatment. **A**

We have scheduled a Type C meeting with the FDA to discuss a potential registrational trial in the neoadjuvant UM setting in the third quarter of 2024 and are targeting a clinical efficacy update on in over 30 patients and an FDA regulatory guidance update are both targeted in the second half of 2024.

The IDE196-009 clinical An amendment to the study protocol includes was submitted to the FDA in July 2024 to enable dosing of darovasertib as neoadjuvant and adjuvant therapy up to 12 months each. As part of this amendment the number of patients in the study was increased from 82 to 122 patients and the part 2 of the study will, once the amendment is effective, consist of adjuvant treatment with darovasertib to maximum benefit up to 6 months, primary treatment, then up to 6 months in combination with crizotinib for patients with disease characteristics suggesting high or intermediate risk of follow-up adjuvant therapy, metastasis.

In the neoadjuvant setting, one cohort of UM patients with large tumors will be treated with darovasertib until maximum benefit or six months, at which time they will undergo a primary interventional treatment. The neoadjuvant endpoint for this large-sized tumor cohort is eye preservation. For example, a patient who would otherwise have undergone enucleation would instead be eligible for radiation treatment. Another neoadjuvant cohort of UM patients with small or medium sized tumors will be treated with darovasertib until maximum benefit or six months, at which time they will undergo radiation therapy. Neoadjuvant endpoints for this small- or medium-sized tumor cohort include (i) reducing the radiation dose that the patient receives, relative to the radiation dose they would have otherwise received without the neoadjuvant treatment, and (ii) functional vision preservation.

In the adjuvant setting, each of the two neoadjuvant cohorts will be treated with darovasertib for up to six months as follow-up adjuvant therapy after the primary interventional treatment. The adjuvant endpoints for this portion of the clinical trial include relapse free survival and useful vision.

We are additionally supporting evaluation of darovasertib as (neo)adjuvant therapy in primary UM in the ongoing NADOM IST. Pursuant to an as-amended protocol for the NADOM study, uveal melanoma patients who would otherwise undergo enucleation are instead treated with single agent darovasertib as neoadjuvant treatment for up to six months or maximum benefit. This reflects an increase in potential treatment duration versus the initial approach of one month neoadjuvant therapy, following which these patients will undergo a primary interventional treatment. Patients will subsequently be treated with darovasertib for up to six months as follow-up adjuvant therapy after the primary interventional treatment. The topline results from the trial have been accepted for an oral presentation at the upcoming 2024 ASCO annual meeting.

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#### *Darovasertib – Expansion Opportunity in GNAQ/11 Melanomas*

We have initiated a Phase 2 expansion arm in our IDE196-001 clinical trial evaluating the darovasertib and crizotinib combination in GNAQ/11 melanomas, including metastatic cutaneous melanoma, based on observed preliminary clinical efficacy. There are currently no FDA approved FDA-approved therapies in this indication in this genetically-defined patient population.

The GNAQ/11 prevalence in cutaneous melanoma has been reported at approximately 5% in The Cancer Genome Atlas. The GNAQ/11 cutaneous melanoma estimated annual incidence is approximately 5,000 patients in the United States and 8,000 patients in the EU28, and the estimated total prevalence of GNAQ/11 cutaneous melanoma is approximately 70,000 patients in the United States and 110,000 patients in the EU28. It has been reported that approximately 12.5% to 15% of cutaneous melanoma patients have been reported to develop metastatic disease.

#### **IDE397 – MAT2A Inhibitor in Tumors with MTAP Deletion**

IDE397 is a clinical-stage, potent, selective small molecule inhibitor of methionine adenosyltransferase 2a, or MAT2A, which we are developing for patients having solid tumors with MTAP deletion. The prevalence of methylthioadenosine phosphorylase, or MTAP, gene deletion is estimated to be approximately 15% of human solid tumors. MTAP deletion in patient tumors is identified by commercial or institutional next generation sequencing, or NGS, panels or by MTAP immunohistochemistry, or IHC, assay with confirmation by NGS.

MTAP-null cells lack the ability to metabolize 5-methylthioadenosine, or MTA, which is an essential step in a biochemical pathway involved in salvaging the metabolite S-adenosyl methionine, or SAM. Increased levels of MTA partially inhibit the methyltransferase PRMT5 for which SAM is the methyl-donor substrate for methylation of various proteins. This partial inhibition of PRMT5 by increased levels of MTA renders MTAP-null cells more dependent on the activity of MAT2A, an enzyme that is responsible for the synthesis of SAM. Because of this enhanced dependence, loss of MTAP results in synthetic lethality when MAT2A is pharmacologically inhibited.

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We are enrolling patients into a Phase 1/2 clinical trial designated as IDE397-001 to evaluate IDE397 for patients having certain tumors with MTAP gene deletion. We are proceeding with enrollment of MTAP-deletion patients into a monotherapy Phase 1/2 expansion cohort with an initial focus on high priority solid tumor types, including squamous non-small cell lung cancer, or NSCLC, and bladder urothelial cancers. We have selected a move-forward Phase 1/2 expansion dose for IDE397 monotherapy in MTAP-deletion squamous NSCLC and urothelial cancer, based on adverse event profile and preliminary clinical efficacy observed, including multiple partial responses by RECIST 1.1. The estimated U.S. MTAP-deletion annual incidence in squamous NSCLC and urothelial cancer is estimated approximately 48,000 patients.

#### *Company-Sponsored Phase 1/2 Monotherapy Expansion in MTAP-Deletion Urothelial and Lung Cancer*

In July 2024, we announced clinical data for the IDE397 Phase 1/2 monotherapy expansion dose demonstrating preliminary clinical efficacy in heavily pre-treated MTAP-deletion urothelial cancer and squamous NSCLC patients. The patients evaluated had a median of two prior lines of therapy, ranging from one to have nine prior lines of treatment. The reported Phase 1/2 clinical data were based on 18 evaluable MTAP-deletion patients, including seven urothelial cancer patients, four adenocarcinoma squamous NSCLC patients, and seven squamous NSCLC patients at the expansion dose of 30 mg once-a-day, or QD, of IDE397. In the interim update for 18 evaluable patients, with a global annual incidence greater than 100,000 patients. In addition, multiple data analysis cutoff date of June 21, 2024, we reported an overall response rate of approximately 39% (one complete response and six partial responses by RECIST 1.1 have evaluation), which includes two unconfirmed partial responses (one urothelial cancer patient that had a 100% tumor reduction in the target lesion at the last CT-scan assessment that has now been confirmed and one adenocarcinoma squamous NSCLC patient that is awaiting confirmation as of July 31, 2024). We also been observed a disease control rate of 94%, including one complete response, six partial responses and ten stable disease by RECIST 1.1 evaluation. In addition, we observed tumor shrinkage in MTAP-deletion bladder 14 of the 18 evaluable patients. 11 of the evaluable patients are still on treatment and five of the seven responses by RECIST 1.1 evaluation remain in response. We also reported a ctDNA molecular response, or MR, rate of 81%, representing 13 of 16 reportable patients with 50% or greater ctDNA reduction (several quality control failures of patient samples precluded the other patients from MR analysis).

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Regarding safety data, we also reported a favorable AE profile at the 30 mg QD expansion dose. Approximately 5.6% of patients experienced a Grade 3 or higher drug-related AE at the 30 mg QD dose, represented by one instance of Grade 3 asthenia, and no drug-related SAEs were observed. We observed no drug-related AEs leading to discontinuations, and one non-evaluable patient discontinued due to rapid clinical progression of cancer with IDE397 monotherapy fatigue and evaluation is ongoing for further drug-unrelated adverse events in the first cycle of treatment. We anticipate that the favorable AE profile and dosing convenience of a 30 mg QD tablet has the potential Phase 2 expansion in this tumor type. to enable long-term dosing and combination development.

We are collaborating with Amgen to clinically evaluate IDE397 in combination with AMG 193, the Amgen investigational MTA-cooperative PRMT5 inhibitor, in patients having tumors with MTAP deletion, in an Amgen-sponsored clinical trial pursuant to our Clinical Trial Collaboration and Supply Agreement with Amgen, or the Amgen CTCSA.

The combination of IDE397 with AMG 193 is a novel and potential first-in-class synthetic lethality combination which targets two distinct and mechanistically complementary nodes of the MTAP methylation pathway – MAT2A and PRMT5, providing a complementary approach for targeting MTAP-null tumors.

In August 2023, Amgen initiated and dosed a first patient in the IDE397 /AMG 193 combination study, following FDA authorization to proceed with the clinical trial. This Phase 1/2 clinical trial (NCT: 05975073) will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of IDE397 in combination with AMG 193, with an initial focus for expansion in NSCLC patients and an estimated enrollment of approximately 180 patients. Enrollment is ongoing in the dose escalation portion of this Phase 1/2 clinical trial. We are targeting the development of a joint publication strategy in 2024. Separately, in consultation with Amgen, we have now financially budgeted to support our obligations for target IDE397 / AMG 193 clinical combination expansion in NSCLC.

We are separately collaborating with Gilead to clinically evaluate IDE397 in combination with sacituzumab-govitecan-hziy, or Trodelvy, Gilead's Trop-2 directed anti-body conjugate, or ADC, in patients having MTAP MTAP- deletion bladder urothelial cancer, in the our Phase 1 IDEAYA-sponsored clinical trial pursuant to a Clinical Study Collaboration and Supply Agreement, or Gilead CSCSA, with Gilead Sciences, Inc., or Gilead. Trial initiation activities A first patient was dosed for the IDE397 Phase 1 trial in June 2024 and Trodelvy clinical combination are ongoing and the dosing of a first patient enrollment is anticipated in mid-year, or the second or third quarters of, 2024. ongoing.

We are also advancing multiple preclinical stage MTAP-deletion programs to enable wholly-owned combinations with IDE397, including a program targeting a development candidate nomination in the second half of 2024. We own all rights, title, and interest in and to IDE397 and the MAT2A program, including all worldwide commercial rights thereto.

#### **IDE161 – PARG Inhibitor in Tumors with Homologous Recombination Deficiency**

We are evaluating IDE161, a small molecule inhibitor of poly (ADP-ribose) glycohydrolase, or PARG, being evaluated in a Phase 1/2 clinical trial designated as IDE161-001 for patients having tumors with homologous recombination deficiency, or HRD, and potentially other genetic and/or molecular signatures. PARG is a novel target in a clinically validated biological pathway. PARG functions as a regulator of DNA repair in the same biochemical pathway as poly-(ADP-ribose) polymerase, or PARP. PARG hydrolyzes poly (ADP-ribose), or PAR, chains that are polymerized by PARP enzymes, completing the PAR cycle. Small molecule inhibitors of PARG result in a dose dependent increase in cellular PAR after DNA damage. PARG is a mechanistically distinct target relative to PARP.

We are progressing with enrollment of patients having tumors with HRD into the Phase 1 expansion portion of the Phase 1/2 clinical trial in selected priority tumors. In parallel, we are also continuing with Phase 1 dose optimization to confirm a move-forward expansion dose for the planned Phase 2 portion of the clinical trial. We are targeting an initial Phase 2 monotherapy expansion in HRD solid tumors in the second half of 2024. We are also validating IDE161 combination opportunities preclinically and targeting identification of potential combination(s) in 2024. The expansion portion of the Phase 1 trial has a strategic focus in estrogen receptor positive, or ER+, human epidermal growth factor receptor 2 negative, or Her2(-), breast cancer with HRD, as well as other solid tumors with

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HRD, such as endometrial cancer, colorectal cancer and prostate cancer. The ER+, Her2-, HRD+ breast cancer focus represents approximately 10% to 14% of breast cancer patients.

In September 2023, we received Fast Track Designation from the FDA for IDE161 for ovarian cancer and breast cancer indications. Specifically, for IDE161, Fast Track Designation was received for the treatment of adult patients having advanced or metastatic ovarian cancer

with germline or somatic BRCA 1/2 mutations who are platinum resistant and have received prior antiangiogenic and PARP inhibitor therapies. The Fast Track Designation was also received for IDE161 for the treatment of adult patients having advanced or metastatic HR+, Her2- breast cancer with germline or somatic BRCA 1/2 mutations who have progressed following treatment with at least one line of a hormonal therapy, a CDK4/6 inhibitor therapy and a PARP inhibitor therapy.

We entered into an exclusive license under the Evaluation, Option and License Agreement, by and among the Company, Cancer Research Technologies Ltd., also known as Cancer Research United Kingdom, or CRT, and the University of Manchester, pursuant to which we hold exclusive worldwide license rights covering a broad class of PARG inhibitors.

In April 2023, we incurred an obligation to pay milestone payments in an aggregate amount of £750,000 to CRT based upon the achievement of certain milestones relating to first and second tumor histologies in connection with the Phase 1 portion of the IDE161-001 Phase 1/2 clinical trial in oncologic diseases. We will be obligated to make additional payments to CRT aggregating up to £18.75 million upon the achievement of specific development and regulatory approval events for development of a PARG inhibitor in oncologic diseases, including an aggregate of up to £1.5 million and up to £2.25 for the achievement of certain Phase 2 and Phase 3 development milestones, respectively, in each case as relating to first and second tumor histologies.

In March 2024, we entered into the **Clinical Trial Collaboration and Supply Agreement, or** Merck CTCSA with MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. We are planning to evaluate IDE161 in a combination study with **KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, KEYTRUDA** in patients with high microsatellite instability, or MSI, and microsatellite stable, or MSS, endometrial cancer. We are targeting a first-patient dosing for this study in the second half of 2024.

**KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.**

We own or control all commercial rights in our PARG program, subject to certain economic obligations pursuant to our exclusive, worldwide license to certain PARG inhibitors, including IDE161, with CRT and University of Manchester.

#### ***GSK101 (IDE705) - Pol Theta Helicase Inhibitor in tumors with Homologous Recombination Deficiency***

We discovered GSK101 (IDE705), our DNA Polymerase Theta, or Pol Theta, Helicase inhibitor clinical development candidate, and evaluated GSK101 in preclinical studies in collaboration with GSK. GSK101 targets the helicase domain of the Pol Theta protein for patients having solid tumors with BRCA or other mutations associated with HRD.

Pol Theta is involved in a DNA repair process called microhomology mediated end joining, or MMEJ, that is utilized when homologous recombination mediated repair is compromised, as happens in the case of certain BRCA1 or BRCA2 mutations. The expression of Pol Theta is largely absent in normal cells, but tumor cells harboring double strand break repair defects, such as BRCA1 or BRCA2 mutations, show higher Pol Theta expression and synthetic lethality when Pol Theta is inhibited. Pol Theta is a large protein with two functional domains: a DNA polymerase domain and an ATP-dependent DNA helicase domain, sometimes referred to as an ATPase domain, linked by a RAD51 central region.

GSK is evaluating GSK101 in combination with niraparib, the GSK small molecule inhibitor of PARP for the treatment of patients having tumors with BRCA or other HR mutations, or HRD, in a GSK-sponsored Phase 1 clinical trial. GSK has dosed the first patient and enrollment is ongoing in the dose escalation portion of this study.



GSK is leading clinical development of GSK101 pursuant to the Collaboration, Option and License Agreement with GSK, or GSK Collaboration Agreement. GSK is responsible for all research and development costs for the Pol Theta program.

We have the potential to receive an additional \$10.0 million milestone payment upon initiation of Phase 1 clinical dose expansion. In August 2023, we achieved and earned a \$7.0 million milestone based on acceptance of the IND by the FDA, for which payment was received in October 2023. An earlier preclinical development \$3.0 million milestone payment from GSK was achieved in August 2022 in connection with ongoing IND-enabling studies to support evaluation of GSK101.

We have the potential to earn further aggregate late-stage development and regulatory milestones of up to \$465 million. Upon commercialization, we will be eligible to receive up to \$475 million of commercial milestones, and tiered royalties on global net sales of GSK101 – ranging from high single-digit to sub-teen double-digit percentages, subject to certain customary reductions.

#### ***WRN Inhibitors in Tumors with High Microsatellite Instability***

We are advancing our preclinical IND-enabling studies and other preclinical research in collaboration with GSK for an inhibitor targeting Werner Helicase, or WRN, for patients having tumors with high MSI.

WRN protein is a RecQ enzyme involved in the maintenance of genome integrity. Germline loss of function mutations in WRN lead to premature aging and pre-disposition to cancer. MSI is a change in the DNA content of a tumor cell in which the number of repeats of microsatellites, short repeated sequences of DNA, differ as cells divide. High MSI is present in about 15% of gastrointestinal tumor cancers, including in approximately 22% of stomach adenocarcinoma and 16% of colorectal cancer. Tumors with high MSI are routinely assessed in multiple diagnostic profiling tests.

WRN is a protein having several functional domains, and we have shown that the helicase functional domain of WRN is responsible for this synthetic lethal interaction, as reflected in our publication in Cell Press - iScience, Werner Syndrome Helicase is Required for the Survival of Cancer Cells with Microsatellite Instability (March 2019).

We have demonstrated *in vivo* efficacy with tumor regression and PD response in a relevant high MSI model. We have observed selectivity of our Werner Helicase inhibitor and validation of the synthetic lethal relationship to tumors with high MSI over tumors with MSS based on a lack of *in vivo* pharmacological response in relevant MSS xenograft models.

A Werner Helicase Inhibitor development candidate, or DC, has been selected in collaboration with GSK. We, in collaboration with GSK, have completed the IND-enabling GLP toxicology studies and we are targeting an IND submission in the second half of 2024 to enable first-in-human clinical evaluation of Werner Helicase Inhibitor DC for patients having tumors with high MSI. Subject to IND submission and clearance, GSK will lead clinical development for the Werner Helicase program. GSK is responsible for 80% of global research and development costs and IDEAYA is we are responsible for 20% of such costs. GSK holds a global, exclusive license to develop and commercialize the Werner Helicase Inhibitor DC.

In October 2023, we achieved and earned a \$3 million \$3.0 million milestone in connection with IND-enabling studies. We have the potential to earn up to an additional \$17 million aggregate milestone payments through early Phase 1 clinical studies, including \$7.0 million upon IND clearance. We are also eligible to receive additional future aggregate total development milestones of up to \$465 million \$465.0 million. Upon commercialization, we will be eligible to receive up to \$475 million \$475.0 million of commercial milestones, 50% of U.S. net profits and tiered royalties on global non-U.S. net sales of the Werner Helicase Inhibitor DC – ranging from high single-digit to sub-teen double-digit percentages, subject to certain customary reductions.



### **B7H3/PTK7 topo-I-payload bispecific antibody drug conjugate (BsADC) program with Biocytogen**

In July 2024, we entered into an option and license agreement with Biocytogen, pursuant to which Biocytogen granted us an option for an exclusive worldwide license from Biocytogen for a potential first-in-class B7H3/PTK7 topoisomerase-I-inhibitor-payload BsADC program, or the Option. B7H3/PTK7 has been found to be co-expressed in multiple solid tumor types, including double-digit percent prevalence in lung, colorectal, and head and neck cancers, among others. Based on preclinical data, the potential first-in-class B7H3/PTK7

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topoisomerase-I-inhibitor-payload BsADC program has the potential to be developed as a monotherapy agent and used in combination with multiple programs in our pipeline targeting DDR-based therapies, including our PARG inhibitor IDE161. A development candidate nomination for the B7H3/PTK7 topoisomerase-I-inhibitor payload BsADC program is targeted for the second half of 2024.

Under the terms of the agreement, we will pay Biocytogen an upfront fee and, upon our potential exercise of the Option, an exercise fee totaling up to \$6.5 million. We may exercise the Option within a specified time period after we obtain all data and results from certain non-GLP toxicology studies specified in the Agreement, which we will conduct at our own cost.

Subject to our exercise of the Option, Biocytogen will be eligible to receive an option exercise fee, development and regulatory milestone payments and commercial milestone payments, as well as low to mid single-digit royalties on net sales. Total potential milestone payments equal an aggregate of \$400.0 million, including development and regulatory milestone payments of up to \$100.0 million. Our royalty obligations continue with respect to each country and each product until the later of (i) the date on which such product is no longer covered by certain intellectual property rights in such country and (ii) the 10<sup>th</sup> anniversary of the first commercial sale of such product in such country.

### **Next-Generation Precision Medicine Pipeline Programs**

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We have initiated early preclinical research programs focused on pharmacological inhibition of several new targets, or NTs, for patients with solid tumors characterized by defined biomarkers based on genetic mutations and/or molecular signatures. We believe these research programs have the potential for discovery and development of first-in-class or unique-in-class or best-in-class therapeutics. We are targeting development candidate nominations in the second half of 2024 for multiple NTs, including a development candidate to treat MTAP-deletion solid tumors to enable a potential wholly-owned clinical combination with IDE397, IDE397, and separately a potential first-in-class program in the KAT6 pathway. Collectively, we believe these efforts will further advance our multi-pronged clinical and business strategy. We own or control all commercial rights in our next-generation NT programs.

### **New Target and Biomarker Discovery Platform**

Since inception of the company, our core research has and continues to be focused on precision medicine oncology, with synthetic lethality as a central tenet. We have invested significantly and continue to invest in capabilities for identification and validation of new precision medicine targets and biomarkers for patient selection. For targets of interest, we advance our research to discover therapeutic drugs and to further qualify relevant biomarkers.

#### **Small and Medium Enterprise Status from the European Medicines Agency**

In June 2024, we were granted Small and Medium Enterprise (SME) status by the European Medicines Agency (EMA). This enables us to have access to administrative, regulatory and financial support, including fee reductions for scientific advice and regulatory procedures across all our programs.

#### **Prospectus Supplement - At-the-Market Facility**

In June 2023, we entered into an Open Market Sales Agreement, or June 2023 Sales Agreement, with Jefferies LLC (Jefferies) relating to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, par value \$0.0001 per share ("common stock"), having aggregate gross proceeds of up to \$250.0 million through Jefferies as sales agent. During the quarter ended March 31, 2024, pursuant to the June 2023 Open Market Sales Agreement, with Jefferies as a sales agent, we sold an aggregate of 6,115,516 shares of common stock through at-the-market offerings for aggregate net proceeds of \$215.9 million, after deducting underwriting discounts and commissions and other offering expenses, at a weighted average sales price of approximately \$36.39 per share.

On January 19, 2024, we entered into a new Open Market Sales Agreement, or January 2024 Sales Agreement, with Jefferies, or Jefferies, relating to an at-the-market offering program under which we may offer and sell, from time to time at our sole discretion, shares of common stock, par value \$0.0001 per share, or common stock, having aggregate gross proceeds of up to \$350.0 million through Jefferies as sales agent.

During the quarter three months ended March 31, 2024 June 30, 2024, pursuant to the January 2024 Sales Agreement, we sold an aggregate of 3,144,866 922,000 shares of common stock through at-the-market offerings for aggregate net proceeds of \$127.6 million at a weighted average sales price of approximately \$41.53 per share. As of March 31, 2024 \$36.5 million, approximately \$219.4 million of common stock remained available to be sold under the ATM facility.

Subsequent to March 31, 2024, from April 1, 2024 through April 24, 2024, we sold an aggregate of 922,000 shares of common stock for aggregate gross proceeds of approximately \$37.2 million after deducting underwriting discounts and commissions and other offering expenses, at a weighted average sales price of approximately \$40.40 per share through at-the-market offerings, generating net proceeds of approximately \$36.5 million, after deducting underwriting discounts and commissions and other estimated offering expense, pursuant to the January 2024 Sales Agreement with Jefferies as sales agent. share. As of April 24, 2024 June 30, 2024, approximately \$182.1 million of common stock remained available to be sold under pursuant to the ATM facility. January 2024 Sales Agreement.

We may cancel our at-the-market program at any time upon written notice, pursuant to its terms.

#### **Corporate Update**

We do not have any products approved for sale and have not generated any product revenue since inception. We have funded our operations primarily through the sale and issuance of common stock and the upfront payment and certain milestone payments received from GSK. As of **March 31, 2024** **June 30, 2024**, we had cash, cash equivalents and marketable securities of **\$941.4 million** **\$952.7 million**, consisting primarily of money market funds, U.S. government securities, commercial paper, and corporate bonds.

Since our inception in June 2015, we have devoted substantially all of our resources to discovering and developing our product candidates. We have incurred significant operating losses to date and expect that our operating expenses

will increase significantly as we advance our product candidates through preclinical and clinical development; seek regulatory approval, and prepare for, and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. Certain program costs that contribute to our operating expenses have been and/or will be reimbursed by GSK pursuant to the GSK Collaboration Agreement, including 100% of costs we incur for research we perform in connection with the Pol Theta program and 80% of the aggregate program costs incurred by us and GSK for research each of us performs for the Werner Helicase program. We anticipate that payments which we may make to Amgen will also contribute to our operating expenses as they are reimbursed by us pursuant to the Amgen CTCSA, including 50% of external costs Amgen incurs in connection with the Amgen-sponsored and executed IDE397 / AMG 193 Combination Study. We anticipate that we will also incur costs in accordance with the Gilead CSCSA. Gilead will bear internal or external costs incurred in connection with its supply of Trodelvy. We will bear all internal and external costs and expenses associated with the conduct of the combination study. We further anticipate that we will also incur costs in accordance with the Merck CTCSA. Merck will provide KEYTRUDA for the combination study at no cost to us. We will bear all internal and external costs and expenses associated with the conduct of the combination study. In addition, we expect to incur additional costs associated with operating as a public company.

Our net losses were **\$39.6 million** **\$92.3 million** and **\$23.6 million** **\$51.6 million** for the **three** **six** months ended **March 31, 2024** **June 30, 2024** and **March 31, 2023** **June 30, 2023**, respectively. As of **March 31, 2024** **June 30, 2024**, we had an accumulated deficit of **\$387.9 million** **\$440.7 million**.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, ourselves, or for some programs, in collaboration with our strategic partners.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

As of **March 31, 2024** **June 30, 2024**, we had cash, cash equivalents, and short-term and long-term marketable securities of **\$941.4 million** **\$952.7 million**.

We believe that our cash, cash equivalents, and short-term and long-term marketable securities will be sufficient to fund our planned operations for at least twelve months from the date of the issuance of our Quarterly Report on Form 10-Q filed **May 7, 2024** **August 6, 2024**.

These funds will support our efforts through potential achievement of multiple preclinical and clinical milestones across multiple programs.

## Components of Operating Results

### Collaboration Revenues

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales unless and until we are able to initiate a registrational clinical trial, obtain regulatory approval and commercialize one of our product candidates in the future. Our revenue consists exclusively of collaboration revenue under the GSK Collaboration Agreement, including amounts that are recognized related to previously received upfront payments and amounts due and payable to us for research and development services. The amount

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of revenue recognized related to the GSK Collaboration Agreement, including as related to the previously received upfront payment or to certain development milestone payments, may vary considerably by period and certain components thereof may generally decrease year-over-year as we satisfy remaining performance obligations, for example, relating to the Pol Theta and WRN R&D Services. As of **March 31, 2024** **June 30, 2024**, we have fully recognized the contract liabilities related to the upfront payment and reimbursements for the research and development performance obligations under the GSK Collaboration Agreement. There are no remaining contract liabilities as of **March 31, 2024** **June 30, 2024** as we concluded all the research and development performance obligations under the GSK Collaboration Agreement. The future revenue recognition will be contingent on additional milestone earned, profit sharing and royalties on any net product sales under our collaborations. We expect that any revenue we recognize or generate under the GSK Collaboration Agreement will fluctuate from period to period due to period to period variability in milestone payments and other payments.

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## **Operating Expenses**

### *Research and Development Expenses*

Substantially all of our research and development expenses consist of expenses incurred in connection with discovery and development of our product candidates. These expenses include certain payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expenses for our research and product development employees, fees to third parties to conduct certain research and development activities on our behalf including fees to CMOs and CROs in support of manufacturing and clinical activity for darovasertib, IDE397, IDE161 and WRN, consulting costs, costs for laboratory supplies, costs for product licenses and allocated overhead, including rent, equipment, depreciation, information technology costs and utilities. We expense both internal and external research and development expenses as they are incurred.

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Costs of certain activities, such as preclinical studies, are generally recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheet. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We do not allocate our internal costs by product candidate, including internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead. With respect to internal costs, several of our departments support multiple product candidate research and development programs, and therefore the costs cannot be allocated to a particular product candidate or development program. The following table summarizes our external clinical development expenses by program:

	Three Months Ended		Three Months Ended	
	March 31, 2024	December 31, 2023	June 30, 2024	March 31, 2024
External clinical development expenses <sup>(1)</sup> :				
Darovasertib	\$ 10,869	\$ 8,050	\$ 14,895	\$ 10,869
IDE397 <sup>(2)</sup>	2,926	3,499	4,064	2,926
IDE161	2,695	3,132	2,059	2,695
Personnel related and stock-based compensation	12,254	10,213	14,534	12,254
Other research and development expenses	14,061	13,876	18,981	14,061
Total research and development expenses	\$ 42,805	\$ 38,770	\$ 54,533	\$ 42,805

	Three Months Ended	
	March 31, 2024	March 31, 2023
External clinical development expenses <sup>(1)</sup> :		
Darovasertib	\$ 10,869	\$ 4,720
IDE397 <sup>(2)</sup>	2,926	3,251
IDE161	2,695	723
Personnel related and stock-based compensation	12,254	8,870
Other research and development expenses	14,061	10,295
Total research and development expenses	\$ 42,805	\$ 27,859

	Six Months Ended	
	June 30, 2024	June 30, 2023
External clinical development expenses <sup>(1)</sup> :		
Darovasertib	\$ 25,764	\$ 9,814
IDE397 <sup>(2)</sup>	6,991	6,718
IDE161	4,754	2,579
Personnel related and stock-based compensation	26,789	18,514
Other research and development expenses	33,040	19,412
<b>Total research and development expenses</b>	<b>\$ 97,338</b>	<b>\$ 57,037</b>

(1) External clinical development expenses include manufacturing and clinical trial costs. These expenses are primarily for services provided by external consultants, CMOs and CROs.

(2) IDE397 includes costs from Amgen Clinical Trial Collaboration and Supply Agreement.

We are focusing substantially all of our resources on the development of our product candidates. We expect our research and development expenses to increase substantially during the next few years, as we seek to initiate and/or advance clinical trials for our product candidates, complete our clinical program, pursue regulatory approval of our product candidates and prepare for a possible commercial launch. Predicting the timing or the cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expense, professional fees for legal, patent, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase, as a result of increased personnel costs, including salaries, benefits and stock-based compensation expense, patent costs for our product candidates, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with our Nasdaq stock exchange listing and requirements of the Securities and

Exchange Commission, or the SEC, investor relations costs and director and officer insurance policy premiums associated with being a public company.

### Other Income (Expense)

#### Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

### Results of Operations

A discussion regarding our financial condition and results of operations for the three months ended **March 31, 2024** **June 30, 2024** compared to the three months ended **December 31, 2023** **March 31, 2024** and **three** six months ended **March 31, 2023** **June 30, 2024** compared to the six months ended **June 30, 2023** is presented below.

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#### Comparison of Three Months Ended **March 31, 2024** **June 30, 2024** and **December 31, 2023** **March 31, 2024**

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended				Three Months Ended			
	March 31, 2024	December 31, 2023	Change	% Change	June 30, 2024	March 31, 2024	Change	% Change
Revenue:								
Collaboration revenue	\$ —	\$ 3,923	\$ (3,923)	(100 %)	\$ —	\$ —	\$ —	—
Operating expenses:								
Research and development	42,805	38,770	4,035	10 %	54,533	42,805	11,728	27 %
General and administrative	8,212	7,068	1,144	16 %	10,394	8,212	2,182	27 %
Loss from operations	(51,017)	(41,915)	(9,102)	22 %	(64,927)	(51,017)	(13,910)	27 %
Interest income and other income, net	11,445	7,960	3,485	44 %	12,155	11,445	710	6 %
Net loss	\$ (39,572)	\$ (33,955)	\$ (5,617)	17 %	\$ (52,772)	\$ (39,572)	\$ (13,200)	33 %

#### Collaboration Revenue

There was no collaboration revenue recognized for the three months ended March 31, 2024 compared to \$3.9 million June 30, 2024 and for the three months ended December 31, 2023 March 31, 2024. We completed all performance obligations related to the upfront payment under the GSK Collaboration Agreement as of December 31, 2023. Future collaboration revenue recognized under the GSK Collaboration Agreement will be related to future milestone payments as they are earned.

#### Research and Development Expenses

Research and development expenses increased by \$4.0 million \$11.7 million, or 10% 27%, during the three months ended March 31, 2024 June 30, 2024 compared to the three months ended December 31, 2023 March 31, 2024 due to an increase of \$3.9 million \$8.2 million primarily driven by our potentially registration-enabling darovasertib clinical trial fees paid to CROs, CMOs and Werner Helicase program expenses, \$0.8 million in stock-based compensation consultants related to the advancement of our annual option grants lead product candidates through preclinical and \$1.2 million clinical studies, increase in \$2.3 million in personnel-related expenses, including stock-based compensation and salaries and benefits to support our growth, and \$0.3 million an increase in \$1.2 million in costs for laboratory supplies, facilities and software to support our research and development programs, which was partially offset by a decrease of \$2.2 million driven by timing of clinical pharmacology studies and CMC manufacturing costs for darovasertib programs.

#### General and Administrative Expenses

General and administrative expenses increased by \$1.1 million \$2.2 million, or 16% 27%, during the three months ended March 31, 2024 June 30, 2024 compared to the three months ended December 31, 2023 March 31, 2024. The increase in general and administrative expenses was primarily due to increases of \$0.7 million \$1.2 million in stock-based compensation related to our annual option grants and \$0.4 million personnel-related expenses, including salaries and benefits to support our growth, growth, and \$1.0 million in fees paid to consultants.

#### Interest Income and Other Income (Expense), Net

Interest income increased by \$3.5 million \$0.7 million, or 44% 6%, during the three months ended March 31, 2024 June 30, 2024 compared to the three months ended December 31, 2023 March 31, 2024, primarily due to higher investment balances and interest rates.

#### Comparison of Three Six Months Ended March 31, 2024 June 30, 2024 and 2023 June 30, 2023

The following table summarizes our results of operations for the periods indicated (in thousands):

Three Months Ended March 31,	Six Months Ended June 30,
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	% 2024 2023 Change Change				% 2024 2023 Change Change			
Revenue:								
Collaboration revenue	\$ —	\$ 7,880	\$ (7,880)	(100)%	\$ —	\$ 11,424	\$ (11,424)	(100)%
Operating expenses:								
Research and development	42,805	27,859	14,946	54%	97,338	57,037	40,301	71%
General and administrative	8,212	6,300	1,912	30%	18,606	13,375	5,231	39%
Loss from operations	(51,017)	(26,279)	(24,738)	94%	(115,944)	(58,988)	(56,956)	97%
Interest income and other income, net	11,445	2,639	8,806	334%	23,600	7,422	16,178	218%
Net loss	\$ (39,572)	\$ (23,640)	\$ (15,932)	67%	\$ (92,344)	\$ (51,566)	\$ (40,778)	79%

#### Collaboration Revenue

There was no collaboration revenue recognized for the three six months ended March 31, 2024 June 30, 2024 compared to \$7.9 million \$11.4 million for the three six months ended March 31, 2023 June 30, 2023. We completed all performance obligations related to the upfront payment under the GSK Collaboration Agreement as of December 31, 2023. Future collaboration revenue recognized under the GSK Collaboration Agreement will be related to future milestone payments as they are earned.

#### Research and Development Expenses

Research and development expenses increased by \$14.9 million \$40.3 million, or 54% 71%, during the three six months ended March 31, 2024 June 30, 2024 compared to the three six months ended March 31, 2023 June 30, 2023. The increase in research and development expenses was primarily due to increases of \$11.0 million \$29.6 million in fees paid to CROs, CMOs and consultants related to the advancement of our lead product candidates through preclinical and clinical studies, \$1.7 million in stock-based compensation and

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\$1.7 million increases of \$8.3 million in personnel-related expenses, including stock-based compensation and salaries and benefits to support our growth, and \$0.5 million increases in \$2.4 million in costs for laboratory supplies, facilities, and software to support our research and development programs.

#### General and Administrative Expenses

General and administrative expenses increased by \$1.9 million \$5.2 million, or 30% 39%, during the three six months ended March 31, 2024 June 30, 2024 compared to three six months ended March 31, 2023 June 30, 2023. The increase in general and administrative expenses was primarily due to increases of \$0.8 million for \$1.8 million of consulting and legal services and \$1.0 million increases in \$3.4 million of

personnel-related expenses, including stock-based compensation and \$0.3 million in personnel-related expenses, including salaries and benefits related to an increase in headcount to support our growth, partially offset by a decrease of \$0.2 million in facility costs due to larger allocation to research & development expenses. growth.

#### *Interest Income and Other Income (Expense), Net*

Interest income increased by \$8.8 million \$16.2 million, or 334% 218%, during the three six months ended March 31, 2024 June 30, 2024 compared to the three six months ended March 31, 2023 June 30, 2023, primarily due to higher investment balances and interest rates.

## **Liquidity and Capital Resources; Plan of Operations**

### **Sources of Liquidity**

We have funded our operations primarily through the sale and issuance of common stock and the upfront payment and certain milestone payments received from GSK. As of March 31, 2024 June 30, 2024, we had cash, cash equivalents and marketable securities of \$941.4 million \$952.7 million, consisting primarily of money market funds, U.S. government securities, commercial paper, and corporate bonds.

### **Material Cash Requirements**

We have incurred net losses since our inception. For the three six months ended March 31, 2024 June 30, 2024 and three six months ended March 31, 2023 June 30, 2023, we had net losses of \$39.6 million \$92.3 million and \$23.6 million \$51.6 million, respectively, and we expect to incur substantial additional losses in future periods. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of \$387.9 million \$440.7 million. Based on our current business plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of this Quarterly Report on Form 10-Q.

To date, we have not generated any product revenue. We do not expect to generate any meaningful product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, it will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional costs associated with operating as a public company.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaboration or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and

when needed would have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies;

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- the cost, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company; and
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise

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additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

We lease our laboratory and office facilities in 7000 Shoreline Court, South San Francisco, California under an operating lease with an expiration date in September 2024. In May 2018, we amended our 7000 Shoreline Court facility lease agreement to expand the size of the original premises by adding approximately 7,340 rentable square feet of additional space. In September 2019, we further amended our 7000 Shoreline Court facility lease agreement to expand the size of the premises by adding 5,588 rentable square feet of additional space. In April 2024, we again amended our 7000 Shoreline Court facility lease agreement to extend the expiration date from July 2024 to September 2024. As a result, we expect to make the total lease payments of \$1.5 million \$0.9 million through September 2024.

In June 2023, we entered into a lease agreement for 43,966 square feet of space at 5000 Shoreline Court, South San Francisco, California. The lease term is expected to commence in the third quarter of 2024 and the lease term is one hundred twenty months. In May 2024, we amended our 5000 Shoreline Court facility lease agreement to expand the size of the original premises by adding approximately 11,321 rentable square feet of additional space.

In November 2023, we additionally entered into a lease for an office located in San Diego, California, where we occupy approximately 5,700 square feet of office space. The lease commenced in December 2023 and expires in March 2028.

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and clinical studies and testing, manufacture and supply of our preclinical and clinical materials and providing other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Pursuant to the GSK Collaboration Agreement, GSK holds a global, exclusive license to develop and commercialize WRN products arising out of the WRN program. We and GSK are collaborating on ongoing preclinical research for the WRN program, and GSK will lead clinical development for the WRN program, with IDEAYA responsible for 20% and GSK responsible for 80% of such global research and development costs. The cost-sharing percentages will be adjusted based on the actual ratio of U.S. to global profits for WRN products, as measured three and six years after global commercial launch thereof.

In September 2018, we entered into a license agreement with Novartis to develop and commercialize Novartis' LXS196 (also known as IDE196), a Phase 1 PKC inhibitor, for the treatment of cancers having GNAQ and GNA11

mutations. We renamed Novartis' LXS196 oncology as IDE196, and which has a non-proprietary name of darovasertib. Under the license agreement, Novartis granted to us a worldwide, exclusive, sublicensable license to research, develop, manufacture, and commercialize certain defined compounds and products, including IDE196 and certain other PKC inhibitors as well as companion diagnostic products, collectively referred to as the licensed products, for any purpose.

We paid Novartis an upfront payment of \$2.5 million and issued 263,615 shares of our Series B redeemable convertible preferred stock concurrently with the execution of the license agreement. Subject to completion of certain clinical and regulatory development milestones, we agreed to make milestone payments in the aggregate of up to \$9.0 million, and subject to achievement of certain commercial sales milestones, we agreed to make milestone payments in the aggregate of up to \$20.0 million. We also agreed to pay mid to high single-digit tiered royalty payments based on annual worldwide net sales of licensed products, payable on a licensed product-by-licensed product and country by country basis until the latest of the expiration of the last to expire exclusively licensed patent, the expiration of regulatory exclusivity, and the ten year anniversary of the first commercial sale of such product in such country. The royalty payments are subject to reductions for lack of patent coverage, loss of market exclusivity, and payment obligations for third-party licenses.

In March 2020, we entered into the Pfizer Agreement. Pursuant to the Pfizer Agreement, as amended in September 2020, April 2021, September 2021 and May 2023, Pfizer supplies us with their MEK inhibitor, binimetinib, and their cMET inhibitor, crizotinib, to evaluate combinations of darovasertib independently with each of the Pfizer compounds, in patients with tumors harboring activating GNAQ or GNA11 mutations. Under the Pfizer Agreement, we are the sponsor of the combination studies and will provide darovasertib and pay for the costs of the combination studies. Pfizer will provide binimetinib and crizotinib for use in the clinical trial at no cost to us. We have further expanded the scope of our relationship with Pfizer, entering into additional agreements to facilitate evaluation of darovasertib in combination with crizotinib in a potential registrations clinical trial in MUM and separately, in combination with crizotinib in other cMET-driven tumor indications.

In March 2022, we and Pfizer entered into the Second Pfizer Agreement pursuant to which we may, subject to FDA feedback and guidance, evaluate darovasertib and crizotinib as a combination therapy in MUM in a planned Phase 2/3 potential registration-enabling clinical trial. Pursuant to the Second Pfizer Agreement, we are the sponsor of the planned combination trial and we will provide darovasertib and pay for the costs of the combination trial; Pfizer will provide crizotinib for the planned combination trial at no cost to us for up to an agreed-upon number of MUM patients. Separately, in March 2022, we and Pfizer also entered into the Third Pfizer Agreement pursuant to which we may, subject to preclinical validation and FDA feedback and guidance, evaluate darovasertib and crizotinib, as a combination therapy in cMET-driven tumors such as NSCLC and/or HCC in a Phase 1 clinical trial. Pursuant to the Third Pfizer Agreement, we are the sponsor of the planned combination trial, and we will provide darovasertib and pay for the costs of the combination trial; Pfizer will provide crizotinib for the planned combination trial at no cost to us. In May 2023, we continued our relationship with Pfizer by entering into Amendment No. 4 to the Pfizer Agreement relating to the supply of crizotinib in support of this Phase 2 clinical trial, pursuant to which Pfizer will continue to provide us with an additional defined quantity of crizotinib at no cost.

We also expanded our relationship with Pfizer in May 2023 under an Amendment No. 1 to the Second Pfizer Agreement to support the Phase 2/3 registrational trial to evaluate darovasertib and crizotinib as a combination therapy in MUM. Under the as-amended Second Pfizer Agreement, Pfizer will provide us with a first defined quantity of crizotinib at no cost, as well as an additional second defined quantity of crizotinib at a lump-sum cost. Under Amendment No. 1 to the Second Pfizer Agreement, we also terminated the Third Pfizer Agreement. In January 2022, we exercised our option for an exclusive worldwide license rights covering a broad class of PARG inhibitors from Cancer Research Technology Ltd. (CRT) and the University of Manchester, and in connection therewith, paid a one-time option exercise fee of £250,000.

In addition to an upfront fee of £100,000 and the one-time option exercise fee of £250,000, each of which have been paid, we have certain potential milestone-dependent financial obligations, including: (a) subject to completion of specific development and regulatory approval events for development of a PARG inhibitor in oncologic diseases, payments of up to £19.5 million per broad disease classification block – for example, in oncologic diseases, up to £13.0 million aggregate for a first achievement of such clinical and regulatory milestones and up to £6.5 million aggregate for a second achievement of such clinical and regulatory milestones; (b) subject to certain sales-based milestones based on net sales of licensed products. payments of up to £9 million per broad disease classification

block – for example, in oncologic diseases, up to £6.0 million aggregate for a first achievement of such sales milestones and up to £3.0 million aggregate for a second achievement of such sales milestones; and (c) low single-digit tiered royalty payments based on aggregate worldwide net sales of all products, payable on a product-by-product and country-by-country basis until the later of the last-to-expire patent covering such product in such country and the ten year anniversary of the first commercial sale of such licensed product in such country. The royalty payments are subject to reductions for payment obligations in the event third-party licenses are required to develop or commercialize the product or if the product is not covered by certain patents.

In April 2023, we incurred an obligation to pay milestone payments in an aggregate amount of £750,000 to CRT based upon the achievement of certain milestones relating to first and second tumor histologies in connection with the Phase 1 portion of the Phase 1/2 clinical trial in oncologic diseases. After the achievement of this milestone, we will be obligated to make future milestone payments to CRT aggregating up to £18.75 million upon the achievement of specific development and regulatory approval events for development of a PARG inhibitor in oncologic diseases. This includes an aggregate of up to £1.5 million and up to £2.25 million for the achievement of certain Phase 2 and Phase 3 development milestones, respectively, in each case as relating to first (e.g., a breast cancer) and second (e.g., ovarian cancer) tumor histologies.

We pay all expenses associated with prosecution and maintenance and each party bears its own costs for enforcement. If we abandon the patents covering inventions developed under the agreement as project intellectual property, Cancer Research UK will thereafter be responsible for prosecuting and maintaining such patents. If we abandon such patents, Cancer Research UK and University of Manchester will be responsible for paying the expenses associated with the prosecution and maintenance of such patents.

Following our exercise of the option, if we sublicense certain intellectual property developed under the agreement or Cancer Research UK background patents specifically relating to PARG, we will also have an obligation to pay to Cancer Research UK low double digit percentage of sublicense revenue we receive, if any. If the agreement is terminated due to our material breach, then we are eligible to receive a percentage of sublicensing revenue that Cancer Research UK receives for licensing intellectual property.

In July 2022, we entered into the Amgen CTCSA to clinically evaluate IDE397 in combination with AMG 193 in patients having MTAP-null solid tumors, in a Phase 1/2 clinical trial. Under the mutually non-exclusive Amgen CTCSA, we will provide IDE397 drug supply to Amgen, who will be the sponsor of the Phase 1 clinical combination trial evaluating IDE397 and AMG 193. Each party will pay for fifty percent (50%) of the external third-party costs of the combination study. Each party will be responsible for its own internal costs and expenses in support of the combination study. We and Amgen will jointly oversee clinical development of the combination therapy through a Joint Oversight Committee responsible for coordinating all regulatory and other activities under the Amgen CTCSA. The parties will jointly own collaboration data and combination-related intellectual property, if any, arising from the combination clinical trial. We and Amgen each retain commercial rights to our respective compounds, including with respect to use as a monotherapy agent or combination agent.

In November 2023, we entered into the Gilead CSCSA with Gilead to clinically evaluate IDE397 in combination with Trodelvy (sacituzumab-govitecan-hziy), a Trop-2 directed ADC, in patients having MTAP-deletion bladder urothelial cancer, in a Phase 1 clinical trial. Under the mutually non-exclusive Gilead CSCSA, we will receive Trodelvy drug supply from Gilead and will sponsor the Phase 1 clinical combination trial

evaluating ID397 and Trodelvy. Gilead will bear internal or external costs incurred in connection with its supply of Trodelvy. We will bear all internal and external costs and expenses associated with the conduct of the combination study. We and Gilead will jointly oversee clinical development of the combination therapy through a Joint Steering Committee responsible for coordinating all regulatory and other activities under the Gilead CSCSA. We and Gilead each retain commercial rights to our respective compounds, including with respect to use as a monotherapy agent or combination agent.

In March 2024, we entered into the Merck CTCSA with Merck. We are planning to evaluate IDE161 in a combination study with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, KEYTRUDA, in patients with MSI-high and MSS endometrial cancer. Pursuant to the Merck CTCSA, we are the sponsor of the combination study and we will provide the IDE161 compound and pay for the costs of the combination study. Merck will provide KEYTRUDA at no cost to us. We will jointly own clinical data from the combination and all inventions relating to the combined use

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of IDE161 and pembrolizumab, KEYTRUDA. Each party retains commercial rights to its respective compounds, including with respect to use as a monotherapy or combination agent.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

In July 2024, we entered into an option and license agreement with Biocytogen, pursuant to which Biocytogen granted us an option for an exclusive worldwide license for a potential first-in-class B7H3/PTK7 topoisomerase-I-inhibitor-payload BsADC program. Under the terms of the agreement, we will pay Biocytogen an upfront fee and, upon IDEAYA's potential exercise of the Option, an exercise fee totaling up to \$6.5 million. We may exercise the Option within a specified time period after we obtain all data and results from certain non-GLP toxicology studies specified in the Agreement, which we will conduct at our own cost. Subject to our exercise of the Option, Biocytogen will be eligible to receive an option exercise fee, development and regulatory milestone payments and commercial milestone payments, as well as low to mid single-digit royalties on net sales. Total potential milestone payments equal an aggregate of \$400.0 million, including development and regulatory milestone payments of up to \$100.0 million.

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Adequate additional funding may not be available to us on acceptable terms or at all.

See the section of this Quarterly Report on Form 10-Q titled "Part I, Item 1A. – Risk Factors" for additional risks associated with our substantial capital requirements.

## Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

## Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents, and restricted cash for each of the periods presented below (in thousands):

	Three Months Ended March 31,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net cash provided by (used in):				
Operating activities	\$ (43,813)	\$ (27,842)	\$ (76,695)	\$ (61,302)
Investing activities	(353,971)	23,521	(285,414)	(97,860)
Financing activities	349,111	2,926	388,294	193,989
Net decrease in cash, cash equivalents and restricted cash	\$ (48,673)	\$ (1,395)		
Net increase in cash, cash equivalents and restricted cash	\$ 26,185	\$ 34,827		

## Cash Flows from Operating Activities

Net cash used in operating activities was \$43.8 million \$76.7 million for the three six months ended March 31, 2024 June 30, 2024. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$39.6 million \$92.3 million, adjusted for net non-cash charges of \$1.1 million \$5.3 million and changes in net operating assets and liabilities of \$5.3 million \$10.4 million. Our non-cash charges consisted of \$6.3 million \$16.0 million in stock-based compensation, \$0.6 million \$1.2 million in depreciation and \$0.5 million \$0.9 million of the amortization of right of use assets, partially offset by \$6.3 million \$13.0 million accretion of discounts on marketable securities. The net change in our operating assets and liabilities consisted primarily of \$3.1 million due to cash inflows from \$9.2 million in prepaid accounts payable and other assets, \$1.3 million \$5.6 million accrued and other liabilities due to CRO fees in support of research and manufacturing activities, \$0.5 million partially offset by outflows from \$3.5 million in prepaid and other assets and \$1.0 million in lease liabilities, and \$0.5 million in accounts payable, liabilities.

Net cash used in operating activities was \$27.8 million \$61.3 million for the three six months ended March 31, 2023 June 30, 2023. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$23.6 million \$51.6 million, adjusted for net non-cash charges of \$3.1 million \$6.2 million and changes in net operating assets and liabilities of \$7.3 million \$16.0 million. Our non-cash charges consisted of \$3.7 million \$8.4 million in stock-based compensation, \$0.6 million \$1.2 million in depreciation and \$0.4 million \$0.8 million amortization of right-of-use assets, partially offset by \$1.6 million \$4.1 million accretion of discount on marketable securities. The net change in our operating assets and liabilities consisted primarily of decreases of \$7.5 million \$10.9 million in contract liabilities due to revenue recognized under the GSK Collaboration Agreement, \$0.5 million in lease liabilities, \$0.4 million \$3.3 million in accrued liabilities and \$0.3 million \$0.9 million in accounts receivable from GSK for estimated program costs under the GSK Collaboration Agreement, partially offset by a decrease lease liabilities, and an increase of \$1.4 million \$2.5 million in prepaid and other current assets, assets, partially offset by an increase in accounts payable of \$1.6 million.

## Cash Flows from Investing Activities



Net cash used in investing activities was \$354.0 million \$285.4 million for the three six months ended March 31, 2024 June 30, 2024, which consisted primarily of \$475.8 million \$640.5 million used to purchase marketable securities and \$1.3 million \$2.3 million used to purchase property and equipment, partially offset by \$123.1 million \$357.4 million provided by maturities of marketable securities.

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Net cash provided by used in investing activities was \$23.5 million \$97.9 million for the three six months ended March 31, 2023 June 30, 2023, which consisted of \$95.9 million \$292.5 million used to purchase marketable securities and \$0.9 million used to purchase property and equipment, partially offset by \$195.6 million provided by maturities of marketable securities, partially offset by \$72.3 million used to purchase marketable securities.

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## Cash Flows from Financing Activities

Net cash provided by financing activities was \$349.1 million \$388.3 million for the three six months ended March 31, 2024 June 30, 2024, which consisted primarily of \$343.7 million \$380.0 million of net proceeds from sales under our ATM facility at-the-market offerings and \$5.5 million \$7.5 million of proceeds from exercise of common stock options. options and \$0.8 million of proceeds from ESPP purchase.

Net cash provided by financing activities was \$2.9 million \$194.0 million for the three six months ended March 31, 2023 June 30, 2023, which consisted primarily of \$2.6 million \$153.8 million of proceeds from issuance of common stock upon public offering, \$35.1 million of proceeds from issuance of pre-funded warrants, \$2.5 million of net proceeds from sales under our ATM facility at-the-market offerings and \$0.4 million \$1.9 million of net proceeds from exercise of common stock options. options and \$0.6 million of proceeds from ESPP purchase.

## Critical Accounting Policies

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported revenue recognized and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are

reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

For more detail on our critical accounting policies, refer to Note 2 in the unaudited interim condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, and the notes to the financial statements appearing elsewhere in our Annual Report on Form 10-K filed with the SEC on February 20, 2024. For the **three** **six** months ended **March 31, 2024** **June 30, 2024**, there were no material changes to our critical accounting policies from those disclosed in our Annual Report on Form 10-K filed with the SEC on February 20, 2024.

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### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

#### *Interest Rate Sensitivity*

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of **March 31, 2024** **June 30, 2024**, we had cash, cash equivalents and marketable securities of **\$941.4 million** **\$952.7 million**, consisting of bank deposits, interest-bearing money market funds, investments in U.S. government securities, commercial paper, and corporate bonds, for which the fair value would be affected by changes in the general level of U.S. interest rates. Even if the fair value of certain government securities, commercial paper, and corporate bonds is affected by changes in U.S. interest rates, the principal of such instruments will be due to us upon maturity.

**The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration and our holdings in U.S. government treasury bonds mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant.** While we are seeing, and expect to continue to see, record inflation **and elevated interest rates** due to geopolitical and macroeconomic events, such as the ongoing Ukraine-Russia conflict and related sanctions, the Israel-Hamas conflict, and the banking sector volatility, we do not believe that inflation, **interest rate changes** or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

### Item 4. Controls and Procedures.

#### *Limitations on Effectiveness of Controls and Procedures*

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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

Our management, with the participation of our Chief Principal Executive Officer and Chief Principal Financial and Accounting Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Principal Executive Officer and Chief Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2024 June 30, 2024.

#### ***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(e) and 15d-15(e) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## **PART II—OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

### **Item 1A. Risk Factors.**

In addition to other information contained elsewhere in this Quarterly Report on Form 10-Q, you should carefully consider the risk factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K filed with the SEC on February 20, 2024 (the “Annual Report”), which could materially affect our business, financial condition, or future results. As of the date of this Quarterly Report on Form 10-Q, there have been no material changes to the risk factors disclosed in our Annual Report.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from the Sale of Registered Securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other information.

Not applicable.

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Exhibit Index

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	5/28/2019	3.1	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	5/28/2019	3.2	
4.1	Reference is made to Exhibits <a href="#">3.1</a> through <a href="#">3.2</a> .				

4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	5/13/2019	4.2	
4.3	<a href="#">Description of Common Stock.</a>	10-K	2/20/2024	4.3	
4.4	<a href="#">Form of April 2023 Pre-funded Warrant</a>	8-K	4/27/2023	4.1	
4.5	<a href="#">Form of October 2023 Pre-funded Warrant</a>	8-K	10/27/2023	4.1	
10.1†	<a href="#">Clinical Trial Collaboration and Supply Agreement by and between MSD International Business GmbH and IDEAYA Biosciences, Inc., dated as of March 8, 2024</a>				X
31.1	<a href="#">Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
31.2	<a href="#">Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1*	<a href="#">Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents .				X
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	5/28/2019	3.1	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	5/28/2019	3.2	
4.1	Reference is made to Exhibits <a href="#">3.1</a> through <a href="#">3.2</a> .				

4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	5/13/2019	4.2	
4.3	<a href="#">Description of Common Stock.</a>	10-K	2/20/2024	4.3	
4.4	<a href="#">Form of April 2023 Pre-funded Warrant.</a>	8-K	4/27/2023	4.1	
4.5	<a href="#">Form of October 2023 Pre-funded Warrant.</a>	8-K	10/27/2023	4.1	
4.6	<a href="#">Form of July 2024 Pre-funded Warrant.</a>	8-K	7/11/2024	4.1	
31.1	<a href="#">Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
31.2	<a href="#">Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1*	<a href="#">Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.				X
104	Cover Page Interactive Data File (embedded with the Inline XBRL document).				X

† Certain information in this exhibit has been excluded pursuant to Regulation S-K, Item 601(b)(10).

\* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of IDEAYA Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

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 thereto duly authorized.

IDEAYA Biosciences, Inc.

Date: May 7, 2024 August 6, 2024

By: /s/ Yujiro Hata  
Yujiro Hata  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 7, 2024 August 6, 2024

By: /s/ Andres Ruiz Briseno  
Andres Ruiz Briseno  
Senior Vice President, Head of Finance and Investor Relations  
(Principal Financial and Accounting Officer)

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Exhibit 10.1

Clinical Trial Collaboration and Supply Agreement

by and between

MSD International Business GmbH

and

Collaborator (as defined below)

Clinical Trial Collaboration and Supply Agreement - Information Sheet

MSD Agreement Number (LKR Number)	***
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Collaborator Entity Name	IDEAYA Biosciences, Inc.
Collaborator Address	7000 Shoreline Court, Suite 350, South San Francisco, CA 94080
Collaborator Class Compound	poly(ADP-ribose) glycohydrolase (PARG) inhibitor
Collaborator Compound	IDE161
Collaborator Clinical Trial	The Phase 1a/1b, open-label, multi-center, dose escalation/optimization and dose expansion study evaluating the safety, PK, PD, and preliminary efficacy of IDE161 as monotherapy and in combination with pembrolizumab in adult participants with advanced or metastatic solid tumors
Collaborator JDC Escalation Person Title	Darrin Beaupre
Collaborator Notice Block	<p>IDEAYA Biosciences, Inc.  11710 El Camino Real  San Diego, CA 92130  Attention: Chief Medical Officer  Email: dbeaupre@ideayabio.com</p> <p>with copy to:  IDEAYA Biosciences, Inc.  7000 Shoreline Court, Suite 350  South San Francisco, CA 94080  Attention: Legal Department  Email: legal@ideayabio.com</p>
Effective Date	March 8, 2024
Safety Gate	Yes

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

## CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This Clinical Trial Collaboration and Supply Agreement is entered into as of the Effective Date, by and between MSD International Business GmbH (“MSD”), having a place of business at [\*\*\*], and Collaborator (as defined below), having a place of business at the Collaborator Address (as defined below). MSD and Collaborator are each referred to herein individually as a “Party” and collectively as the “Parties”.



## RECITALS

- A. MSD holds intellectual property rights to the MSD Compound (as defined below) and is developing the MSD Compound for the treatment of certain tumor types.
- B. Collaborator is developing the Collaborator Compound (as defined below) for the treatment of certain tumor types.
- C. Collaborator desires to sponsor the Collaborator Clinical Trial (as defined below) in which the Collaborator Compound and the MSD Compound would be dosed in Combination (as defined below).
- D. MSD and Collaborator, consistent with the terms of this Agreement (as defined below), desire to collaborate described herein, including by providing the MSD Compound and the Collaborator Compound for the MSD Compound Study (as defined below).

NOW, THEREFORE, in consideration of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, hereby agree as follows:

### **1. DEFINITIONS.**

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

- 1.1. "Affiliate"** means, with respect to either Party, a firm, corporation or other entity that, now or hereafter, directly or indirectly owns or controls such Party, or, now or hereafter, is owned or controlled by such Party, or is under common ownership or control with such Party for so long as such control exists. The word "**control**" as used in this definition means: (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity; or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

- 1.2. "Agreement"** means this agreement (including all appendices, Exhibits and Schedules attached hereto), as this agreement may be amended by the Parties from time to time, in accordance with Section 16 (Entire Agreement; Amendment; Waiver).

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

- 1.3. "Alliance Manager"** means the alliance managers appointed by the Parties in accordance with Section 2.3 (Joint Development Committee; Managers).

- 1.4. "Applicable Law"** means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including: (i) those promulgated by any Regulatory Authority; (ii) cGMP and GCP; (iii) Data Protection Law; (iv) export control

and economic sanctions regulations that prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; (v) anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; (vi) laws and regulations governing payments to healthcare providers; (vii) the listing or other rules or regulations of any stock exchange; and (viii) health, safety and environmental protections.

- 1.5. **“Arising IP”** shall have the meaning given to such term in Section 3.10.3.
- 1.6. **“Business Day”** means any day other than a Saturday, Sunday, or a day on which commercial banks located in the country (or, if in the United States, in the state) where the applicable obligations are to be performed are authorized or required by law to be closed.
- 1.7. **“cGMP”** means the Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities as applicable to the Manufacture of the Compounds.
- 1.8. **“Change of Control”** means: (a) the sale of all or substantially all of such Collaborator’s assets or business relating to the Collaborator Compound; or (b) a merger, reorganization or consolidation involving Collaborator in which the voting securities immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) any Third Party (or group of Third Parties acting in concert) becoming the beneficial owner directly or indirectly, of fifty percent (50%) or more of the total voting power of Collaborator.
- 1.9. **“Clinical Supply Quality Agreement”** means an agreement to be entered into by the Parties pursuant to Section 2.4 (Clinical Supply Quality Agreement) to address and govern the quality and handling of clinical drug to be supplied by the Parties for use in the MSD Compound Study.
- 1.10. **“Clinical Data”** means Collaborator Clinical Data, Joint Clinical Data and MSD Clinical Data.
- 1.11. **“Clinical Safety Data”** means all safety and tolerability data from the portions of the Collaborator Clinical Trial that do not contain the MSD Compound or other clinical trials involving the Collaborator Compound, including all safety reports containing information on

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adverse events, SAEs, and other information required by any applicable Regulatory Authority, including summary tables of laboratory and radiographic data.

- 1.12. **“CMC”** means **“Chemistry Manufacturing and Controls”**, as such term of art is used in the pharmaceutical industry.
- 1.13. **“Collaborator”** means the entity specified in the “Collaborator Entity Name” row of the Information Sheet.
- 1.14. **“Collaborator Address”** means the address set forth for Collaborator in the “Collaborator Address” row of the

Information Sheet.

**1.15. “Collaborator Background Patents”** means any Patent Controlled by Collaborator or its Affiliate [\*\*\*].

**1.16. “Collaborator Class Compound”** means the class of compounds set forth in the “Collaborator Class Compound” row of the Information Sheet.

**1.17. “Collaborator Clinical Data”** means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the Collaborator Compound Arm(s), if any Collaborator Compound Arm(s) are included in the Collaborator Clinical Trial. Collaborator Clinical Data does not include Sample Testing Results, Joint Clinical Data or MSD Clinical Data.

**1.18. “Collaborator Clinical Trial”** means the clinical trial set forth in the “Collaborator Clinical Trial” row of the Information Sheet, as further described in Section 2.1 (The Collaborator Clinical Trial).

**1.19. “Collaborator Compound”** means the compound set forth in the “Collaborator Compound” row of the Information Sheet, [\*\*\*].

**1.20. “Collaborator Compound Arm(s)”** means any portion of the Collaborator Clinical Trial where patients are intended to receive the Collaborator Compound either alone or in concomitant or sequential administration with one or more treatments, but not in combination with the MSD Compound.

**1.21. “Collaborator Escalation Contact”** means the person set forth in the “Collaborator JDC Escalation Person Title” row of the Information Sheet.

**1.22. “Collaborator Inventions”** means all Inventions relating to [\*\*\*].

**1.23. “Combination”** means the use or method of using the Collaborator Compound and the MSD [\*\*\*].

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

**1.24. “Combination Arm(s)”** means the portion of the Collaborator Clinical Trial where patients are intended to receive the Collaborator Compound and the MSD Compound in Combination [\*\*\*].

**1.25. “Compounds”** means the Collaborator Compound and the MSD Compound. A **“Compound”** means either the Collaborator Compound or the MSD Compound.

**1.26. “Confidential Information”** means any information (including personal data), Know-How or other proprietary information or materials furnished to a Receiving Party by or on behalf of a Disclosing Party in connection with this Agreement, except to the extent that such information or materials, as demonstrated by competent evidence: (i) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through a breach of this Agreement by the Receiving Party;

(iv) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (v) was subsequently developed by the Receiving Party without use of the Disclosing Party's Confidential Information. MSD Clinical Data is deemed the Confidential Information of MSD (and MSD is the "Disclosing Party" and Collaborator the "Receiving Party" with respect to the same). [\*\*\*] is deemed the Confidential Information of Collaborator (and Collaborator is the "Disclosing Party" and MSD the "Receiving Party" with respect to the same). [\*\*\*] deemed to be the Confidential Information of both Parties.

**1.27. "Control" or "Controlled"** means, with respect to particular information or intellectual property, that the applicable Party or its Affiliate owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense as provided for herein [\*\*\*].

**1.28. "Controlling Party"** shall have the meaning given to such term in Section 10.5.5.

**1.29. "Cost Sharing Countries"** shall have the meaning given to such term in Section 10.3 (Prosecution).

**1.30. "CTA"** means an investigational new drug application, clinical trial authorization application, Investigational Medicinal Product Dossier, or similar application or submission (including any supplements of any of the foregoing) for approval to conduct human clinical investigations of a product filed with or submitted to a Regulatory Authority in accordance with requirements of such Regulatory Authority.

**1.31. "Data Protection Law"** means any applicable data protection or privacy law to which a Party is subject in connection with this Agreement.

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**1.32. "Data Protection Terms"** means Exhibit C hereto.

**1.33. "Data Sharing Schedule"** means the schedule attached hereto as Schedule I.

**1.34. "Defending Party"** means a Party controlling the defense of an action pursuant to Section 14.2.3 (Procedure).

**1.35. "Delivery"** means, with respect to a given quantity of (i) the MSD Compound[\*\*\*] and, (ii) the Collaborator Compound, [\*\*\*]. "Deliver" shall have a correlative meaning.

**1.36. "Developing Party"** shall have the meaning given to such term in Section 3.10.3.

**1.37. "Disclosing Party"** means a Party (or its Affiliate) disclosing Confidential Information of such Party hereunder.

**1.38. "Effective Date"** means the date set forth in the "Effective Date" row of the Information Sheet.

**1.39. "EMA"** means the European Medicines Agency and any successor agency.

**1.40. "Exclusions List"** means: (i) List of Excluded Individuals and Entities on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website including 42 U.S.C. 1320a-7 (<https://www.oig.hhs.gov/exclusions/index.asp>); (ii) the U.S. General Services Administrator's list of Parties

Excluded from Federal Programs – System for Award Management (<https://sam.gov/content/exclusions>) and (iii) the debarment list promulgated under 21 U.S.C.335a (<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications>).

**1.41. “FCPA”** means the U.S. Foreign Corrupt Practices Act.

**1.42. “FDA”** means the United States Food and Drug Administration.

**1.43. “Freedom-to-Operate License”** means a license to be granted by a Party to the other Party in the event this Agreement is amended or a new agreement is executed for the purpose of conducting a Subsequent Study in accordance with Section 2.9.

**1.44. “GCP”** means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use that may be in effect from time to time and applicable to the testing of the Compounds.

**1.45. “Government Official”** means: (i) any officer or employee of a government or any department, agency or instrument of a government; (ii) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (iii) any officer or employee of a company or business owned in whole or part

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by a government; (iv) any officer or employee of a public international organization such as the World Bank or United Nations; (v) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; or (vi) any candidate for political office; who, in each of the foregoing cases (i) through (vi), when such Government Official is acting in an official capacity or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either Party.

**1.46. “Information Sheet”** means the table entitled Information Sheet set forth just before the preamble to this Agreement.

**1.47. “Inventions”** means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together: [\*\*\*].

**1.48. “Joint Clinical Data”** means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the Combination Arm(s), [\*\*\*]; provided however, that Joint Clinical Data does not include [\*\*\*].

**1.49. “Joint Development Committee” or “JDC”** means the committee to be established by the Parties pursuant to Section 2.3 (Joint Development Committee; Managers).

**1.50. “Joint Patent”** means a Patent with respect to any Joint Invention.

**1.51. “Joint Invention”** means any [\*\*\*].

**1.52. “Know-How”** means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

**1.53. “Liability”** means any loss, damage, reasonable costs and expenses (including reasonable attorneys’ fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out [\*\*\*].

**1.54. “Manufacture,” “Manufactured,” or “Manufacturing”** means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply.

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**1.55. “Manufacturer’s Release” or “Release”** has the meaning ascribed to release of the MSD Compound in the Clinical Supply Quality Agreement.

**1.56. “Manufacturing Site”** means the facilities where a Compound is Manufactured by or on behalf of a Party.

**1.57. “MSD”** has the meaning set forth in the preamble to this Agreement.

**1.58. “MSD Background Patents”** means any Patent Controlled by MSD or its Affiliate that claims or covers the Combination and is not a Joint Patent. [\*\*\*].

**1.59. “MSD Clinical Data”** means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the MSD Compound Arm(s), if any MSD Compound Arm(s) are included in the Collaborator Clinical Trial; provided however, that MSD Clinical Data does not include [\*\*\*].

**1.60. “MSD Compound”** means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody[\*\*\*].

**1.61. “MSD Compound Arm(s)”** means any portion of the Collaborator Clinical Trial where patients are intended to receive the MSD Compound either alone or in combination with one or more treatments but not in Combination with the Collaborator Compound.

**1.62. “MSD Compound Study”** means the arms of the Collaborator Clinical Trial where patients are intended to receive the MSD Compound either alone or in combination with one or more treatments (including the Collaborator Compound), as further described in Section 2.1 (The Collaborator Clinical Trial).

**1.63. “MSD Compound Study Completion”** means: (i) the date when the last patient enrolled in the MSD Compound Study has completed their last study-related assessment for evaluation excluding survival follow-up; or (ii) an alternative date as agreed to by the JDC in writing.

**1.64. “MSD Inventions”** means all Inventions related to or covering [\*\*\*], and not related to or covering [\*\*\*], and any improvements related thereto, regardless of whether such Invention was invented solely by MSD or Collaborator or jointly by the Parties.

**1.65. “NDA”** means a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in a country or group of countries.

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**1.66. “Non-Conformance”** means, with respect to a given unit of Compound: (i) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound; or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Article 8 (Supply and Use of Compounds) or Section 13.2 (Compounds). **“Non-Conforming”** shall have a correlative meaning.

**1.67. “Non-Cost Sharing Countries”** shall have the meaning given to such term in Section 10.3 (Prosecution).

**1.68. “Non-Pursuing Party”** shall have the meaning given to such term in Section 10.3 (Prosecution).

**1.69. “Parties”** and **“Party”** have the meanings set forth in the preamble to this Agreement.

**1.70. “Patent”** means (i) a patent application, (ii) any additions, priority applications, divisions, continuations, and continuations-in-part of the patent application, and (iii) all patents issuing on any of the foregoing patent applications, together with all invention certificates, substitutions, reissues, reexaminations, registrations, supplementary protection certificates, confirmations, renewals, and extensions of any of (i), (ii), or (iii), in any and all jurisdictions worldwide.

**1.71. “PD-1 Antagonist”** means any [\*\*\*].

**1.72. “Person”** means any entity, including any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, or governmental entity.

**1.73. “Pharmacovigilance Agreement”** means the pharmacovigilance agreement to be executed by the Parties pursuant to Section 2.6 (Pharmacovigilance Agreement).



**1.74. “Project Manager”** means the Project Managers to be designated by the Parties pursuant to Section 2.3 (Joint Development Committee; Managers).

**1.75. “Protocol”** means the written documentation that describes the Collaborator Clinical Trial and sets forth specific activities to be performed as part of the conduct of the Collaborator Clinical Trial.

**1.76. “Pursuing Party”** shall have the meaning given to such term in Section 10.3 (Prosecution).

**1.77. “Receiving Party”** means a Party (or its Affiliate or representative) receiving Confidential Information of the other Party hereunder.

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**1.78. “Regulatory Approvals”** means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from any Regulatory Authority or other competent authority for the development, registration, importation and distribution of such Compound in any jurisdiction for use in the MSD Compound Study.

**1.79. “Regulatory Authorities”** means the FDA, national regulatory authorities, the EMA, any successor agency to the FDA or EMA and any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction.

**1.80. “Regulatory Documentation”** means all submissions to Regulatory Authorities in connection with the development of a Compound, including all CTAs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse-event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including any documents that include Clinical Data).

**1.81. “Related Agreements”** means the Pharmacovigilance Agreement and the Clinical Supply Quality Agreement.

**1.82. “Related Entities”** means, with respect to each of Collaborator and MSD, such Party’s Affiliates and its and their directors, officers, employees and others acting on its or their behalf, including their respective Subcontractors.

**1.83. “Restricted Rights”** shall have the meaning given to such term in Section 10.3 (Prosecution)

**1.84. “Right of Reference”** means the “right of reference” defined in Title 21 of the U.S. Code of Federal Regulations, Part 314.3(b) or any non-U.S. equivalent including, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information and data (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation filed with such Regulatory Authority with respect to a Party’s Compound.

**1.85. “SAE”** means a serious adverse event.

**1.86. “Samples”** means biological specimens collected from subjects participating in the MSD Compound Study.



including any urine, blood and tissue samples.

**1.87. "Sample Testing"** means the analyses to be performed by each Party using the applicable Samples, as described in the Sample Testing Schedule.

**1.88. "Sample Testing Results"** means the data and results arising from the Sample Testing.

**1.89. "Sample Testing Schedule"** means the schedule attached hereto as Schedule II.

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**1.90. "Sensitive Information"** means [\*\*\*] Confidential Information relating to MSD Inventions, the MSD Compound or the Combination.

**1.91. "Specifications"** means the requirements to which a Compound must conform. The Specifications for a Compound will be set forth in the certificate of analysis accompanying each batch of Compound supplied for use in the MSD Compound Study.

**1.92. "Subcontractors"** means any and all Third Parties to whom a Party delegates any of its obligations hereunder.

**1.93. "Subsequent Study"** means a registrational study for the Combination in the same indication(s) and line(s) of therapy as that included in the Combination Arm(s).

**1.94. "Sunshine Act"** shall mean the Physician Payments Sunshine Act as amended from time to time.

**1.95. "Term"** means the term of this Agreement, as set forth in Section 6.1 (Term).

**1.96. "Third Party"** means any Person or entity other than Collaborator, MSD or their respective Affiliates.

**1.97. "Third-Party Infringement"** means any [\*\*\*].

**1.98. "Toxicity and Safety Data"** means all clinical adverse-event information or patient-related safety data [\*\*\*].

**1.99. "Transparency Report"** means a transparency report in connection with reporting payments and other transfers of value made to health-care professionals, including investigators, steering-committee members, data-monitoring committee members, and consultants in connection with the MSD Compound Study in accordance with reporting requirements under Applicable Law, including the Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and a Party's applicable policies.

**1.100. "VAT"** means a value-added or similar tax.

**1.101. "Vial"** means a single vial of MSD Compound[\*\*\*].

**1.102. "Violation"** means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (i) convicted of any of the felonies identified among the Exclusion Lists or (ii) identified or listed as having an active exclusion on any Exclusion List; or (iii) listed by any

US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under any Exclusion List.

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## 2. PERFORMANCE OF THE AGREEMENT. RELATED AGREEMENTS.

2.1. The Collaborator Clinical Trial. Collaborator is conducting or intends to conduct the Collaborator Clinical Trial, which Collaborator Clinical Trial has or is intended to have a Combination Arm(s). In addition, the Collaborator Clinical Trial may (or may not) have a Collaborator Compound Arm(s), an MSD Compound Arm(s), or both. The term “Collaborator Clinical Trial” as used in this Agreement refers to the Collaborator Clinical Trial as a whole, including the Combination Arm(s), and any Collaborator Compound Arm(s) or MSD Compound Arm(s) that form or are intended to form a part of the Collaborator Clinical Trial. The term “MSD Compound Study” refers to the Combination Arm(s) and any MSD Compound Arm(s) that form or are intended to form a part of the Collaborator Clinical Trial. Collaborator Clinical Trial, Collaborator Compound Arm(s), Combination Arm(s), MSD Compound Arm(s) and MSD Compound Study all refer to such arms as are intended to be conducted in accordance with the Protocol, including the Protocol as may be amended in accordance with Article 4 (PROTOCOL AND INFORMED CONSENT; CERTAIN COVENANTS).

2.2. Generally. Each Party shall: (i) contribute such resources as are necessary to conduct the activities contemplated by this Agreement; and (ii) act in good faith in performing its obligations under this Agreement and each Related Agreement to which it is a Party.

2.3. Joint Development Committee; Managers; Escalation.

2.3.1. The Parties shall form the Joint Development Committee made up of an equal number of representative MSD and Collaborator, which shall have responsibility for coordinating all regulatory and other activities under and pursuant to, this Agreement (except for activities under, and pursuant to, Article 10 (INTELLECTUAL PROPERTY)). Representatives of MSD and Collaborator on the JDC shall be entitled to one collective vote on behalf of each of MSD and Collaborator, respectively, on all matters upon which the JDC have the right to decide under this Agreement. Each Party shall designate a Project Manager who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties with respect to the MSD Compound Study and shall be entitled to attend meetings of the JDC. JDC members will be agreed by both Parties.

2.3.2. Unless otherwise agreed by the JDC, the JDC shall meet a minimum of \*\*\* (with the Parties agreeing to the timing of the first meeting within \*\*\* days following the Effective Date), to provide an update on the progress of the MSD Compound Study. The JDC may meet in person or by means of teleconference, internet conference, videoconference or similar means. Prior to any such meeting, Collaborator’s Project Manager shall provide

written update to MSD's Project Manager and Alliance Manager containing information about the overall progress of the MSD Compound

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Study, recruitment status, interim analysis (if available), final analysis and other information relevant to the conduct of the MSD Compound Study (and data relating to the Collaborator Clinical Trial reasonably requested by MSD and relevant to the MSD Compound Study).

**2.3.3.** In addition to a Project Manager, each Party shall designate an Alliance Manager who shall serve as primary point of contact for any issues arising under this Agreement and shall endeavor to ensure clear responsive communication and the effective exchange of information between the Parties. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matter either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree.

**2.3.4.** In the event that (i) an issue arises and the Alliance Managers do not, after good faith efforts, reach agreement on such issue, (ii) there is a decision to be made by the JDC on which the members of the JDC do not agree, or (iii) the Parties cannot agree on a matter in respect of the Protocol, the issue shall be elevated to the Senior Vice President of Clinical Research for MSD and the Collaborator Escalation Contact. In the event such escalation does not result in resolution or consensus: (x) MSD shall have final decision-making authority with respect to issues related to MSD Compound (including, but not limited to PD-1 Antagonists and any biomarkers related to MSD Compound); and (y) Collaborator shall have final decision-making authority with respect to issues related to Collaborator Compound.

**2.4.** Clinical Supply Quality Agreement. The Parties will execute the Clinical Supply Quality Agreement prior to any supply of MSD Compound hereunder, and no later than \*\*\* days after the Effective Date. The Clinical Supply Quality Agreement shall, among other things: (i) detail classification of any Non-Conforming MSD Compound; (ii) include criteria for Manufacturer's Release and related certificates and documentation; (iii) include criteria and timeframes for acceptance of MSD Compound; (iv) include procedures for the resolution of disputes regarding any Non-Conforming MSD Compound; (v) detail procedures and rights with respect to audit and inspection rights for Manufacturing sites; and (vi) include provisions governing the recall of Compounds. Quality matters and the Manufacture of the MSD Compound shall be governed by the terms of the Clinical Supply Quality Agreement in addition to the relevant quality provisions of this Agreement.

**2.5.** Data Protection. The Parties will comply with the Data Protection Terms set forth on Exhibit C.

**2.6.** Pharmacovigilance Agreement. The Parties will execute the Pharmacovigilance Agreement prior to MSD Delivering MSD Compound to Collaborator hereunder. The Pharmacovigilance

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material and would likely cause competitive harm to the registrant if publicly disclosed.

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Agreement will: (i) include safety data exchange procedures; (ii) facilitate appropriate safety reviews; (iii) govern the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the MSD Compound and Collaborator Compound in the MSD Compound Study; and (iv) enable the Parties and their Affiliates to fulfill local and international regulatory reporting obligations to Regulatory Authorities, all of the foregoing in accordance with Applicable Law. For the avoidance of doubt, the obligations to provide safety data under the Pharmacovigilance Agreement will be independent of any obligations to provide safety data pursuant to this Agreement.

**2.7. *Delegation of Obligations.*** Each Party shall have the right to delegate any portion of its obligations hereunder only:

(i) to such Party's Affiliates; (ii) to Third Parties for purposes of performing MSD Compound Study activities or conducting Sample Testing for such Party; provided that such Third Parties shall be reputable and possess necessary skills and experience in relevant disciplines to undertake such activities in accordance with industry standards; (iii) to the extent related to the Manufacture of such Party's Compound; or (iv) upon the other Party's prior consent. Notwithstanding any delegation of its obligations hereunder, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by its Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement. Upon MSD's request, Collaborator shall provide to MSD a complete and accurate list of Collaborator's Subcontractors.

**2.8. *Relationship.*** Without prejudice to [Section 2.9](#) (Subsequent Study), this Agreement does not create any obligation for either Party to provide any compound other than its Compound or to provide its Compound for any activities other than the MSD Compound Study. Except as expressly set forth in [Section 2.9](#) (Subsequent Study), nothing in this Agreement shall: [\*\*\*]. Each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, [\*\*\*]. Notwithstanding the foregoing, and notwithstanding any implication to the contrary in this Agreement, [\*\*\*]. Collaborator and MSD have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Collaborator Clinical Trial. Except as expressly set forth in [Section 2.9](#) (Subsequent Study), nothing in this Agreement obligates

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the Parties to enter into any agreement other than the Related Agreements now or in the future.

**2.9. Subsequent Study.** During the Term and for a period of [\*\*\*] thereafter, either Party shall have the option to propose amending this Agreement (and the Related Agreements as necessary) or negotiating a new agreement, as appropriate, for the purpose of conducting a Subsequent Study. Neither Party will have any obligation to agree upon the details of or execute any such amendment or agreement; provided, however, in the event this Agreement is amended or a new agreement is executed for the purpose of conducting a Subsequent Study, the Parties shall grant to each other a non-exclusive, worldwide, royalty-free, fully paid-up, transferable, and sublicensable license [\*\*\*]. Notwithstanding such [\*\*\*]License, in no event shall: [\*\*\*].

### **3. CONDUCT OF THE MSD COMPOUND STUDY.**

**3.1. Sponsor.** Collaborator shall act as the sponsor of the Collaborator Clinical Trial under its own CTA for the Collaborator Compound with a Right of Reference to the CTA of the MSD Compound as described in Section 3.5 (Regulatory Matters); provided, however, that in no event shall Collaborator file an additional CTA for the MSD Compound Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests such an additional CTA for the MSD Compound Study, the Parties shall meet and agree on an approach to address such requirement.

**3.2. Clinical Safety Data Review.** If the Information Sheet indicates that this Agreement contains a safety gate (i.e. “Yes” is selected for the Safety Gate (Yes/No) row), then this Section 3.2 (Clinical Safety Data Review) shall apply to this Agreement. If “No” is selected, for such Safety Gate row, then this Section 3.2 (Clinical Safety Data Review) shall be deemed omitted from this Agreement and shall not apply. [\*\*\*].

**3.3. Performance.** Collaborator shall ensure that the MSD Compound Study and all related activities are performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP.

**3.4. Debarred Personnel; Exclusions Lists.** Collaborator certifies that it has not and shall not use in any capacity the services of any person, including any subcontractor or individual, that has been excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs including Title 21 U.S.C. Section 335a or any foreign equivalent thereof. Collaborator has, as of the Effective Date screened itself, and its Affiliates’ officers and directors against the Exclusions Lists and has informed MSD whether it or any of its employees, officers or directors is or has been in Violation. Collaborator shall notify MSD in writing immediately if any suspension, proposed debarment, debarment or Violation occurs or comes to its attention with respect to any

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Person performing activities related to the MSD Compound Study or otherwise related to activities under this Agreement.

### **3.5. Regulatory Matters.**

**3.5.1.** Collaborator shall: (i) obtain all Regulatory Approvals from all Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the MSD Compound Study prior to its initiation; and (ii) follow directions from any such Regulatory Authorities, ethics committees and institutional review boards.

**3.5.2.** MSD shall have the right (but not the obligation) to participate in any discussions (including meetings) with the Regulatory Authority regarding matters related to the MSD Compound Study or the MSD Compound and shall collaborate on questions posed to Regulatory Authorities regarding design and conduct of the MSD Compound Study. Regardless of whether a Party participates in such discussions, each Party shall share with the other Party formal minutes of such discussions (subject to any necessary redactions to protect the Party's Confidential Information) to the extent they concern the other Party's Compound or the MSD Compound Study. For the avoidance of doubt, this includes formal minutes of such discussions prior to the execution of the Agreement.

**3.5.3.** Prior to submission of any Regulatory Documentation related to [\*\*\*], MSD shall have the right to review and comment on such Regulatory Documentation and Collaborator shall consider all comments from MSD in good faith. To the extent the Parties cannot agree regarding the contents of the Regulatory Documentation: (x) Collaborator shall have final decision-making authority with respect to matters in the Regulatory Documentation related to [\*\*\*]; (y) MSD shall have final decision-making authority with respect to matters in the Regulatory Documentation related to [\*\*\*]; and (z) all other matters in respect of the Regulatory Documentation on which the Parties cannot agree shall be resolved in accordance with Section 2.3 (Joint Development Committee; Managers; Escalation).

**3.5.4.** MSD shall authorize Collaborator to cross-reference the appropriate MSD Compound NDA or CTA as necessary to enable Collaborator to conduct the MSD Compound Study. If MSD's NDA or CTA is not available in a given country or region or cannot be cross referenced, MSD and Collaborator will discuss and agree on an approach to support Collaborator's CTA in such country or region, [\*\*\*].

**3.5.5.** If Collaborator receives a query from any Regulatory Authority that pertains specifically to the MSD Compound Study, Collaborator shall promptly provide such query to MSD and MSD shall provide written response to Collaborator to forward to the Regulatory Authority.

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**3.6. Investigator's Brochure for MSD Compound.** MSD shall provide Collaborator with (i) the current investigator's brochure for the MSD Compound promptly following the Effective Date and before the initiation of the MSD Compound Study and (ii) any material updates or changes to the investigator's brochure for the MSD Compound within [\*\*\*] of internal approval during the Term for use by Collaborator as needed for regulatory and safety purposes. All versions of MSD's investigator's brochure for the MSD Compound provided by MSD to Collaborator shall be MSD Confidential Information.

**3.7. Documentation.** Collaborator shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Collaborator shall provide to MSD all Collaborator Clinical Trial information and documentation reasonably requested by MSD to enable MSD to: (i) comply with any of its legal, regulatory or contractual obligations, or any request by any Regulatory Authority related to the MSD Compound; and (ii) determine whether the MSD Compound Study has been performed in accordance with this Agreement.

**3.8. Copies.** Collaborator shall provide to MSD copies of all Joint Clinical Data and any MSD Clinical Data in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing Schedule or mutually agreed; provided, however, that a complete copy of the Joint Clinical Data and any MSD Clinical Data shall be provided to MSD no later than [\*\*\*] days following MSD Compound Study Completion or any sooner termination of this Agreement. Collaborator shall ensure that: (i) all patient authorizations and consents required under Applicable Law in connection with the Collaborator Clinical Trial permit such sharing of Joint Clinical Data and any MSD Clinical Data with MSD; and (ii) it complies with Applicable Law in transferring personal data hereunder.

**3.9. Sample Testing.** Each Party shall provide Samples to the other Party as specified in the Protocol and as agreed to by the Joint Development Committee. Each Party shall use the Samples only for Sample Testing in accordance with the Sample Testing Schedule and the Protocol. [\*\*\*].

**3.10. Ownership and Use of Clinical Data.**

**3.10.1**[\*\*\*]. Collaborator shall maintain the Joint Clinical Data and any MSD Clinical Data in its internal database; [

**3.10.2**All Collaborator Clinical Data shall be solely owned by Collaborator. All MSD Clinical Data shall be solely owned by MSD. In accordance with the foregoing, each Party hereby assigns to the other its entire right, and interest, if any, in, to and under the MSD Clinical Data (with respect to Collaborator) and the Collaborator Clinical Data (with respect to MSD). Where such assignment is precluded by Applicable Law or otherwise cannot occur, the Party otherwise obligated to assign such interest hereby grants the other Party a perpetual, irrevocable, worldwide,

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royalty-free, fully paid-up exclusive license with the right to grant sublicenses and to assign such rights, to the MSD Clinical Data (with respect to the grant by Collaborator to MSD) and the Collaborator Clinical Data (with

respect to the grant by MSD to Collaborator) in each case without the consent of or any accounting to the granting Party. MSD Clinical Data may be used by Collaborator solely to evaluate the safety or performance of the Combination or to register the Collaborator Compound in the Combination. Notwithstanding the foregoing, except as [\*\*\*].

**3.10.** Before publication or presentation of a summary of the Joint Clinical Data, neither Party may disclose the Clinical Data publicly or to a Third Party without the consent of the other Party. Notwithstanding the foregoing, either Party may use and disclose such unpublished Joint Clinical Data : [\*\*\*].

**3.10.4** Notwithstanding anything to the contrary in this Section 3.10 (Ownership and Use of Clinical Data), Collaborator may: [\*\*\*].

**3.11. Regulatory Submission.** It is understood and acknowledged by the Parties that positive Clinical Data may be used to [\*\*\*].

**3.12. Certain Memoranda and Reports.** Promptly following MSD Compound Study Completion, Collaborator shall provide to MSD an electronic draft of the top-line results memorandum and an electronic draft of the final report of the results of the MSD Compound Study. MSD shall have [\*\*\*] days after receipt of such results memorandum and [\*\*\*] days after receipt of such final report to provide comments thereon. Collaborator shall consider any comments provided by MSD on either document and shall not include any statements in either document relating to the MSD Compound or the MSD Clinical Data that have not been approved by MSD. Collaborator shall deliver to MSD a final version of each such document promptly following finalization thereof.

**3.13. Licensing.**

**3.13.1** Nothing in this Agreement shall prohibit or restrict a Party from licensing, assigning or transferring to an Affiliate or Third Party such Party's Compound [\*\*\*] owned solely by such Party.

**3.13.2** A Party may license, assign or transfer to an Affiliate or Third Party, subject to any obligations or restrictions set forth in this Agreement, such Party's interest in the [\*\*\*] owned jointly by the Parties [\*\*\*], solely to the extent that such licensee, assignee or transferee agrees to be bound by the terms of this Agreement with respect to which agreement shall be in writing with respect to any license, assignment or transfer to a Third Party.

#### **4. PROTOCOL AND INFORMED CONSENT; CERTAIN COVENANTS.**

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**4.1. Protocol.** A synopsis of the Protocol, and any agreed draft statistical analysis plan for the MSD Compound Study or Collaborator Clinical Trial, are attached hereto as Exhibit A. Collaborator shall: (i) provide a draft of the Protocol (and any subsequent revisions thereof) to MSD for MSD's review and comment; (ii) consider any changes to the draft of the Protocol requested by MSD; (iii) incorporate any changes requested by MSD with respect to MSD Compound; and (iv) submit the draft Protocol to MSD for final approval. The country or countries in which the MSD



Compound Study will be performed will be reviewed and agreed upon by the Parties before MSD Compound Study initiation and any changes thereto will be subject to review and approval of MSD; provided, however, that MSD will be deemed to have consented to Collaborator performing the MSD Compound Study in the countries identified on Exhibit D. To the extent the Parties cannot agree regarding the contents of the Protocol for final approval: (x) [\*\*\*] shall have final decision-making authority with respect to matters in the Protocol related to [\*\*\*]; (y) [\*\*\*] shall have final decision-making authority with respect to matters in the Protocol related [\*\*\*]; and (z) all other matters in respect of the Protocol on which the Parties cannot agree shall be resolved in accordance with Section 2.3 (Joint Development Committee; Managers; Escalation). Notwithstanding anything to the contrary contained herein, each Party, in its sole discretion, shall have the sole right to determine the dose and dosing regimen for its Compound and shall have the final decision on all matters relating to its Compound and any information regarding its Compound included in the Protocol.

**4.2. Informed Consent.** Collaborator shall prepare the patient informed-consent form for the MSD Compound Study (which shall include provisions regarding MSD Compound safety, data sharing and the use of Samples in Sample Testing) in consultation and with approval of MSD (it being understood and agreed that the portions of the informed-consent form relating to the MSD Compound will be provided to Collaborator by MSD and adopted without modification by Collaborator).

**4.3. Changes to Protocol or Informed Consent.** Any proposed changes to: (i) the approved final Protocol (other than changes that are solely related to Collaborator Compound); or (ii) the informed consent form relating to the MSD Compound, including Sample Testing of the MSD Compound, shall be made only with MSD's prior written consent. Any proposed changes (including those which do not require MSD's consent) will be sent to MSD's Project Manager and MSD's Alliance Manager. For those changes requiring MSD's consent, MSD will provide such consent, or a written explanation for why such consent is being withheld, within [\*\*\*] Business Days after MSD receives a copy of the requested changes. If Protocol revisions made in accordance with this Section 4.3 would necessitate corresponding revisions to the definitions of Collaborator Clinical Trial, Combination Arm(s) or MSD Compound Study, such definitions shall be deemed to be revised consistent with such Protocol revisions.

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#### **4.4. Transparency Reporting.**

**4.4.1. Responsibilities of the Parties.** Collaborator is solely responsible for reporting payments and other transfers of value, (including supply of MSD Compound), made to health-care professionals, including investigators, steering-committee members, data-monitoring committee members, and consultants in connection with the MSD Compound Study in accordance with reporting requirements under Applicable Law, including the Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and Collaborator's applicable policies. Promptly after the Effective Date, Collaborator will notify MSD of Collaborator's point of contact for purposes of receiving

information from MSD pursuant to this Section 4.4, along with such contact's full name, email address, and telephone number. Collaborator may update such contact from time to time by notifying MSD pursuant to Article 21 (NOTICES). Where applicable, MSD will provide to such Collaborator contact all information regarding the value of the MSD Compound provided for use in the MSD Compound Study as required for such reporting. In the event that the value of the MSD Compound provided pursuant to this Section 4.4 materially changes, MSD shall notify Collaborator of such revised value and the effective date thereof.

**4.4.2.Periods Collaborator is Not Required to Report.** With respect to any annual reporting period in which Collaborator is not an entity that is required to make a Transparency Report under Applicable Law, Collaborator will: (i) notify MSD within [\*\*\*] days after the commencement of such reporting period that Collaborator is not so required; and (ii) during such reporting period Collaborator will track and provide to MSD data regarding "indirect" payments or other transfers of value by Collaborator to health care professionals to the extent such payments or other transfers of value were required, instructed, directed or otherwise caused by MSD pursuant to this Agreement in the format requested by MSD and provided on a basis to be agreed upon by the Parties. Collaborator represents and warrants that any data provided by Collaborator to MSD pursuant to this Section 4.4 will be complete and accurate to the best of Collaborator's knowledge.

**4.5. Financial Disclosure.** To the extent required by Applicable Law, Collaborator will be responsible for preparing and submitting the Financial Disclosure Module 1.3.4 components to the FDA for any Regulatory Documentation in connection with the Collaborator Clinical Trial. Collaborator shall promptly notify MSD of any reportable financial interest in MSD.

## **5. ADVERSE EVENT REPORTING.**

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**5.1. Pharmacovigilance.** Collaborator will be solely responsible for safety reporting for the Collaborator Clinical Trial and related activities, all in accordance with Applicable Law.

**5.2. Transmission of SAEs.** Collaborator will transmit to MSD all SAEs from the MSD Compound Study as set forth below. All cases will be transmitted on a CIOMS-1 form in English.

**5.2.1.**For fatal and life-threatening SAEs, Collaborator will transmit a processed case within [\*\*\*] days after receipt by Collaborator of notice of such SAEs.

**5.2.2.**For all other SAEs and newly diagnosed cancer, Collaborator will transmit a processed case within [\*\*\*] days after receipt by Collaborator of notice of such SAEs.

**5.2.3.**Cases of disease progression will be handled as outlined in the Protocol, and if the Protocol specifies that

such cases are collected as SAEs, Collaborator will transmit such cases to MSD within the applicable timeframe set forth in Section 5.2.1 or Section 5.2.2.

**5.2.4.** For all other reportable information that includes: (i) overdose, exposure during pregnancy or lactation; and cases of potential drug-induced liver injury where the patient was exposed to the MSD Compound (if required to be collected or identified per the Protocol), Collaborator will transmit a processed case within [\*\*\*] days of receipt by Collaborator of such information.

## **6. TERM AND TERMINATION.**

**6.1. Term.** The Term shall commence on the Effective Date and shall continue in full force and effect until delivery of final documents by Collaborator pursuant to Section 3.12 (Certain Memoranda and Reports), unless terminated earlier by either Party pursuant to this Article 6 (TERM AND TERMINATION).

**6.2. MSD Termination for Unsafe Use.** In the event MSD notifies Collaborator that it in good faith believes that the MSD Compound is being used unsafely in the MSD Compound Study and the grounds for such belief, and if either MSD believes such matter is not reasonably capable of remedy or if Collaborator fails to promptly remedy such issue to MSD's reasonable satisfaction, MSD may terminate this Agreement and the supply of the MSD Compound by notice to Collaborator with immediate effect.

**6.3. Termination for Breach.** Either Party may terminate this Agreement by notice with immediate effect if the other Party commits a material breach of this Agreement and such material breach continues for [\*\*\*] days after receipt of notice thereof from the non-breaching Party; provided that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement by notice effective at the expiration of such [\*\*\*]-day cure period. Either Party shall have the right to terminate this Agreement by notice to the

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other Party with immediate effect if such other Party fails to perform any of its obligations under Section 13.4 (Anti-Corruption) or breaches any representation or warranty contained in Section 13.4 (Anti-Corruption). In addition: (i) this Agreement may be terminated by the non-breaching Party for material breach of any other Clinical Trial Collaboration and Supply Agreement between the Parties (or their Affiliates) involving MSD Compound if such material breach occurred or was discovered during the Term and such material breach is not cured in accordance with the terms of such other Clinical Trial Collaboration and Supply Agreement; and (ii) in the event this Agreement is terminated pursuant to this Section 6.3, the terminating Party will have the right to terminate any or all other Clinical Trial Collaboration and Supply Agreements between the Parties by written notice given within [\*\*\*] days after termination of this Agreement becomes effective pursuant to this Section 6.3.

**6.4. Termination for Patient Safety.** If either Party determines in good faith that the MSD Compound Study or Collaborator Clinical Trial may unreasonably adversely affect patient safety, such Party shall promptly notify the

other Party of such determination. The Party receiving such notice may propose modifications to the MSD Compound Study or Collaborator Clinical Trial to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the proposed modifications and may instead terminate this Agreement immediately by notice to the other Party with immediate effect. Furthermore, the notifying Party may terminate this Agreement by notice to the other Party with immediate effect if, in its sole discretion, it believes that the modifications proposed by the other Party will not resolve the patient safety issue.

- 6.5. Termination for Regulatory Action; Other Reasons.** Either Party may terminate this Agreement by notice to the other Party with immediate effect in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the MSD Compound Study. Additionally, either Party shall have the right to terminate this Agreement by notice with immediate effect to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound for medical, scientific or legal reasons. Subject to Section 6.11 (Wind-Down), it is understood that if a Party withdraws any applicable Regulatory Approval for its Compound in a subset of countries in which the MSD Compound Study will be performed, such Party's right to terminate this Agreement shall be limited suspending its obligation to perform the MSD Compound Study in such countries.
- 6.6. Return of MSD Compound.** If Collaborator remains in possession (including through any Affiliate or Subcontractor) of MSD Compound at the time this Agreement expires or is

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terminated, Collaborator shall promptly return or destroy all unused MSD Compound as instructed by MSD in its sole discretion. Collaborator shall provide certification of any requested destruction.

- 6.7. Survival.** The provisions of Sections 2.9 (Subsequent Study), 3.4 (Debarred Personnel; Exclusions Lists) through 3.11 (Regulatory Submission)(inclusive), 6.7 (Survival) through 6.11 (Wind-Down)(inclusive), 8.5 (Provision of Compounds), 8.11 (Quality Control), 8.12 (VAT), 13.4.6, 14.2 (Indemnification), and 14.3 (LIMITATION OF LIABILITY), and Articles 1 (DEFINITIONS), 5 (ADVERSE EVENT REPORTING), 9 (CONFIDENTIALITY) through 12 (PUBLICATIONS; PRESS RELEASES)(inclusive), 16 (ENTIRE AGREEMENT; AMENDMENT; WAIVER), and 19 (INVALID PROVISION) through 24 (CONSTRUCTION)(inclusive) shall survive the expiration or termination of this Agreement.
- 6.8. No Prejudice.** Termination of this Agreement shall be without prejudice to any claim or right of action of either Party for any breach of this Agreement. Except as set forth in Section 6.10 (Manufacturing Costs) and the foregoing

sentence, the non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement.

**6.9. Confidential Information.** Upon expiration or termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Inventions) furnished to the Receiving Party; provided, however, that the Receiving Party may retain one copy of such Confidential Information in its confidential files, solely for purposes of exercising the Receiving Party's rights hereunder, satisfying its obligations hereunder or complying with any legal proceeding or requirement with respect thereto, and provided further that the Receiving Party shall not be required to erase electronic files created in the ordinary course of business during automatic system back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information so long as such electronic files are: (i) maintained only on centralized storage servers (and not on personal computers or devices); (ii) not accessible by any of its personnel (other than its information technology specialists); and (iii) not otherwise accessed subsequently except with the written consent of the Disclosing Party or as required by law or legal process. Such retained copies of Confidential Information shall remain subject to the confidentiality and non-use obligations herein.

**6.10. Manufacturing Costs.** In the event of termination by MSD pursuant to Section 6.2 (MSD Termination for Unsafe Use) or 6.3 (Termination for Breach), [\*\*\*]:

[\*\*\*]

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**6.11. Wind-Down.** In the event of termination by either Party pursuant to this Article 6, Collaborator shall perform wind-down activities in accordance with the Protocol.

## **7. COSTS.**

Each Party will be responsible for its own internal costs and expenses to support the Collaborator Clinical Trial, including: [\*\*\*].

## **8. SUPPLY AND USE OF COMPOUNDS.**

**8.1. Supply of the Compounds.** Subject to the terms and conditions of this Agreement, each of Collaborator and MSD will use commercially reasonable efforts to supply, or cause to be supplied, its Compound in the quantities and on the timelines set forth in Exhibit B, for use in the MSD Compound Study. If a change to the Protocol in accordance with Article 4 (PROTOCOL AND INFORMED CONSENTS; CERTAIN COVENANTS) requires an increase of the quantity of MSD Compound to be provided of more than [\*\*\*], the Parties shall amend Exhibit B to reflect such changes. Each Party shall also provide the other Party a contact person for the supply of its Compound under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, if a Party is: (i) not supplying its

Compound in accordance with the terms of this Agreement, then the other Party shall have no obligation to supply its Compound; or (ii) allocating under Section 8.10 (Shortage; Allocation), then the other Party may allocate proportionally.

**8.2. Manufacturing Delay.** Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound hereunder.

**8.3. Compound Commitments.** Each Party agrees, at its own cost, to Manufacture and supply its Compound in accordance with this Agreement and the Related Agreements. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that Collaborator shall be responsible for obtaining Regulatory Approvals for the MSD Compound Study as set forth in Section 3.5 (Regulatory Matters)).

**8.4. Minimum Shelf Life Requirements.** Each Party shall use commercially reasonable efforts to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the MSD Compound Study requirements.

**8.5. Provision of Compounds.**

**8.5.1.** MSD will Deliver the MSD Compound to the location specified by Collaborator. Title for the MSD Compound shall transfer from MSD to Collaborator [\*\*\*]. All costs

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associated with the subsequent transportation, warehousing and distribution of MSD Compound shall be borne by Collaborator. Collaborator will, or will cause its designee to: (i) take Delivery of the MSD Compound supplied hereunder; (ii) perform the acceptance (including testing) procedures allocated to it under the Clinical Supply Quality Agreement; (iii) subsequently label and package the MSD Compound (in accordance with Section 8.6 (Labeling and Packaging; Use, Handling and Storage)); and promptly ship the MSD Compound to the MSD Compound Study sites for use in the MSD Compound Study, in compliance with Applicable Law and the Clinical Supply Quality Agreement; (iv) keep complete and accurate records pertaining to the use and disposition of MSD Compound, including records relating to its storage, shipping (cold chain), in-transport temperature recorder(s), receipt verification, chain-of-custody activities and usage and inventory reconciliation; (v) make the records described in subsection (iv) and such other documentation as may be reasonably requested by MSD available for review by MSD for the purpose of conducting investigations for the determination of MSD Compound safety or efficacy and Collaborator's compliance with this Agreement with respect to the MSD Compound.

**8.5.2.** Collaborator is solely responsible for supplying (including all Manufacturing, acceptance and release testing) the Collaborator Compound for the Collaborator Clinical Trial and the subsequent handling, storage, transportation, warehousing and distribution of all such Collaborator Compound. Collaborator shall ensure



all such activities are conducted in compliance with Applicable Law and, with respect to the MSD Compound, the Clinical Supply Quality Agreement.

**8.6. Labeling and Packaging; Use, Handling and Storage.**

**8.6.1.** The Parties' obligations with respect to the labeling and packaging of the MSD Compound are as set forth in the Clinical Supply Quality Agreement. MSD shall provide the MSD Compound to Collaborator in the form of [\*\*\*].

**8.6.2.** Collaborator shall: (i) use the MSD Compound solely for purposes of performing the MSD Compound Study and (ii) not use the MSD Compound in any manner that is inconsistent with this Agreement or for any commercial purpose. Collaborator shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the MSD Compound, and Collaborator shall not analyze the MSD Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Supply Quality Agreement.

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**8.7. Product Specifications.** A certificate of analysis shall accompany each shipment of the MSD Compound to Collaborator.

**8.8. Changes to Manufacturing.** Each Party may make changes from time to time to its Compound or the Manufacturing Site, provided that such changes shall be in accordance with the Clinical Supply Quality Agreement.

**8.9. Product Testing; Nonconformance.**

**8.9.1. After Manufacturer's Release.** After Manufacturer's Release of the MSD Compound and concurrently with Delivery of the Compound to Collaborator, MSD shall provide Collaborator with the documentation described in the Clinical Supply Quality Agreement. Collaborator shall conduct the acceptance procedures under the Clinical Supply Quality Agreement within the time frames set forth therein. Collaborator shall be solely responsible for taking all steps necessary to determine that MSD Compound or Collaborator Compound, as applicable, is suitable for release before making such Compound available for human use, and MSD shall assist Collaborator as Collaborator reasonably requests in making such determination for the MSD Compound. Collaborator shall be responsible for storage and maintenance of the MSD Compound until it is tested and released, which storage and maintenance shall be in compliance with: (i) the Specifications for the MSD Compound, (ii) the Clinical Supply Quality Agreement, (iii) Applicable Law, and (iv) any specific storage and maintenance requirements as may be provided by MSD from time to time. Collaborator shall be responsible for any failure of the MSD Compound to meet the Specifications to the extent caused after Delivery to Collaborator hereunder.

**8.9.2. Non-Conformance.**

8.9.2.1 In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.9.1 (After Manufacturer's Release)), such Party shall immediately notify the other Party. Notification related to MSD Compound shall be in accordance with the Clinical Supply Quality Agreement. MSD shall investigate any Non-Conformance of the MSD Compound in accordance with the Clinical Supply Quality Agreement.

8.9.2.2 In the event that all or any portion of any proposed or actual shipment of the MSD Compound is agreed to be Non-Conforming at the time of Delivery to Collaborator then MSD shall replace any such Non-Conforming MSD Compound that has not been administered. [\*\*\*]. In the event MSD Compound is damaged by Collaborator after Delivery, MSD shall [\*\*\*].

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[\*\*\*]

MSD shall have no obligation to provide additional MSD Compound more than once. Except as set forth in this Section 8.9.2.2, MSD shall have no obligation to replace any MSD Compound supplied hereunder.

8.9.2.3 Collaborator shall be responsible for, and MSD shall have no obligation or liability with respect to Collaborator Compound that is found to have a Non-Conformance. Collaborator shall replace any Collaborator Compound that has not been administered. The sole and exclusive remedies of MSD with respect to any Collaborator Compound that is found to have a Non-Conformance at the time of Delivery shall be: [\*\*\*].

**8.9.3. Resolution of Discrepancies.** Disagreements regarding any determination of Non-Conformance by Collaborator shall be resolved in accordance with the Clinical Supply Quality Agreement or, in situations where the Clinical Supply Quality Agreement does not apply, Section 20 (GOVERNING LAW; DISPUTE RESOLUTION).

**8.10. Shortage; Allocation.** If a Party believes in good faith that it will not be able to fulfill its supply obligations hereunder because its Compound is in short supply, such Party will provide prompt written notice to the other Party of such shortage, the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply and the Parties will promptly discuss the situation (including allocation of Compound supplied hereunder within the MSD Compound Study). The Party experiencing the shortage shall have sole discretion, subject to Applicable Law, to determine how much Compound it will supply during the shortage, and such Party shall not be deemed to be in breach of this Agreement for failure to supply any quantities of its Compound as a result of such shortage. In case of one Party's shortage of its Compound, the other Party shall be relieved of its obligations under this Agreement to the extent impacted by such shortage.



**8.11. Quality Control.** Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality-assurance and quality-control procedures as are required by the Specifications, cGMPs and (with respect only to the MSD Compound) the Clinical Supply Quality Agreement.

**8.12. VAT.** Where MSD is treated as making a supply of goods in a particular jurisdiction for no consideration for VAT purposes, and Collaborator is treated as receiving such supply in the same jurisdiction, thus resulting in an amount of VAT being properly chargeable on such supply, Collaborator shall be obliged to pay to MSD the amount of VAT properly chargeable

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on such supply. Collaborator shall pay such VAT to MSD on receipt of a valid VAT invoice from MSD issued in accordance with the laws and regulations of the jurisdiction in which the VAT is properly chargeable. MSD will: (i) determine, in accordance with Applicable Law, the value of the supply that has been made and, as a result, the corresponding amount of VAT that is properly chargeable; and (ii) provide Collaborator any information or copies of documents in MSD's Control as are reasonably necessary for VAT purposes to evidence that such supply will take, or has taken, place in the same jurisdiction.

## **9. CONFIDENTIALITY.**

**9.1. Confidential Information.** Subject to Section 13.4.8 (Anti-Corruption), Collaborator and MSD agree to hold in confidence all Confidential Information of the other Party and use such Confidential Information only to fulfill its obligations or exercise its rights hereunder. Without limiting the foregoing, the Receiving Party may not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent such disclosure is: (i) required by Applicable Law; (ii) pursuant to the terms of this Agreement; or (iii) necessary for the conduct of the MSD Compound Study, and in each case ((i) through (iii)), provided that the Receiving Party shall provide reasonable advance notice to the Disclosing Party before making such disclosure. For the avoidance of doubt, Collaborator may, without MSD's consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing the MSD Compound Study, the data safety monitoring and advisory boards relating to the MSD Compound Study, and Regulatory Authorities working with Collaborator on the MSD Compound Study, in each case as necessary for the performance of the MSD Compound Study and provided that such Persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein.

**9.2. Inventions.** Notwithstanding the foregoing: [\*\*\*] and such Party shall have the right to use and disclose such Confidential Information in accordance with Articles 10 (INTELLECTUAL PROPERTY), 11 (REPRINTS; REFERENCES IN PUBLICATION) and 12 (PUBLICATIONS; PRESS RELEASES).

**9.3. Personal Identifiable Data.** All Confidential Information containing personal identifiable data shall be handled in

accordance with all applicable data-protection and privacy laws, rules and regulations.

- 9.4. *Publicity/Use of Names.*** Except as set forth in Section 12.3 (Press Releases), no Party shall use in any manner the name, trademark, trade name, logo or any other designation of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter without the prior express written permission of such Person, except as may be required by Applicable Law. In

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the event of any such use required by Applicable Law, the Party using the name, trademark, trade name, or logo of the other Party, its Affiliates, or their respective employees shall provide such Party with reasonable prior written notice and the opportunity to provide comments on such use.

## **10. INTELLECTUAL PROPERTY.**

- 10.1. *Joint Ownership.*** Collaborator and MSD shall jointly own all rights to all Joint Inventions and any Joint Patent claiming such Joint Invention(s). [\*\*\*]. For clarity, the terms of this Agreement do not provide either Party with any right, title or interest or any license to the other Party's intellectual property except as necessary to conduct the MSD Compound Study and as expressly provided under this Agreement, including as set forth in Section 10.7 (Mutual Freedom to Operate).

- 10.2. *Right to*** [\*\*\*]. Each Party shall have the right to [\*\*\*].

- 10.3. *Prosecution.*** As necessary following the Effective Date, but in any event as soon as practicable after the discovery of a Joint Invention, patent representatives of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Joint Inventions that may arise. In particular, the Parties shall discuss which Party will file a Joint Patent or whether outside counsel will file any such Joint Patent. Unless otherwise agreed, the Parties shall appoint mutually acceptable outside counsel to prosecute and maintain any Joint Patents. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of each Joint Patent, including the timely execution of any assignments reasonably necessary to continue the filing, prosecution or maintenance of each Joint Patent. [\*\*\*] The Non-Pursuing Party shall timely execute a power of attorney and any additional documents as may be reasonably necessary to allow the Party pursuing such filing, prosecution or maintenance of such Joint Invention or Joint Patent in the relevant countries (the "**Pursuing Party**"), [\*\*\*]. The Pursuing Party shall be solely responsible for [\*\*\*]. Unless otherwise agreed, the scope of the claim(s) of any Joint Patent in any country including a Cost Sharing Country or a Non-Cost Sharing Country shall be limited to combinations of: [\*\*\*].

- 10.4. *Prohibition of Patenting.*** Except as expressly provided in Section 10.3 (Prosecution) and in furtherance and not in limitation of Section 9.1 (Confidential Information), each Party agrees [\*\*\*].

## 10.5. Patent Enforcement.

10.5. Each Party shall promptly notify the other of any Third-Party Infringement in any country of which such Party becomes aware.

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10.5.2 Subject to the Restricted Rights provision of Section 10.3 (Prosecution), \*\*\* shall have the first right to initiate, prosecute and control any legal action in consultation with MSD to enforce all Joint Patents and Joint Inventions against Third-Party Infringement resulting \*\*\* or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that \*\*\* fails to initiate, prosecute, maintain or defend such action by the earlier of: (i) \*\*\* days after first being notified or made aware of such Third-Party Infringement; and (ii) \*\*\* days before the expiration date for initiating or defending such action, MSD shall have the right to do so at its sole expense.

10.5.3 Subject to the Restricted Rights provision of Section 10.3 (Prosecution), \*\*\* shall have the first right to initiate, prosecute and control any legal action in consultation with Collaborator to enforce all Joint Patents and Joint Inventions against Third-Party Infringement \*\*\* or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that \*\*\* fails to initiate, prosecute, maintain or defend such action by the earlier of: (i) \*\*\* days after first being notified or made aware of such Third-Party Infringement; and (ii) \*\*\* days before the expiration date for initiating or defending such action, Collaborator shall have the right to do so at its sole expense.

10.5.4 Subject to the Restricted Rights provision of Section 10.3 (Prosecution), the Parties shall cooperate to jointly initiate, prosecute and control any legal action to enforce \*\*\* against any Third-Party Infringement where such Third-Party Infringement results from \*\*\*. Notwithstanding the foregoing, either Party \*\*\* by the earliest of: (i) \*\*\* days after first being noticed of such Third-Party Infringement; (ii) \*\*\* days before the expiration date for filing such action; (iii) \*\*\* before the expiration date for filing an answer to a complaint in a declaratory judgment action; and (iv) \*\*\* days after notice is received, by one Party from other Party, informing the receiving Party that an application has been filed with the U.S. Food & Drug Administration under Section 351(k) of the U.S. Public Health Services Act (42 U.S.C. 262(k)) seeking approval of a biosimilar interchangeable biological product of the MSD Compound (when MSD is notifying party) or the Collaborator Compound (if Collaborator Compound is a biological product and Collaborator is notifying Party), which comes first. \*\*\*

10.5.5 If one Party pursuant to any of Sections 10.5.2, 10.5.3 or 10.5.4 brings any enforcement action or proceeding against a Third Party with respect to any \*\*\* ("**Controlling Party**"), the other Party agrees to be joined as a party plaintiff if requested and to give the Controlling Party reasonable assistance and authority to

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file and prosecute the suit. The Party being joined shall have the right to review and comment on, and approve, any material submissions to be made by the Controlling Party in connection with such a proceeding. The Controlling Party shall have final decision-making authority and shall bear \*\*\*, and any damages or other monetary awards recovered shall be shared as follows: \*\*\*.

**10.5.** For any action brought under this Section 10.5 (Patent Enforcement), each Party shall have the right to be represented by counsel of its own choice at its own expense.

**10.6. Inventions Owned by Each Party.** Notwithstanding anything to the contrary contained in Section 10.1 (Joint Ownership), the Parties agree that all rights to Collaborator Inventions shall be the exclusive property of Collaborator and all rights to MSD Inventions shall be the exclusive property of MSD. Each Party shall: (i) be entitled to file and prosecute in its own name applications for Patents in respect of Inventions it owns; and (ii) own Patents that issue from any such applications. For the avoidance of doubt: (a) any Invention generically encompassing \*\*\*; and (b) any Invention \*\*\*, is an MSD Invention. MSD hereby assigns its right, title and interest to any and all Collaborator Inventions to Collaborator, and Collaborator hereby assigns its right, title and interest to any and all MSD Inventions to MSD.

**10.7. Mutual Freedom to Operate.** Each Party hereby grants to the other Party a non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license to the \*\*\* solely for the purposes of: \*\*\*. For clarity, the terms of this Section 10.7 (Mutual Freedom to Operate) do not provide either Party with any rights, title or interest or any license to the Collaborator Background Patents, or the MSD Background Patents except as expressly set forth in the previous sentence.

**10.8. Termination.** \*\*\*; provided, however that the license granted in subsection (c) of Section 10.7 (Mutual Freedom to Operate) shall survive such expiration or termination except that if a Party terminates the Agreement pursuant to Section 6.3 (Termination for Breach), then only the grant to the terminating Party from the non-terminating Party shall survive.

**10.9. Ownership of Other Inventions.** Ownership of all Inventions other than Joint Inventions, MSD Inventions and Collaborator Inventions shall be based on inventorship as determined under United States patent law.

## **11. REPRINTS; REFERENCES IN PUBLICATION.**

Consistent with Applicable Law (including copyright law), each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences or symposia relating to the MSD Compound Study that

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disclose the name of a Party, provided, however, that such use does not constitute an endorsement of any commercial product or service by the other Party.

## **12. PUBLICATIONS; PRESS RELEASES.**

**12.1. Clinical Trial Registry.** Collaborator shall register the MSD Compound Study and Collaborator Clinical Trial with the clinical trials registry located at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (or any non-U.S. equivalent clinical trial registry), shall list MSD as a collaborator with respect to the Collaborator Clinical Trial, and shall timely publish the results following completion of the MSD Compound Study, after taking appropriate action to secure any intellectual property rights arising from the MSD Compound Study. The results of the MSD Compound Study will be published in accordance with the Protocol.

**12.2. Publication.** Each Party shall use reasonable efforts to publish or present scientific papers with respect to the MSD Compound Study in accordance with accepted scientific practice. The Parties agree that, prior to submission of the results of the MSD Compound Study for publication or presentation or any other dissemination of such results (including oral dissemination), the publishing Party shall invite the other to comment on the content of the material to be published, presented, or otherwise disseminated according to the following procedure:

**12.2.1** At least [\*\*\*] days prior to submission for [\*\*\*], or [\*\*\*] days prior to submission for presentation of [\*\*\*], publishing Party shall provide to the other Party the full details of the proposed publication, presentation or dissemination in an electronic version as an email attachment. Upon written request from the other Party publishing Party agrees not to submit data for publication/presentation/dissemination for an additional [\*\*\*] days to allow for actions to be taken to preserve rights for patent protection.

**12.2.2** The publishing Party shall reasonably consider any request by the other Party made within the periods set forth in Section 12.2.1 to modify the publication and the Parties shall work together to timely resolve any issue regarding the content for publication. Notwithstanding the foregoing, MSD Clinical Data shall be subject to final review and approval by MSD, not to be unreasonably withheld.

**12.2.3** The publishing Party shall remove all Confidential Information of the other Party before finalizing publication.

**12.3. Press Releases.** Promptly following the Effective Date, Collaborator may issue the press release attached hereto as Exhibit E. Except as provided herein or as otherwise required by Applicable Law, neither Party shall make any public announcement concerning this Agreement or the MSD Compound Study without the prior written consent of the other

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Party. To the extent a Party desires to make such public announcement, including any such public announcement required by Applicable Law, such Party shall request permission of the other Party and provide the other Party with a draft thereof including drafts of all translations for review and comment at least ten [\*\*\*]Days prior to the date on which such Party would like to make the public announcement (or, if it is not possible to provide a draft at least [\*\*\*] Business Days in advance of a disclosure required by Applicable Law, such draft shall be provided as soon as reasonably practicable).

### **13. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS.**

**13.1. Due Authorization.** Each of Collaborator and MSD represents and warrants to the other that: (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

#### **13.2. Compounds.**

**13.2.1 Collaborator Compound.** Collaborator hereby represents and warrants to MSD that: (i) Collaborator has the full right, power and authority to grant all of the licenses granted to MSD under this Agreement; (ii) the Collaborator Compound is the proprietary compound of Collaborator; (iii) Collaborator solely owns or has exclusive rights to any Patents claiming the Collaborator Compound as a composition of matter and the unfettered ability on a worldwide basis to grant a license or sublicense to such Patents to promote an initial or an updated label indication for the Combination in the same indication as the Combination Arm during the longer of the Term and the life of such Patents; and (iv) at the time of Delivery of the Collaborator Compound, such Collaborator Compound shall have been Manufactured and supplied in compliance with its Specifications and all Applicable Law.

**13.2.2 MSD Compound.** MSD hereby represents and warrants to Collaborator that: (i) MSD has the full right, power and authority to grant all of the licenses granted to Collaborator under this Agreement; (ii) MSD Controls the MSD Compound; and (iii) at the time of Delivery of the MSD Compound, such MSD Compound shall have been Manufactured and supplied in compliance with its Specifications, the Clinical Supply Quality Agreement, and all Applicable Law.

**13.3. Results.** Neither Party undertakes that the MSD Compound Study shall lead to any particular result, nor is the success of the MSD Compound Study guaranteed. Neither Party

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shall be liable for any use that the other Party may make of the Joint Clinical Data nor for advice or information given in connection therewith.

#### **13.4 Anti-Corruption.**

**13.4.1** The Parties acknowledge that the corporate policies or Codes of Conduct of Collaborator and MSD and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. Each Party agrees to conduct the business contemplated herein in a manner that is consistent with all Applicable Law, including the FCPA.

**13.4.2** Each Party represents and warrants that it and its Related Entities have not, and covenants that it and its Related Entities will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to seek an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, in any way with the purpose or effect of public or commercial bribery.

**13.4.3** Neither Party shall contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

**13.4.4** Each Party represents and warrants that it: (i) is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; (ii) has not employed or subcontracted with any Person for the performance of the MSD Compound Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs; and (iii) has conducted anti-corruption and bribery (e.g. FCPA) due-diligence review of all Third Parties it may hire to act on its behalf in connection with its performance under this Agreement.

**13.4.5** Each Party represents and warrants that, except as disclosed to the other in writing prior to the Effective Date of this Agreement, such Party: (i) does not have any interest that directly or indirectly conflicts with its proper and efficient performance of this Agreement; (ii) shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (iii) has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of any due

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diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures to the other Party as are necessary to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that prior to hiring or retaining any Government Official to assist in its performance of this Agreement it shall obtain the written consent of the other Party and complete a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official consistent with industry standards. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

**13.4.6** Each Party shall have the right during the Term, and for a period of [\*\*\*] following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.4. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit.

**13.4.7** Each Party shall use commercially reasonable efforts to ensure that all transactions under the Agreement properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar fraudulent accounts will be maintained or used in connection with this Agreement.

**13.4.8** Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of this Section 13.4, such other Party may make full disclosure of such belief and related information (including, if necessary, Confidential Information) needed to support such belief at any time and for any reason to any competent government bodies and agencies, and to anyone else such Party determines in good faith has a legitimate need to know.

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**13.4.9** Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees



participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to their performance of any obligations or activities under this Agreement. Each Party shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.

**13.4.10** Each Party shall have the right to terminate this Agreement immediately in accordance with Section 6.3 (Termination for Breach) in the event of any violation of this Section 13.4 by the other Party.

**13.5. Sufficient Resources.** Collaborator represents and warrants that it has sufficient resources to perform the activities for which it is responsible under this Agreement in accordance herewith.

**13.6. DISCLAIMER.** EXCEPT AS EXPRESSLY PROVIDED HEREIN, MSD MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE MSD COMPOUND, AND COLLABORATOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE COLLABORATOR COMPOUND, IN EACH CASE INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

#### **14. INSURANCE; INDEMNIFICATION; LIMITATION OF LIABILITY.**

**14.1. Insurance.** Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, a Party shall provide evidence of such insurance.

#### **14.2. Indemnification.**

**14.2.1 Indemnification by Collaborator.** Collaborator agrees to defend, indemnify and hold harmless MSD, its Affiliates, and its and their employees, officers, directors, Subcontractors and agents [\*\*\*].

**14.2.2 Indemnification by MSD.** MSD agrees to defend, indemnify and hold harmless Collaborator, its Affiliates, and its and their employees, officers, directors, Subcontractors and agents [\*\*\*].

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**14.2.3 Procedure.** The obligations of MSD and Collaborator under this Section 14.2 (Indemnification) are conditioned upon the delivery of written notice to the indemnifying Party of any potential Liability within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; provided that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner). The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Defending Party shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall

consider recommendations made by the other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the other Party from all liability with respect thereto or that imposes any liability or obligation on the other Party without the prior written consent of the other Party.

**14.2.4 MSD Compound Study Subjects.** Neither Party shall offer compensation on behalf of the other Party to any MSD Compound Study subject or bind the other Party to any indemnification obligations in favor of any MSD Compound Study subject.

**14.3. LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY, ITS AFFILIATES AND ITS OR THEIR EMPLOYEES, DIRECTORS, SUBCONTRACTORS OR AGENTS BE LIABLE TO THE OTHER PARTY UNDER ANY THEORY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES, ANY PUNITIVE DAMAGES, ANY LOST PROFIT, LOST SALE OR LOST OPPORTUNITY DAMAGES (WHETHER SUCH CLAIMED DAMAGES ARE DIRECT OR INDIRECT), ARISING DIRECTLY OR INDIRECTLY OUT OF OR RELATED TO THIS AGREEMENT, THE ACTIVITIES TO BE CONDUCTED BY THE PARTIES HEREUNDER OR THE COLLABORATOR CLINICAL TRIAL (INCLUDING THE MSD COMPOUND STUDY). SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH IT IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT WITH RESPECT TO USE, DISCLOSURE, LICENSE, ASSIGNMENT OR OTHER

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## TRANSFER OF JOINT CLINICAL DATA, CONFIDENTIAL INFORMATION, OR JOINT INVENTIONS.

### 15. FORCE MAJEURE.

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, fire, strike, acts of terror, governmental action and governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed. The non-performing Party shall notify the other Party of any such event within [\*\*\*] days after such occurrence by giving notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of

no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

#### **16. ENTIRE AGREEMENT; AMENDMENT; WAIVER.**

This Agreement, together with the appendices, Exhibits and Schedules hereto and the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. All appendices, Exhibits and Schedules to this Agreement are incorporated herein by reference and will be deemed part of this Agreement. In the event of a conflict between a Related Agreement and this Agreement, the terms of this Agreement shall control except: (i) in the event of any inconsistencies between the terms of this Agreement and the Data Protection Terms, the Data Protection Terms shall control; (ii) in the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement that relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), the terms of the Pharmacovigilance Agreement shall control; and (iii) in the event of any inconsistencies between the terms of this Agreement and the Clinical Supply Quality Agreement that relate directly to quality matters, the terms of the Clinical Supply Quality Agreement shall control. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right

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hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

#### **17. ASSIGNMENT AND AFFILIATES.**

Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign all or any part of this Agreement without the other Party's consent: (i) to one or more of its Affiliates, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided in each case, that such Affiliates agree to be bound by this Agreement; or (ii) in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether by merger, acquisition or similar transaction or series of related transactions. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing

herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of the Agreement. Any assignment not in accordance with this Article 17 shall be null, void and of no legal effect.

## **18. CHANGE OF CONTROL.**

If Collaborator undergoes a Change of Control in which the acquiring party owns or controls a competing PD-1 Antagonist, then upon MSD's request, the Parties and the acquiring party shall engage in discussion and shall adopt reasonable procedures to be agreed with MSD to prevent the disclosure of Sensitive Information beyond Collaborator's personnel having access to or knowledge of Sensitive Information prior to the Change of Control and other personnel of the acquiring party approved by MSD, and to control the dissemination of Sensitive Information disclosed after the Change of Control to prevent the use of Sensitive Information for the development or commercialization of competing PD-1 Antagonist products.

## **19. INVALID PROVISION.**

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

## **20. GOVERNING LAW; DISPUTE RESOLUTION.**

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

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**20.1.** The Parties shall attempt to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles.

**20.2.** Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

## **21. NOTICES.**

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by email to the applicable Party's Alliance Manager and the e-mail address set forth in each

Party's Notice Block on the Information Sheet or below (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Collaborator, to the address(es) set forth in the Collaborator Notice Block on the Information Sheet.

If to MSD, to:

MSD International Business GmbH

Tribschenstrasse 60

6005 Luzern

Switzerland

Attention: Director

With copies (which shall not constitute notice) to:

[\*\*\*]

## 22. RELATIONSHIP OF THE PARTIES.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or bind the other Party, except with the other Party's express prior written consent. All Persons employed by a Party will be the

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

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employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

## 23. COUNTERPARTS AND DUE EXECUTION.

This Agreement and any amendment may be executed in any number of counterparts (including by electronic transmission), each of which shall be deemed an original, but all of which together constitute one and the same instrument, notwithstanding any electronic transmission, storage or printing of this Agreement. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage or printing of this Agreement. For clarity, signatures transmitted by PDF shall be treated as original signatures.

## 24. CONSTRUCTION.

Except where the context otherwise requires, wherever used, the singular includes the plural and vice versa, the use of any gender will be applicable to all genders, and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers

to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term **“including”** as used herein shall be deemed to be followed by the phrase **“without limitation”** or like expression. The term **“will”** as used herein means shall. The terms **“hereof”**, **“hereto”**, **“herein”** and **“hereunder”** and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement. References to **“Article,” “Section,” “Exhibit”** or **“Schedule”** are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. A reference to any statute, law, rule, regulation or directive will be construed as a reference to such statute, law, rule, regulation or directive as amended, extended, repealed and replaced or re-enacted from time to time. A definition of or reference to any agreement, instrument or document herein shall refers to such agreement, instrument or other document as it may be amended, supplemented or otherwise modified from time to time (subject to any restrictions on such amendments, supplements or modifications set forth herein). Any reference to “agree,” “consent,” “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding instant messaging). Except where the context otherwise requires, references to this **“Agreement”** shall include the appendices, Exhibits and Schedules attached to this Agreement. The language of this

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Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank. Signature page follows.]

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

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IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

**IDEAYA Biosciences, Inc.**

By: /s/ Yujiro Hata

Yujiro Hata

Name

Chief Executive Officer

Title

**MSD International Business GmbH**

By: /s/ Darko Obradovic

Darko Obradovic

Name

Procurist

Title

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**Exhibit A**

**PROTOCOL SYNOPSIS**

[\*\*\*]

1.

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**Exhibit B**

**SUPPLY OF COMPOUND**

(MSD Tracking # PNF86-00)

(Collaborator Tracking # IDE161-001)

## **Schedule of Deliveries for Collaborator Compound (IDE-161)**

[\*\*\*]

## **Schedule of Deliveries for MSD Compound<sup>1,2</sup>**

[\*\*\*]

### **Notes:**

1) MSD Compound delivery dates and quantities are estimated. Dates and quantities may change based on study requirements in agreement between the parties. Total quantities should not exceed [\*\*\*] of the estimated total quantity listed in this Appendix.

2) [\*\*\*]

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

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## **EXHIBIT C**

### **DATA PROTECTION TERMS**

**25. DEFINITIONS.** The terms listed below shall have the meanings ascribed to them in this Section 1. Capitalized terms used in this Exhibit C and not defined herein shall have the meanings ascribed to them in the Agreement to which this Exhibit C is attached. Section and Article references in this Exhibit C shall refer to the Sections and Articles of this Exhibit C unless otherwise specified.

**25.1.**“Clinical Personal Data” means Personal Data contained in the Clinical Data and any Personal Data contained in Sample Testing Results Personal Data.

**25.2.**“CPS Data” means Clinical Personal Data and Safety Data.

**25.3.**“Data Controller” means a natural or legal person who, alone or with others, determines the purposes and means of Processing of Personal Data pursuant to applicable Data Protection Law, or the equivalent term as defined under Data Protection Law.

**25.4.**“Data Protection Law” means any applicable data security, data protection or privacy Applicable Laws, including GDPR and the U.S. state and federal laws.

**25.5.**“Data Subject” means an identified or identifiable individual. An identifiable individual is one who can be identified directly or indirectly, in particular by reference to an identifier such as a name, 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 individual, or the equivalent term as defined by Data Protection Law.

**25.6.**“General Data Protection Regulation” or “GDPR” means Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and any implementing directive or related legislation, rule, regulation, and regulatory guidance, as amended, extended, repealed and replaced, or re-enacted from time-to-time.



**25.7.** “Joint Data Controller” means one or more Data Controllers who jointly determine the purposes and means Processing of Personal Data.

**25.8.** “Joint Scope” means within the course of each Party’s performance of the Study and until a complete copy of Clinical Data has been provided to MSD, in accordance with Section 3.8 (Copies) of the Agreement.

**25.9.** “Personal Data” means any information that relates to any Data Subject.

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

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**25.11.** “Personal Data Breach” means a breach of security leading to the accidental, inadvertent, unauthorized, or unlawful disclosure, access, alteration, corruption, transfer, sale, rental, destruction, loss or use of Personal Data.

**25.1.** “Process” means any operation or set of operations performed on Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment, combination, restriction, erasure, destruction, or any equivalent term as defined by Data Protection Law.

**25.1.** “Safety Data” means safety reports containing information on adverse events, serious adverse events (SAEs), and FDA-reporting requirements, including summary tables of laboratory and radiographic data.

**25.13.** “Sample Testing Results Personal Data” means Personal Data contained in the Sample Testing Results.

**25.1.** “Third-Party Communication” means any communication, inquiry, request, or complaint from any third party, including any public authority or Data Subject, relating to Clinical Personal Data or Safety Data.

## **26. SCOPE.**

**26.1.** This EXHIBIT C is appended to and forms part of the Agreement. If any of the provisions of this EXHIBIT C conflict with the provisions of any other written or oral agreement concluded between the Parties, then the provisions of this Exhibit shall prevail with respect to data protection, data security and privacy matters.

**26.2.** MSD and Collaborator shall act as Joint Data Controllers in respect of Processing CPS Data within the Joint Scope; each Party shall act as independent Data Controllers for all other Processing of CPS Data. For clarity, each Party’s obligations as Joint Data Controllers shall continue with respect to any Processing of CPS Data performed by a Party within the Joint Scope.

**26.3.** Data Processing Activities. In relation to Personal Data Processed by one Party on behalf of the other Party pursuant to the Pharmacovigilance Agreement, the scope and purpose of the processing, duration of the processing, the data subjects concerned and the categories of personal information are specified in Table 1 hereto.

## **27. GENERAL.**

**27.1.** Each Party shall comply with Data Protection Law in Processing CPS Data.

**27.2.** All CPS Data shall be Confidential Information under the Agreement and subject to Article 9 (CONFIDENTIALITY)

of the Agreement.

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**27.3.** Each Party shall do all things reasonably necessary to assist the other in complying with its obligations under Data Protection Law, including ensuring that any international transfers of CPS Data are lawful, including, without limitation, in the case of Clinical Personal Data or Safety Data collected in, or of individuals in, the EEA, Switzerland, Serbia or United Kingdom, entering into the Standard Contractual Clauses. The “Standard Contractual Clauses” are the standard contractual clauses published by the European Commission or the Information Commissioners Office (“ICO”), as applicable, for such purpose, as the same may be amended or replaced from time to time by the European Commission or ICO decisions or other applicable Data Protection Law. In case of conflict between the terms of this Exhibit C and the Standard Contractual Clauses, the terms of the Standard Contractual Clauses shall prevail.

## **28. JOINT CONTROLLER TERMS.**

**28.1.** Each Party shall comply with Data Protection Law in Processing CPS Data. Each Party acknowledges and agrees it is a Joint Data Controller within the Joint Scope and this Article 4 shall apply to such Processing.

**28.2.** Purpose. Each Party shall only Process CPS Data in accordance with the Agreement, including Section 3.10 (Ownership and Use of Joint Clinical Data) of the Agreement. Each Party shall ensure at all times the CPS Data are processed only to the minimum extent necessary to accomplish the purpose of the Processing permitted hereunder and under the Agreement.

**28.3.** Provision of Information to Data Subjects and Lawful Basis for Processing. With respect to the CPS Data, Collaborator provide Data Subjects with all information required by Data Protection Law, including Articles 13 and 14 of the GDPR, and for ensuring that there is a legal basis for Processing the CPS Data.

**28.4.** Data Protection Impact Assessments and Prior Consultation. With respect to the CPS Data, Collaborator shall, where relevant, carry out data protection impact assessments and engage in prior consultations with the relevant supervisory authorities, and ensure that any Processing of the CPS Data is proportionate and complies with the data minimization principles of Data Protection Law.

**28.5.** Data Subject Requests and Third-Party Communications. Collaborator shall:

**28.5.1.** notify MSD promptly of the receipt of any Third-Party Communication;

**28.5.2.** respond to and resolve the Third-Party Communication (including any Third-Party Communication notified to Collaborator by MSD) and shall provide MSD with a reasonable opportunity to comment on and contribute to any response before it is sent; and

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**28.5.** keep MSD informed as to the status of the resolution of any Third-Party Communication and provide all information to MSD as may be reasonably requested in respect of the same.

**28.6.** Contact Point for Data Subjects. With respect to the CPS Data, Collaborator shall publicize a contact point for Data Subjects to facilitate the exercise of their rights under Data Protection Law.

**28.7.** Provision of Essence of the Arrangement. Collaborator shall make available to Data Subjects an agreed summary of the arrangement between Collaborator and MSD under this Article 4.

**28.8.** Personal Data Breach. With respect to CPS Data, Collaborator shall be responsible for complying with all required Personal Data Breach notification obligations under Data Protection Law, including Articles 33 and 34 of the GDPR. Upon becoming aware of any Personal Data Breach, Collaborator shall notify MSD without undue delay, and take reasonable steps to mitigate the effects of and remediate the Personal Data Breach.

**28.9.** Exercise of Obligations. In performing its obligations under this Article 4, Collaborator shall reasonably take into account the views of MSD and, unless required by Applicable Law, not take any action that would materially prejudice MSD without MSD's prior written consent.

**28.10.** Each Party is prohibited: (i) from selling Personal Data; and (ii) from retaining, using, or disclosing Personal Data: for a commercial purpose other than as set out in the Agreement; or (b) in any manner outside their direct business relationship.

**29. CERTIFICATION.** Each Party hereby certifies that it understands the restrictions set forth in Articles 3 and 4 of this Exhibit C and will comply with them and all applicable Data Protection Laws.

**30. TERM AND TERMINATION.** The terms and conditions of this Exhibit C shall become effective upon execution of the Agreement and shall remain in effect during the Term.

**Table 1 – DESCRIPTION OF PROCESSING**

<u>Personal information:</u> Individual patient case safety information will be shared as part of the legally required exchange of adverse event
<u>Categories of personal information:</u> Including but not limited to: patient health information, including details from their medical records; patient identifiers including age, sex, country of residence; reporter contact information
<u>Categories of data subjects:</u> Participants in a clinical trial; exposed to company drug; healthcare professional reporters

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

<b>Processing operations:</b> Case exchange of adverse event; inclusion of such information in the global safety database and the resulting periodic reports generated from the database for regulatory authorities globally
<b>Duration of Processing:</b> The duration of the Agreement to which this <u>Exhibit C</u> relates
<b>Purpose of processing:</b> Compliance with global and local regulatory safety and quality reporting requirements
<b>Security measures:</b> <ul style="list-style-type: none"> <li>(i) IT systems are protected from malicious code through the use of updated anti-virus software.</li> <li>(ii) IT systems are protected from unauthorized network access through the use of firewalls.</li> <li>(iii) Wireless networks, except for guest networks, are encrypted and require a digital certificate or access code to prevent unauthorized network access and eavesdropping.</li> <li>(iv) Reasonable steps are taken to keep software updated and patched to mitigate security vulnerabilities and ensure the ongoing resilience of processing systems.</li> <li>(v) Reasonable steps are taken to protect IT systems, computers, mobile devices, data storage media and printed copies from theft, unauthorized access and disclosure, e.g. via logon restrictions, passwords, locks, role-based access and similar.</li> <li>(vi) Password procedures are in place, including requiring strong passwords, periodically updating passwords and ensuring that passwords are stored securely and protected from unauthorized access</li> <li>(vii) Failed login attempts are logged and access is blocked after a certain number of failed login attempts</li> <li>(viii) Measures are implemented to ensure the safe disposal of IT systems, computers, mobile devices, data storage media (incl. printed copies) to prevent data from being retrieved from discarded equipment or documents.</li> <li>(ix) Measures are implemented to be able to restore the availability and access to data in a timely manner in the event of a physical or technical incident.</li> </ul>

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

## EXHIBIT D

### PRE-APPROVED COUNTRIES FOR MSD COMPOUND STUDY

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

**EXHIBIT E**

**PRESS RELEASE**

**IDEAYA Announces Clinical Collaboration to Evaluate IDE161 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Endometrial Cancer**

Trial will evaluate IDE161, IDEAYA's investigational PARG inhibitor, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with MSI-high and MSS endometrial cancer

Potential first-in-class PARG inhibitor, in combination with anti-PD-1 therapy, targets two complementary mechanisms of anti-tumor immune response in endometrial cancer

IDEAYA will sponsor the clinical trial and Merck will provide KEYTRUDA

**South San Francisco, CA, March [XX], 2024** – IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, today announced that it has entered into a clinical trial collaboration and supply agreement with Merck (known as MSD outside the US and Canada) to evaluate the IDE161, the company's investigational, potential first-in-class, small molecule poly (ADP-ribose) glycohydrolase, or PARG, inhibitor, in combination with KEYTRUDA® (pembrolizumab) Merck's anti-PD-1 therapy, in patients with microsatellite instability-, or MSI-, high and microsatellite stable, or MSS, endometrial cancer, in a Phase 1 clinical trial.

"We are excited to enter this collaboration as it allows study within and beyond the homologous recombination deficient (HRD) setting in endometrial cancer," said Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

"We are very pleased to collaborate with Merck on this trial evaluating IDE161 in combination with KEYTRUDA in patients with MSI-high and MSS endometrial cancer. IDEAYA's IDE161 combination strategy is focused on advancing multiple high conviction rational combinations, including beyond the HRD biomarker setting," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

IDE161 is a small molecule inhibitor targeting PARG, that is being evaluated in a Phase 1 clinical trial, which is currently in its monotherapy expansion stage. The trial is strategically focused on estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (Her2-) breast cancer with HRD, as well as other solid tumors with HRD, such as endometrial cancer, colorectal cancer and prostate cancer. In parallel, IDEAYA is continuing with a Phase 1 dose optimization. Of note, multiple partial responses by RECIST 1.1. and tumor shrinkage in priority solid tumor types were observed early in the Phase 1 dose escalation and dose expansion. IDE161 received the U.S. Food & Drug Administration Fast-Track designation for *BRCA1/2* ovarian and breast cancers.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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Under the clinical trial collaboration and supply agreement, Merck will provide KEYTRUDA to IDEAYA, which will be the sponsor of the Phase 1 clinical combination trial. IDEAYA and Merck each retain all commercial rights to their respective compounds, including as monotherapy or as combination therapies. The mechanistic rationale and preclinical data to support the IDE161 and PD-1 clinical combination will be provided as part of a future R&D update.

### About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

### Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related the potential therapeutic benefits of IDE161 in combination with KEYTRUDA. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of IDEAYA in general, see IDEAYA's recent Annual Report on Form 10-K filed on February 20, 2024 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.


### Investor and Media Contact

IDEAYA Biosciences

Andres Ruiz Briseno

SVP, Head of Finance and Investor Relations

[investor@ideavabio.com](mailto:investor@ideavabio.com)

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

### Schedule I

#### DATA SHARING SCHEDULE

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

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Schedule II  
SAMPLE TESTING SCHEDULE

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

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Exhibit 31.1

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Yujiro Hata, certify that:

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

statements for external purposes in accordance with generally accepted accounting principles;

- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2024 August 6, 2024

By:

/s/ Yujiro Hata

Yujiro Hata

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION OF THE PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andres Ruiz Briseno, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IDEAYA Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;



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

Date: May 7, 2024 August 6, 2024

By: /s/ Andres Ruiz Briseno

Andres Ruiz Briseno

Senior Vice President, Head of Finance and Investor Relations  
(Principal Financial and Accounting Officer)

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Exhibit 32.1

**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**

In connection with the Quarterly Report on Form 10-Q of IDEAYA Biosciences, Inc. (the “Company”) for the period ended **March 31, 2024** **June 30, 2024** as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Yujiro Hata, President and Chief Executive Officer of the Company, and I, Andres Ruiz Briseno, Senior Vice President and Head of Finance and Investor Relations of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

Date: May 7, 2024 August 6, 2024

Yujiro Hata  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 7, 2024 August 6, 2024

Andres Ruiz Briseno  
Senior Vice President, Head of Finance and Investor Relations  
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### DISCLAIMER

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