REFINITIV

DELTA REPORT

10-Q

BENITEC BIOPHARMA INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - DECEMBER 31, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1294
CHANGES	159
DELETIONS	172
ADDITIONS	963

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM10-Q
FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31,2023 March 31, 2024

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

For the transition period from_____to_____

Commission File Number001-39267

BENITEC BIOPHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-462-0206**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

3940 Trust Way, Hayward, California 94545
(Address of principal executive offices & zip code)

(510)780-0819
(Registrant's 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, par value $0.0001	**BNTC**	**The Nasdaq Stock Market LLC**

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of RegulationS-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, anon-acceleratedfiler, 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 Rule12b-2of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2of the Exchange Act). Yes ☐ or No ☒

We had 2,592,434
9,367,485 shares of our common stock outstanding as of the close of business on February 2nd, 2024. May 6, 2024.

BENITEC BIOPHARMA INC.

INDEX TO FORM 10-Q

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. Our forward-looking statements relate to future events or our future performance and include, but are not limited to, statements concerning our business strategy, future commercial revenues, market growth, capital requirements, new product introductions, expansion plans and the adequacy of our funding. All statements, other than statements of historical fact included in this Report, are forward-looking statements. When used in this Report, the words “could,” “believe,” “anticipate,” “intend,” “estimate,” “expect,” “may,” “continue,” “predict,” “potential,” “project,” or the negative of these terms, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include the following:

- the success of our plans to develop and potentially commercialize our product candidates;
- the timing of the initiation and completion of our preclinical studies and clinical trials;
- the timing and sufficiency of patient enrollment and dosing in our clinical trials;
- the timing of the availability of data from clinical trials;
- the timing and outcome of regulatory filings and approvals;
- unanticipated delays;
- sales, marketing, manufacturing and distribution requirements;
- market competition and the acceptance of our products in the marketplace;
- regulatory developments in the United States of America, France and Canada;
- the development of novel AAV vectors;
- the plans of licensees of our technology;
- the clinical utility and potential attributes and benefits of ddRNAi and our product candidates, including the potential duration of treatment effects and the potential for a “one shot” cure;
- our dependence on our relationships with collaborators and other third parties;
- expenses, ongoing losses, future revenue, capital needs and needs for additional financing, and our ability to access additional financing given market conditions and other factors, including our capital structure;

- our ability to continue as a going concern;
- the length of time over which we expect our cash and cash equivalents to be sufficient to execute on our business plan;
- our intellectual property position and the duration of our patent portfolio;
- the impact of local, regional, and national and international economic conditions and events; and
- the impact of the COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus and similar events, which may adversely impact our business and preclinical and future clinical trials;
    - the impact of the COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus and similar events, which may adversely impact our business and preclinical and clinical trials;

as well as other risks detailed under the caption “Risk Factors” in this Report and in other reports filed with the SEC. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Report, we caution you that these statements are based on a combination of facts and important factors currently known by us and our expectations of the future, about which we cannot be certain. Such statements are based on assumptions and the actual outcome will be affected by known and unknown risks, trends, uncertainties and factors that are beyond our control or ability to predict. We have based the forward-looking statements included in this Report on information available to us on the date of this Report or on the date thereof. Except as required by law we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised to consult any additional disclosures that we may make directly to you or through reports that we, in the future, may file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K.

All forward-looking statements included herein or in documents incorporated herein by reference are expressly qualified in their entirety by the cautionary statements contained or referred to elsewhere in this Report.

PART I—FINANCIAL INFORMATION

ITEM 1. Financial Statements

BENITEC BIOPHARMA INC.
Consolidated Balance Sheets
(in thousands, except par value and share amounts)

	December 31, 2023 (Unaudited)	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 20,374	$ 2,477
Restricted cash	14	13
Trade and other receivables	53	55
Prepaid and other assets	355	1,184
Total current assets	20,796	3,729
Property and equipment, net	51	87
Deposits	25	25
Prepaid and other assets	81	97

Right-of-use assets	400	526
Total assets	$ 21,353	$ 4,464
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 4,937	$ 3,231
Accrued employee benefits	523	472
Lease liabilities, current portion	286	275
Total current liabilities	5,746	3,978
Lease liabilities, less current portion	137	284
Total liabilities	5,883	4,262
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value - 160,000,000 shares authorized; 2,592,434 shares and 1,671,485 shares issued and outstanding at December 31, 2023 and June 30, 2023, respectively	—	—
Additional paid-in capital	197,063	168,921
Accumulated deficit	(180,641)	(167,889)
Accumulated other comprehensive loss	(952)	(830)
Total stockholders' equity	15,470	202
Total liabilities and stockholders' equity	$ 21,353	$ 4,464

The accompanying notes are an integral part of these consolidated financialstatements.

BENITEC BIOPHARMA INC.

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
Revenue:				
Licensing revenues from customers	$ —	$ 14	$ —	$ 14
Total revenues	—	14	—	14
Operating expenses:				
Royalties and license fees	1	—	(105)	—
Research and development	5,102	3,761	9,531	6,421
General and administrative	1,824	1,863	3,375	3,783
Total operating expenses	6,927	5,624	12,801	10,204
Loss from operations	(6,927)	(5,610)	(12,801)	(10,190)
Other income (loss):				
Foreign currency transaction gain (loss)	152	161	96	(346)
Interest expense, net	(6)	(9)	(12)	(18)
Other income (expense), net	(16)	50	(34)	50
Unrealized loss on investment	(1)	(3)	(1)	—
Total other income (loss), net	129	199	49	(314)
Net loss	$ (6,798)	$ (5,411)	$ (12,752)	$ (10,504)
Other comprehensive income (loss):				
Unrealized foreign currency translation gain (loss)	(172)	(160)	(122)	347
Total other comprehensive income (loss)	(172)	(160)	(122)	347

Total comprehensive loss	$ (6,970)	$ (5,571)	$ (12,874)	$ (10,157)
Net loss	$ (6,798)	$ (5,411)	$ (12,752)	$ (10,504)
Net loss per share:				
Basic and diluted	$ (2.64)	$ (3.34)	$ (5.39)	$ (9.30)
Weighted average number of shares outstanding: basic and diluted	2,576,347	1,621,280	2,366,706	1,129,926

The accompanying notes are an integral part of these consolidated financialstatements.

BENITEC BIOPHARMA INC.

Consolidated Statements of Stockholders' Equity

(Unaudited)

(in thousands, except share amounts)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at June 30, 2022	480,688	—	$ 152,454	$ (148,327)	$ (1,245)	$ 2,882
Issuance of common stock, pre-funded warrants, and common warrants sold for cash, net of offering costs of $1,869	1,037,520	—	16,015	—	—	16,015
Stock-based compensation			302	—	—	302
Foreign currency translation gain	—	—	—	—	507	507
Net loss	—	—	—	(5,093)	—	(5,093)
Balance at September 30, 2022	1,518,208	—	168,771	(153,420)	(738)	14,613
Exercise of pre-funded warrants	127,743	—	—	—	—	—
Share-based compensation			(48)			(48)
Foreign currency translation loss	—	—	—	—	(160)	(160)
Net loss	—	—	—	(5,411)	—	(5,411)
Balance at December 31, 2022	1,645,951	—	$ 168,720	$ (158,831)	$ (898)	$ 8,994
Balance at June 30, 2023	1,671,485	—	$ 168,921	$ (167,889)	$ (830)	$ 202
Issuance of common stock, pre-funded warrants, and common warrants sold for cash, net of offering costs of $2,964	875,949	—	27,919	—	—	27,919
Share-based compensation	—	—	91	—	—	91
Foreign currency translation gain	—	—	—	—	50	50
Net loss	—	—	—	(5,954)	—	(5,954)
Balance at September 30, 2023	2,547,434	—	196,931	(173,843)	(780)	22,308
Exercise of pre-funded warrants	25,000	—	—	—	—	—
Exercise of Series 2 warrants	20,000	—	39	—	—	39
Share-based compensation	—	—	93	—	—	93
Foreign currency translation loss	—	—	—	—	(172)	(172)
Net loss	—	—	—	(6,798)	—	(6,798)
Balance at December 31, 2023	2,592,434	—	$ 197,063	$ (180,641)	$ (952)	$ 15,470

The accompanying notes are an integral part of these consolidated financialstatements.

BENITEC BIOPHARMA INC.

Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Six Months Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (12,752)	$ (10,504)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36	83
Amortization of right-of-use assets	126	121
Unrealized loss on investment	1	—
Share-based compensation expense	184	254
Changes in operating assets and liabilities:		
Trade and other receivables	—	(50)
Prepaid and other assets	846	388
Trade and other payables	1,707	(50)
Accrued employee benefits	46	(5)
Lease liabilities	(136)	(125)
Net cash used in operating activities	(9,942)	(9,888)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from issuance and exercise of common stock, pre-funded warrants, and common warrants	30,922	17,884
Shares and pre-funded warrant issuance costs	(2,964)	(1,869)
Net cash provided by financing activities	27,958	16,015
Effects of exchange rate changes on cash, cash equivalents, and restricted cash	(118)	348
Net increase in cash, cash equivalents, and restricted cash	17,898	6,475
Cash, cash equivalents, and restricted cash, beginning of period	2,490	4,076
Cash, cash equivalents, and restricted cash, end of period	$ 20,388	$ 10,551

	March 31, 2024 (Unaudited)	June 30, 2023
Assets		
Current assets:		
Cash at bank	$ 14,143	$ 2,477
Restricted cash	13	13
Trade and other receivables	53	55
Prepaid and other assets	157	1,184
Total current assets	14,366	3,729
Property and equipment, net	204	87
Deposits	25	25
Prepaid and other assets	69	97
Right-of-useassets	335	526
Total assets	$ 14,999	$ 4,464
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 2,628	$ 3,231
Accrued employee benefits	517	472
Lease liabilities, current portion	292	275
Total current liabilities	3,437	3,978

Lease liabilities, less current portion	62	284
Total liabilities	3,499	4,262
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value—160,000,000 shares authorized; 2,724,794 shares and 1,671,485 shares issued and outstanding at March 31, 2024 and June 30, 2023, respectively	—	—
Additionalpaid-incapital	197,255	168,921
Accumulated deficit	(184,920)	(167,889)
Accumulated other comprehensive loss	(835)	(830)
Total stockholders' equity	11,500	202
Total liabilities and stockholders' equity	$ 14,999	$ 4,464

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

BENITEC BIOPHARMA INC.

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2024	2023	2024	2023
Revenue:				
Licensing revenues from customers	$ —	$ 54	$ —	$ 68
Total revenues	—	54	—	68
Operating expenses:				
Royalties and license fees	(3)	—	(108)	—
Research and development	2,566	3,167	12,097	9,588
General and administrative	1,578	1,228	4,953	5,011
Total operating expenses	4,141	4,395	16,942	14,599
Loss from operations	(4,141)	(4,341)	(16,942)	(14,531)
Other income (loss):				
Foreign currency transaction loss	(118)	(45)	(22)	(391)
Interest expense, net	(4)	(7)	(16)	(25)
Other income (expense), net	(16)	—	(50)	50
Unrealized loss on investment	—	(4)	(1)	(4)
Total other income (loss), net	(138)	(56)	(89)	(370)
Net loss	$ (4,279)	$ (4,397)	$ (17,031)	$ (14,901)
Other comprehensive income (loss):				
Unrealized foreign currency translation gain (loss)	117	45	(5)	392
Total other comprehensive income (loss)	117	45	(5)	392
Total comprehensive loss	$ (4,162)	$ (4,352)	$ (17,036)	$ (14,509)
Net loss	$ (4,279)	$ (4,397)	$ (17,031)	$ (14,901)
Net loss per share:				
Basic and diluted	$ (1.64)	$ (2.67)	$ (6.95)	$ (11.47)
Weighted average number of shares outstanding: basic and diluted	2,616,288	1,645,951	2,449,295	1,299,423

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

BENITEC BIOPHARMA INC.
Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at June 30, 2022	480,688	$ —	$ 152,454	$ (148,327)	$ (1,245)	$ 2,882
Issuance of common stock,pre-fundedwarrants, and Series 2warrants sold for cash, net of offering costs of $1,869	1,037,520	—	16,015	—	—	16,015
Stock-based compensation			302	—	—	302
Foreign currency translation gain	—	—	—	—	507	507
Net loss	—	—	—	(5,093)	—	(5,093)
Balance at September 30, 2022	1,518,208	—	168,771	(153,420)	(738)	14,613
Exercise ofpre-fundedwarrants	127,743	—	—	—	—	—
Share-based compensation			(48)			(48)
Foreign currency translation loss	—	—	—	—	(160)	(160)
Net loss	—	—	—	(5,411)	—	(5,411)
Balance at December 31, 2022	1,645,951	$ —	$ 168,723	$ (158,831)	$ (898)	$ 8,994
Share-based compensation			71	—	—	71
Foreign currency translation gain	—		—	—	45	45
Net loss	—		—	(4,397)	—	(4,397)
Balance at March 31, 2023	1,645,951	$ —	$168,794	$ (163,228)	$ (853)	$ 4,713
Balance at June 30, 2023	1,671,485	$ —	$ 168,921	$ (167,889)	$ (830)	$ 202
Issuance of common stock,pre-fundedwarrants, and common warrants sold for cash, net of offering costs of $2,964	875,949	—	27,919	—	—	27,919
Share-based compensation	—	—	91	—	—	91
Foreign currency translation gain	—	—	—	—	50	50
Net loss	—	—	—	(5,954)	—	(5,954)
Balance at September 30, 2023	2,547,434	—	196,931	(173,843)	(780)	22,308
Exercise ofpre-fundedwarrants	25,000	—	—	—	—	—
Exercise of Series 2 warrants	20,000	—	39	—	—	39
Share-based compensation	—	—	93	—	—	93
Foreign currency translation loss	—	—	—	—	(172)	(172)
Net loss	—	—	—	(6,798)	—	(6,798)
Balance at December 31, 2023	2,592,434	$ —	$ 197,063	$ (180,641)	$ (952)	$ 15,470
Exercise ofpre-fundedwarrants	132,360	—	—	—	—	—
Share-based compensation	—	—	192	—	—	192
Foreign currency translation gain	—	—	—	—	117	117
Net loss	—	—	—	(4,279)	—	(4,279)
Balance at March 31, 2024	2,724,794	$ —	$ 197,255	$ (184,920)	$ (835)	$ 11,500

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

BENITEC BIOPHARMA INC.
Consolidated Statements of Cash Flows

(Unaudited)
(in thousands)

	Nine Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (17,031)	$ (14,901)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	61	115
Amortization ofright-of-useassets	191	182
Unrealized loss on investment	1	4
Share-based compensation expense	376	325
Changes in operating assets and liabilities:		
Trade and other receivables	—	(50)
Prepaid and other assets	1,051	(14)
Trade and other payables	(602)	580
Accrued employee benefits	48	30
Lease liabilities	(205)	(188)
Net cash used in operating activities	(16,110)	(13,917)
Cash flows from investing activities:		
Purchase of property and equipment	(179)	—
Net cash used in investing activities	(179)	
Cash flows from financing activities:		
Proceeds from issuance and exercise of common stock,pre-fundedwarrants, Series 2 warrants, and common warrants	30,922	17,884
Shares andpre-fundedwarrant issuance costs	(2,964)	(1,869)
Net cash provided by financing activities	27,958	16,015
Effects of exchange rate changes on cash, cash equivalents, and restricted cash	(3)	391
Net increase in cash, cash equivalents, and restricted cash	11,666	2,489
Cash, cash equivalents, and restricted cash, beginning of period	2,490	4,076
Cash, cash equivalents, and restricted cash, end of period	$ 14,156	$ 6,565

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

BENITEC BIOPHARMA INC.
Notes to Consolidated Financial Statements
(Unaudited)

1. Business

Benitec Biopharma Inc. (the “Company”, “we”, “our”) is a corporation formed under the laws of Delaware, United States of America, on November 22, 2019 and listed on the Nasdaq Capital Market (“Nasdaq”) under the symbol “BNTC”. Benitec Biopharma Inc. is the parent entity of a number of subsidiaries including the previous parent entity Benitec Biopharma Limited (“BBL”). BBL was incorporated under the laws of Australia in 1995 and was listed on the Australian Securities Exchange, or ASX, from 1997 until April 15, 2020. On August 14, 2020, BBL reorganized as a Proprietary Limited company and changed its name to Benitec Biopharma Proprietary Limited. The Company’s business focuses on the development of novel genetic medicines. Our proprietary platform, calledDNA-directedRNA interference, or ddRNAi, combines RNA interference, or RNAi, with gene therapy to create medicines that facilitate sustained silencing of disease-causing genes.

During the year ended June 30, 2021, the Company completed an organization restructuring as part of the commercial desire to provide a more efficient structure for the future as the Company transitioned its operations to the United States.

The Company’s fiscal year end is June 30. References to a particular “fiscal year” are to our fiscal year end June 30 of that calendar year.

The consolidated financial statements of Benitec Biopharma Inc. are presented in United States dollars and consist of Benitec Biopharma Inc. and its wholly owned subsidiaries as listed below. Aside from Benitec Biopharma Proprietary Limited, the international subsidiaries are dormant.

	Principal place of business/country of incorporation
Benitec Biopharma Proprietary Limited ("BBL")	Australia
Benitec Australia Proprietary Limited	Australia
Benitec Limited	United Kingdom
Benitec, Inc.	USA
Benitec LLC	USA
RNAi Therapeutics, Inc.	USA
Tacere Therapeutics, Inc.	USA
Benitec IP Holdings, Inc.	USA

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements contained in this Quarterly Report on Form10-Qhave been prepared in accordance with generally accepted accounting principles in the U.S. ("GAAP") for interim financial information and with the instructions to Form10-Qand Article 8 of U.S. Securities and Exchange Commission ("SEC") RegulationS-X.Accordingly, certain information and disclosures required by GAAP for annual financial statements have been omitted. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Interim financial results are not necessarily indicative of results anticipated for the full year. These consolidated financial statements should be read in conjunction with the Company's audited financial statements andaccompanyingnotes included in the Company's Annual Report on Form10-Kfor the year ended June 30, 2023.

On July 26, 2023, the Company effected a1-for-17reverse stock split (the "Reverse Stock Split") of its common stock. In accordance with the Reverse Stock Split, 17pre-splitshares of the Company's common stock were automatically converted into one issued and outstanding post-split share. Proportional adjustments were also made to all outstanding stock options,pre-fundedwarrants, and common warrants in accordance with their respective terms. The Reverse Stock Split did not change the par value of the Company's common stock or the authorized number of shares. No fractional shares were issued in connection with the Reverse Stock Split. All fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock. All share and earnings per share amounts presented in this Form10-Qreflect the impact of this reverse split as if it had taken effect on June 30, 2022.

Reference is frequently made herein to the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC"). This is the source of authoritative GAAP recognized by the FASB to be applied tonon-governmentalentities.

Principles of Consolidation

The consolidated financial statements include the Company's accounts and the accounts of its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of the Company's consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates and assumptions in the Company's consolidated financial statements include the estimates of useful lives of property relate to accrued research and equipment, valuation of the operating lease liability development expense and related right-of-use asset, valuation of equity-based instruments issued for other than cash, the valuation allowance on deferred tax assets, and accrued research and development expense. cash. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will beaffected.

Reclassifications

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

Risks and Uncertainties

The Company 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, reliance on single-source single-source vendors and collaborators, availability of raw materials, patentability of the Company's products and processes and clinical efficacy and safety of the Company's products under development, compliance with government regulations and the need to obtain additional financing to fund operations.

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 any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid technological change 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.

Moreover, theCOVID-19pandemic, which impacted and may in the future impact worldwide economic activity, and similar events pose risks that the Company or its employees, contractors, suppliers, and other partners may be prevented or inhibited from conducting business activities for an indefinite period of time, which may delay thestart-upand conduct of the Company's clinical trials, and negatively impact manufacturing and testing activities performed by third parties. Any significant delays may impact the use and sufficiency of the Company's existing cash reserves, and the Company may be required to raise additional capital earlier than it had previously planned. The Company may be unable to raise additional capital if and when needed, which may result in delays or suspension of its development plans. The extent to which the pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Foreign Currency Translation and Other Comprehensive Income (Loss)

The Company's functional currency and reporting currency is the United States dollar. BBL's functional currency is the Australian dollar (AUD). Assets and liabilities are translated at the exchange rate in effect at the balance sheet date. Revenues and expenses are translated at the average rate of exchange prevailing during the reporting period. Equity transactions are translated at each historical transaction date spot rate. Translation adjustments arising from the use of different exchange rates from period to period are included as a component of stockholders' equity as "Accumulated other comprehensive loss." Gains and losses resulting from foreign currency translation are included in the consolidated statements of operations and comprehensive loss as other comprehensive income (loss).

Other comprehensive income for all periods presented consists entirely of foreign currency translation gains and losses.

Fair Value Measurements

The Company measures its financial assets and liabilities in accordance with GAAP using ASC 820, Fair Value Measurements. For certain financial instruments, including cash and cash equivalents, accounts receivable, and accounts payable, the carrying amounts approximate fair value due to their short maturities.

The Company follows accounting guidance for financial assets and liabilities. ASC 820 defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

Level 1:	Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
Level 2:	Inputs, other than quoted prices that are observable, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
Level 3:	Unobservable inputs in which little or no market data exists, therefore developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and at banks, short-term deposits with an original maturity of three months or less with financial institutions, and bank overdrafts. Bank overdrafts are reflected as a current liability on the consolidated balance sheets. There were no other forms of cash equivalents as of December 31, 2023 March 31, 2024 and June 30, 2023.

Restricted cash balances of $14 thousand as of December 31, 2023 and $13 thousand as of March 31, 2024 and June 30, 2023 are used to secure the Company's credit card.

Concentrations of Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits at federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Trade and Other Receivables

The Company adopted ASC 326—*Financial Instruments—Credit Losses (Topic 326).*as of July 1, 2023. As such, the Company estimates current expected credit losses (CECL) on trade and other receivables on an ongoing basis, and will recognize those expected credit losses immediately. Estimates of current expected credit losses will be based on analyses of individual customer circumstances and historicalwrite-offexperience. The Company's analyses will consider the aging of receivable accounts, customer creditworthiness, and general economic conditions.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Expenditures for maintenance and repairs are expensed as incurred; additions, renewals, and improvements are capitalized. When property and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation and amortization are removed from the respective accounts, and any gain or loss is included in operations. Depreciation and amortization of property and equipment is calculated using the straight-line basis over the following estimated useful lives:

Software	3-4years
Lab equipment	3-7years
Computer hardware	3-5years
Leasehold improvements	shorter of the lease term or estimated useful lives

Impairment of Long-Lived Assets

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of long-lived assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the assets. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable.

Trade and other payables

These amounts represent liabilities for goods and services provided to the Company prior to the end of the period and which are unpaid. Due to their short-term nature, they are measured at cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term. The Company calculates the present value of lease payments using the discount rate implicit in the lease, unless that rate cannot be readily determined. In that case, the Company uses its incremental borrowing rate, which is the rate of interest that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments over the expected lease term. The Company records a correspondingright-of-uselease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement; and (ii) theright-of-uselease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

Basic and Diluted Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding plus potential common shares. Stock options, warrants and convertible instruments are considered potential common shares and are included in the calculation of diluted net loss per share using the treasury stock method when their effect is dilutive. Potential common shares are excluded from the calculation of diluted net income (loss) per share when their effect is anti-dilutive. As of December 31, 2023 March 31, 2024, and June 30, 2023, there were 33,644,413 34,481,458 and 2,456,032 potential common shares, respectively, that were excluded from the calculation of diluted net loss per share because their effect was anti-dilutive.

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606—*Revenue from Contracts with Customers*(“ASC 606” 606”). The core principle of ASC 606 is that entities are to recognize revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

The Company recognizes revenue in accordance with that core principle by applying the following steps:

Step 1: Identify the contract(s) with a customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract.

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies judgement in determining whether contracts entered into fall within the scope of ASC 606. In doing so, management considers the commercial substance of the transaction and how risks and benefits of the contract accrue to the various parties to the contract.

Management has also made the judgement that the grant of the license and transfer of associatedknow-howand materials are accounted for as one performance obligation as they are not considered to be distinct; they are highly interrelated and could not provide benefits to the customer independently from each other. Judgements were made in relation to the transfer of the license andknow-howand whether this should be recognized over time or a point in time. The point in time has been determined with regard to the point at which the transfer ofknow-howhas substantially been completed and the customer has control of the asset and the ability to direct the use of and receive substantially all of the remaining benefits.

Licensing revenues

Revenue from licensees of the Company's intellectual property reflects the transfer of a right to use the intellectual property as it exists at the point in time in which the license is transferred to the customer. Consideration can be variable and is estimated using the most likely amount method and is constrained to the extent that it is probable that a significant reversal will not occur. Revenue is recognized as or when the performance obligations are satisfied.

The Company recognizes contract liabilities for consideration received in respect of unsatisfied performance obligations and reports these amounts as other liabilities in the consolidated balance sheet. Similarly, if the Company satisfies a performance obligation before it receives the consideration, the Company recognizes either a contract asset or a receivable in its consolidated balance sheet, depending on whether something other than the passage of time is required before the consideration is due.

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Royalties

Revenue from licensees of the Company's intellectual property reflect a right to use the intellectual property as it exists at the point in time in which the license is granted. Where consideration is based on sales of product by the licensee, revenue is recognized when the customer's subsequent sales of products occur.

Services revenue

Revenue is earned (constrained by variable considerations) from the provision of research and development services to customers. Services revenue is recognized when performance obligations are either satisfied over time or at a point in time. Generally, the provision of research and development services under a contract with a customer will represent satisfaction of a performance obligation over time where the Company retains the right to payment for services performed but not yet completed.

Research and Development Expense

Research and development expenses relate primarily to the cost of conducting clinical andpre-clinicaltrials.Pre-clinicaland clinical development costs are a significant component of research and development expenses. The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct ofpre-clinicalstudies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in trade and other payables on the consolidated balance sheets and within research and development expenses on the consolidated statements of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred.

Share-based Compensation Expense

The Company records share-based compensation in accordance with ASC 718,*Stock Compensation*. ASC 718 requires the fair value of all share-based compensation awarded to employees andnon-employeesto be recorded as an expense over the shorter of the service period or the vesting period. The Company determines employee andnon-employeeshare-based compensation based on the grant-date fair value using the Black-Scholes Option Pricing Model.

Income Taxes

The Company is subject to Australia and United States income tax laws. The Company follows ASC 740,*Accounting for Income Taxes*, when accounting for income taxes, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for temporary differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount more likely than not to be realized.

For uncertain tax positions that meet a "more likely than not" threshold, the Company recognizes the benefit of uncertain tax positions in the consolidated financial statements. The Company's practice is to recognize interest and penalties, if any, related to uncertain tax positions in income tax expense in the consolidated statements of operations.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASUNo. 2016-13:*Financial Instruments—Credit Losses (Topic 326).*This ASU represents a significant change in the accounting for credit losses model by requiring immediate recognition of management's estimates of current expected credit losses (CECL). Under the prior model, losses were recognized only as they were incurred. The Company adopted this ASU effective July 1, 2023 and determined that its impact on the accompanying consolidated financial statements is immaterial.

Recently Issued Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASUNo. 2023-09,*Income Taxes*(Topic 740) – Improvements to Income Tax Disclosures, which enhances the transparency, effectiveness, and comparability of income tax disclosures by requiring consistent categories and greater disaggregation of information related to income tax rate reconciliations and the jurisdictions in which income taxes are paid. This guidance is effective for annual periods beginning after December 15, 2024 with early adoption permitted. The Company is currently evaluating the impact of the ASU on its income tax disclosures within the consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures", which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. This ASU also expands disclosure requirements to enable users of financial statements to better understand the entity's measurement and assessment of segment performance and resource allocation. This guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of the ASU on its disclosures within the consolidated financial statements.

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3. Liquidity

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. For the six nine months ended December 31, 2023 March 31, 2024, and 2022, 2023, the Company incurred a net loss losses of $12.8 $17.0 million and $10.5 $14.9 million, respectively, and used cash of $9.9 million in operations in both six-month periods. of $16.1 million and $13.9 million, respectively. The Company expects to continue to incur additional operating losses in the foreseeable future.

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The Company's business focuses on the development of novel genetic medicines and, at this stage in the Company's development, the Company has not established a source of revenue to cover its full operating costs, and as such, is dependent on funding operations through capital financing activities. As of December 31, 2023 March 31, 2024, the Company had $20.4 million $14.1 million in cash and cash equivalents. On April 18, 2024 we closed a private investment in public equity (PIPE) financing in which we sold 5,749,152 shares of common stock at a price per share of $4.80 and, in lieu of shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,584,239 shares of common stock at a price per pre-funded warrant of $4.7999, to certain accredited institutional investors. The pre-funded warrants were immediately exercisable until exercised in full at an exercise price of $0.0001 per share of common stock. Gross proceeds from the financing totaled $40.0 million. We estimate that our cash and cash equivalents will be sufficient to fund the Company's operations for at least the next twelve months from the date of this report.

The Company's ability to continue as a going concern is dependent upon its ability to generate revenue and obtain adequate financing. While the Company believes in its ability to generate revenue and raise additional funds, there can be no assurances to that effect. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern due to unsuccessful product development or commercialization, or the inability to obtain adequate financing in the future.

4. Cash, cash equivalents, and restricted cash

(US$'000)	December 31, 2023	June 30, 2023
Cash at bank	$ 20,374	$ 2,477
Restricted cash	14	13
Total	$ 20,388	$ 2,490

(US$'000)	March 31, 2024	June 30, 2023
Cash at bank	$ 14,143	$ 2,477
Restricted cash	13	13
Total	$ 14,156	$ 2,490

5. Prepaid and other assets

(US$'000)	December 31, 2023	June 30, 2023
Prepaid expenses	$ 435	$ 1,280
Market value of listed shares	1	1
Total other assets	436	1,281
Less: non-current portion	(81)	(97)
Current portion	$ 355	$ 1,184

(US$'000)	March 31, 2024	June 30, 2023
Prepaid expenses	$ 225	$ 1,280
Market value of listed shares	1	1
Total other assets	226	1,281
Less:non-currentportion	(69)	(97)
Current portion	$ 157	$ 1,184

6. Property and equipment, net

(US$'000)	December 31, 2023	June 30, 2023
Software	$ 6	$ 6
Lab equipment	1,343	1,343
Computer hardware	32	32
Leasehold improvements	24	24
Total property and equipment, gross	1,405	1,405
Accumulated depreciation and amortization	(1,354)	(1,318)
Total property and equipment, net	$ 51	$ 87

(US$'000)	March 31, 2024	June 30, 2023
Software	$ 6	$ 6
Lab equipment	1,522	1,343
Computer hardware	32	32
Leasehold improvements	24	24
Total property and equipment, gross	1,584	1,405
Accumulated depreciation and amortization	(1,380)	(1,318)
Total property and equipment, net	$ 204	$ 87

Depreciation and amortization expense was $17 $25 thousand and $36
$61 thousand for the three and six nine months ended December 31, 2023 March 31, 2024, and $41 $32 thousand and
$83 $115 thousand, respectively, for the same periods in 2022. 2023.

7. Trade and other payables

(US$'000)	December 31, 2023	June 30, 2023
Trade payable	$ 2,619	$ 1,140
Accrued license fees	2	109
Accrued professional fees	71	75
Accrued clinical development project costs	2,171	1,838
Other payables	74	69
Total	$ 4,937	$ 3,231

(US$'000)	March 31, 2024	June 30, 2023
Trade payable	$ 815	$1,140
Accrued license fees	—	109
Accrued consultant fees	85	88
Accrued professional fees	64	75
Accrued clinical development project costs	1,585	1,750
Other payables	79	69
Total	$ 2,628	$ 3,231

8. Leases

The Company has entered into an operating lease for office space under an agreement that expires in 2025. The lease requires the Company to pay utilities, insurance, taxes, and other operating expenses. The Company's lease does not contain any residual value guarantees or material restrictive covenants.

The tables below show the changes during the six nine months ended December 31, 2023 March 31, 2024:

(US$'000)	Operating lease right-of-use assets
Balance at July 1, 2023	$ 526
Amortization of right of use asset	(126)
Operating lease right-of-use asset at December 31, 2023	$ 400

(US$'000)	Operating lease right-of-use assets
Balance at July 1, 2023	$ 526
Amortization of right of use asset	(191)
Operating leaseright-of-useasset at March 31, 2024	$ 335

(US$'000)	Operating lease liabilities
Balance at July 1, 2023	$ 559

Principal payments on operating lease liabilities	(136)
Operating lease liabilities at December 31, 2023	423
Less: non-current portion	(137)
Current portion at December 31, 2023	$ 286

(US$'000)	Operating lease liabilities
Balance at July 1, 2023	$ 559
Principal payments on operating lease liabilities	(205)
Operating lease liabilities at March 31, 2024	354
Less:non-currentportion	(62)
Current portion at March 31, 2024	$ 292

As of December 31, 2023 March 31, 2024, the Company's operating lease has a remaining lease term of 1.45 1.21 years and a discount rate of 4.67%. The maturities of the operating lease liabilities are as follows:

(US$'000)	December 31, 2023
2024	$ 147
2025	291
Total operating lease payments	438
Less imputed interest	(15)
Present value of operating lease liabilities	$ 423

(US$'000)	March 31, 2024
2024	$ 74
2025	291
Total operating lease payments	365
Less imputed interest	(11)
Present value of operating lease liabilities	$ 354

The Company recorded lease liabilities andright-of-uselease assets for the lease based on the present value of lease payments over the expected lease term, discounted using the Company's incremental borrowing rate. Rent expense was $0.1 million $0.1 million and $0.1 million $0.2 million for the three and six nine months ended December 31, 2023 March 31, 2024, respectively, $0.1 million respectively; and $0.1 million and $0.2 million for the same periods in 2022. 2023, respectively.

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9. Stockholders' equity

Common Stock

On December 8, 2021, the stockholders of the Company approved an amendment (the "Charter Amendment") to the Company's Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of common stock of the Company from 10,000,000 to 40,000,000, which became effective on December 17, 2021. On December 7, 2022, the stockholders of the Company approved another amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 40,000,000 to 160,000,000. The Charter Amendment was filed with the Secretary of State of the State of Delaware and became effective December 9, 2022. On July 26, 2023, the Company effected a1-for-17reverse stock split (the "Reverse Stock Split") (see Note 2. Basis of Presentation and Summary of Significant Accounting Policies – Basis of Presentation).

Warrants

On December 6, 2019, investors were
issued 4 Purchase Warrants that were exercisable into 12,600 fully paid shares of common stock should the Purchase Warrants be exercised in full ("Purchase Warrants"). The exercise price for the Purchase Warrants is US$178.50 per share issued on exercise of a Purchase Warrant. The Purchase Warrants are exercisable, in whole or in part, any time from the date of issue until the fifth anniversary of the date of issue (December 6, 2024). On April 22, 2020, the Company issued 2,201 shares of common stock in connection with a cashless exercise of Purchase Warrants exercisable for 6,300 shares of common stock. The Company did not have an effective registration statement registering the resale of the Warrant Shares by the Holder at the time the Holder wanted to exercise the warrant; therefore, the Holder carried out a cashless exercise. The formula for conducting a cashless exercise was outlined in the Warrant agreement. Based on this formula, the Holder would have been entitled to receive 6,300 shares of common stock if they had exercised the Purchase Warrants for cash. Because of the cashless exercise, the holder received 2,201 shares.

On September 15, 2022, we closed an underwritten public offering in which we issued and sold (i) 1,037,520 shares of the Company's common stock, (ii) 12,171,628pre-fundedwarrants, which, after giving effect to the Reverse Stock Split, are currently exercisable into 715,979 shares of common stock at an exercise price of $0.0017 per share until exercised in full and (iii) 29,809,471 Series 2 warrants (the "Series 2 Warrants"), which, after giving effect to the Reverse Stock Split, are currently exercisable into 1,753,503 shares of common stock at an exercise price of $11.22 per share. The Series 2 warrants sold in the offering became exercisable commencing December 9, 2022, the date on which the Company had both (a) received approval from its stockholders to increase the number of shares of common stock it is authorized to issue and (b) effected such stockholder approval by filing with the Secretary of State of the State of Delaware a certificate of amendment to its Amended and Restated Certificate of Incorporation, and will expire on the fifth anniversary of such initial exercise date. The combined purchase price for each share of common stock common stock and accompanying common warrant was $10.20, which was allocated as $10.03 per share of common stock and $0.17 per common warrant. The Series 2 Warrants contain an exercise price adjustment mechanism providing that certain issuances of common stock (or common stock equivalents), if made at a price lower than the then existing exercise price of such Series 2 Warrants would reset the exercise price to such lower price. As a result of the August 11, 2023 public offering, the exercise price of the Series 2 Warrants has been automatically reset as of the closing time of such public offering to $1.9299.

On October 17, 2022 and October 27, 2022, investors exercised 117,939 and 9,804pre-fundedwarrants, respectively, at an exercise price of $0.0017 per share.

On August 11, 2023 we closed an underwritten public offering in which we sold 875,949 shares of common stock, 15,126,226pre-fundedwarrants to purchase 15,126,226 shares of common stock, and 16,002,175 common warrants to purchase up to 16,002,175 shares of common stock. The combined purchase price for each share of common stock and accompanying common warrant was $1.93, which was allocated as $1.9299 per share of common stock and $0.0001 per common warrant. Eachpre-fundedwarrant was sold together with one common warrant at a combined price of $1.9299, which was allocated as $1.9298 perpre-fundedwarrant and $0.0001 per common warrant. Thepre-fundedwarrants were immediately exercisable until exercised in full at an exercise price of $0.0001 per share of common stock. The common warrants were immediately exercisable at an exercise price of $3.86 per share of common stock and will expire on the fifth anniversary of such initial exercisable date. In addition, the Company granted the underwriter aa 30-dayoption to purchase up to 2,331,606 additional shares of common stock and/or up to 2,331,606additional common warrants. As ofDecember 31, 2023, the The underwriter had partially exercised this option and purchased 458,134 additional shares of common stock and 458,134additional common warrants. These additional shares are included in the total sold on August 11, 2023. Net proceeds from the offering, including the impact of the underwriter's partial exercise of its option and net of underwriting discounts, commissions, and other offering expenses, totaled $27.9 million. $

27.9 million.

On October 17, 2023 an investor exercised 25,000pre-fundedwarrants at an exercise price of $0.0001 per share. On November 24, 2023, an investor exercised 20,000 Series 2 warrants at an exercise price of $1.93 per share. On March 15, 2024 and March 18, 2024, investors exercised 105,888 and 26,472pre-fundedwarrants, respectively, at an exercise price of $0.0001 per share.

As of December 31, 2023 March 31, 2024, there were 33,431,440 33,299,080 warrants outstanding.

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The activity related to warrants for the three and six nine months ended December 31, 2023 March 31, 2024, is summarized, after giving effect to the Reverse Stock Split, as follows:

	Common Stock from Warrants	Weighted-average Exercise Price (per share)
Outstanding at July 1, 2023	2,348,039	$ 1.92
Pre-funded warrants issued August 11, 2023	15,126,226	$ 0.0001
Common warrants issued August 11, 2023	16,002,175	$ 3.86
Outstanding at September 30, 2023	33,476,440	$ 1.98
Pre-funded warrants exercised	25,000	$ 0.0001
Series 2 warrants exercised	20,000	$ 1.93
Outstanding at December 31, 2023	33,431,440	$ 1.98
Exercisable at December 31, 2023	33,431,440	$ 1.98

	Common Stock from Warrants	Weighted-average Exercise Price (per share)
Outstanding at July 1, 2023	2,348,039	$ 1.92
Pre-fundedwarrants issued August 11, 2023	15,126,226	$ 0.0001
Common warrants issued August 11, 2023	16,002,175	$ 3.86
Outstanding at September 30, 2023	33,476,440	$ 1.98
Pre-fundedwarrants exercised	25,000	$ 0.0001
Series 2 warrants exercised	20,000	$ 1.93
Outstanding and exercisable at December 31, 2023	33,431,440	$ 1.98
Pre-fundedwarrants exercised	132,360	$ 0.001
Outstanding and exercisable at March 31, 2024	33,299,080	$ 1.99

Equity Incentive Plan

Employee Share Option Plan

In connection with itsre-domiciliationto the United States, the Company assumed BBL's obligations with respect to the settlement of options that were issued by BBL prior to the Re- domiciliation re-domiciliationpursuant to the Benitec Officers' and Employees' Share Option Plan (the "Plan"). This includes the Company's assumptions of the Plan and all award agreements pursuant to which each of the options were granted. Each option when exercised entitles the option holder to one share in the Company. Options are exercisable on or before an expiry date, do not carry any voting or dividend rights and are not transferable except on death of the option holder or in certain other limited circumstances . Employee options vest one third on each anniversary of the applicable grant date for three years. If an employee dies, retires, or otherwise leaves the organization, and certain other conditions have been satisfied, generally the employee has 12 months to exercise their options, or the options are cancelled. After theRe-domiciliation,no new options have been or will be issued under the Plan.

Equity and Incentive Compensation Plan

On December 9, 2020, the Company's stockholders approved the Company's 2020 Equity and Incentive Compensation Plan (the "2020 Plan"). The 2020 Plan provides for the grant of various equity awards. Currently, only stock options are outstanding under the 2020 Plan. Each option when exercised entitles the option holder to one share of the Company's common stock. Options are exercisable on or before an expiry date, do not carry any voting or dividend rights, and are not transferable except on death of the option holder or in certain other limited circumstances. Employee stock options vest in increments ofone-thirdon each anniversary of the applicable grant date over three years.Non-employeedirector options vest in increments ofone-thirdon the day prior to each of the Company's next three annual stockholder meetings following the grant date. If an option holder dies or terminates employment or service due to Disability (as defined in the 2020 Plan), the option holder generally has 12 months to exercise their vested options, or the options are cancelled. If an option holder otherwise leaves the Company, other than for a termination by the Company for Cause (as defined in the 2020 Plan), the option holder generally has 90 days to exercise their vested options, or the options are cancelled. The maximum contractual term of options granted under the 2020 Plan is ten years. Upon the consummation of a Change in Control (as defined in the 2020 Plan), all unvested stock options will immediately vest as of immediately prior to the Change in Control.

On December 8, 2021, the Company's stockholders approved an amendment to the 2020 Plan, which increased the number of shares of the Company's common stock reserved under the 2020 Plan to 108,823 (as adjusted for the Reverse Stock Split). For the fiscal year ended June 30, 2023, our named executive officers ("NEO's") were each granted equity incentive awards under the 2020 Plan. On December 6, 2023, the Company's stockholders approved an amendment to the 2020 Plan, which increased the number of shares of the Company's common stock reserved under the 2020 Plan to 1,204,537.

Equity Awards

The activity related to equity awards, which are comprised of stock options during the six nine months ended December 31, 2023 March 31, 2024 is summarized as follows:

	Stock Options	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at June 30, 2023	107,993	$ 31.88	8.96 years	$ 11,888
Granted	104,980	$ 3.13	9.94 years	—
Outstanding at December 31, 2023	212,973	$ 17.71	9.18 years	$ 11,283
Exercisable at December 31, 2023	38,853	$ 76.43	6.84 years	$ 261

	Stock Options	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at June 30, 2023	107,993	$ 31.88	8.96 years	$ 11,888
Granted	1,076,538	$ 5.01	9.91 years	—
Expired	(1,800)	$ 470.37	—	—
Forfeited	(353)	$ 74.18	—	—
Outstanding at March 31, 2024	1,182,378	$ 6.73	9.76 years	$ 353,286
Exercisable at March 31, 2024	36,984	$ 57.30	6.78 years	$ 1,685

Share-Based Compensation Expense

The classification of share-based compensation expense is summarized as follows:

	Three Months Ended		Six Months Ended	
	December 31,			
(US$'000)	2023	2022	2023	2022
Research and development	$ 33	$ 30	$ 67	$ 60
General and administrative	60	(78)	117	194
Total share-based compensation expense	$ 93	$ (48)	$ 184	$ 254

	Three Months Ended		Nine Months Ended	
	March 31,			
(US$'000)	2024	2023	2024	2023
Research and development	$ 45	$ 27	$ 112	$ 87
General and administrative	147	44	264	238
Total share-based compensation expense	$ 192	$ 71	$ 376	$ 325

As of December 31, 2023 March 31, 2024, there was $0.5 million $4.7 million of unrecognized share-based compensation expense related to stock options issued under the Share Option Plan and the 2020 Plan, which is expected to be recognized over a weighted average

period of 2.6 2.9 years.

10. 10. Income taxes

For the three and six nine months ended December 31, 2023 March 31, 2024, and December 31, 2022 March 31, 2023, respectively, the Company did not recognize a provision or benefit for income taxes as it has incurred net losses. In addition, the net deferred tax assets generated from net operating losses are fully offset by a valuation allowance as the Company believes it is not more likely than not that the benefit will be realized.

11. 11. Commitments and contingencies

Contract commitments

The Company enters into contracts in the normal course of business with third-party contract research organizations, contract development and manufacturing organizations and other service providers and vendors. These contracts generally provide for termination on notice and, therefore, are cancellable contracts and not considered contractual obligations and commitments.

Contingencies

From time to time, the Company may become subject to claims and litigation arising in the ordinary course of business. The Company is not a party to any material legal proceedings, nor is it aware of any material pending or threatened litigation.

12. 12. Related party transactions

During the six nine month periods ended December 31, 2023 March 31, 2024 and December 31, 2022 March 31, 2023, the Company did not enter into any related party transactions.

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13. Subsequent events

There were no subsequent events for the six months ended December 31, 2023.

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13. Subsequent events

On April 10, 2024 and April 19, 2024, investors exercised 25,000 Series 2 warrants on each date, at an exercise price of $1.93 per share. On April 22, 2024, an investor exercised 28,039 Series 2 warrants at an exercise price of $1.93 per share.

14 On April 18, 2024 we closed a private investment in public equity (PIPE) financing in which we sold 5,749,152 shares of common stock at a price per share of $4.80 and, in lieu of shares of common stock,pre-fundedwarrants to purchase up to an aggregate of 2,584,239 shares of common stock at a price perpre-fundedwarrant of $4.7999, to certain accredited institutional investors. Thepre-fundedwarrants were immediately exercisable until exercised in full at an exercise price of $0.0001 per share of common stock. Gross proceeds from the financing totaled $40.0 million. Net proceeds, net of commissions and other offering expenses, totaled approximately $ 37.2 million.

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

You should read the following discussion and analysis of financial condition and operating results together with our consolidated financial statements and the related notes and other financial information included elsewhere in this document.

Company Overview

We endeavor to become the leader in discovery, development, and commercialization of therapeutic agents capable of addressing significant unmet medical need via the application of the silence and replace approach to the treatment of genetic disorders.

Benitec Biopharma Inc. (“Benitec” or the “Company” or in the third person, “we” or “our”) is a clinical-stage biotechnology company focused on the advancement of novel genetic medicines with headquarters in Hayward, California. The proprietary platform, called DNA-directed RNA interference, or ddRNAi, combines RNA interference, or RNAi, with gene therapy to create medicines that facilitate sustained silencing of

disease-causing genes following a single administration. The unique therapeutic constructs also enable the simultaneous delivery of wildtype replacement genes, facilitating the proprietary “silence and replace” approach to the treatment of genetically defined diseases. The Company is developing a silence and replace-based therapeutic (BB-301) for the treatment of Oculopharyngeal Muscular Dystrophy (OPMD), a chronic, life- threatening genetic disorder.

BB-301 is a silence and replace-based genetic medicine currently under development by Benitec. BB-301 is an AAV-based gene therapy designed to permanently silence the expression of the disease-causing gene (to slow, or halt, the biological mechanisms underlying disease progression in OPMD) and to simultaneously replace the mutant gene with a wildtype gene (to drive restoration of function in diseased cells). This fundamental therapeutic approach to disease management is called “silence and replace.” The silence and replace mechanism offers the potential to restore the normative physiology of diseased cells and tissues and to improve treatment outcomes for patients suffering from the chronic, and potentially fatal, effects of OPMD. BB-301 has been granted Orphan Drug Designation in the United States and the European Union.

The targeted gene silencing effects of RNAi, in conjunction with the durable transgene expression achievable via the use of modified viral vectors, imbues the silence and replace approach with the potential to produce permanent silencing of disease-causing genes along with simultaneous replacement of the wild type gene function following a single administration of the proprietary genetic medicine. We believe that this novel mechanistic profile of the current and future investigational agents developed by Benitec could facilitate the achievement of robust and durable clinical activity while greatly reducing the frequency of drug administration traditionally expected for medicines employed for the management of chronic diseases. Additionally, the achievement of permanent gene silencing and gene replacement may significantly reduce the risk of patient
non-compliance during the course of medical management of potentially fatal clinical disorders.

We will require additional financing to progress our product candidates through to key inflection points.

Our proprietary technology platforms are designated as DNA-directed RNA interference, or “ddRNAi”, and “silence and replace.” ddRNAi is designed to produce permanent silencing of disease-causing genes, by combining RNA interference, or RNAi, with viral delivery agents typically associated with the field of gene therapy (i.e., viral vectors). Modified AAV vectors are employed to deliver genetic constructs which encode short hairpin RNAs that are, then, serially expressed and processed to produce siRNA molecules within the transduced cell for the duration of the life of the target cell. These newly introduced siRNA molecules drive

permanent silencing of the expression of the disease-causing gene. The silence and replace approach further bolsters the biological benefits of permanent silencing of disease-causing genes by incorporating multifunctional genetic constructs within the modified AAV vectors to create an AAV-based gene therapy agent that is designed to silence the expression of disease-causing genes (to slow, or halt, the underlying mechanism of disease progression) and to simultaneously replace the mutant genes with normal, “wildtype” genes (to drive restoration of function in diseased cells). This fundamentally distinct therapeutic approach to disease management offers the potential to restore the underlying physiology of the treated tissues and, in the process, improve treatment outcomes for patients suffering from the chronic and, potentially, fatal effects of diseases like Oculopharyngeal Muscular Dystrophy (OPMD).

Traditional gene therapy is defined by the introduction of an engineered transgene to correct the pathophysiological derangements derived from mutated or malfunctioning genes. Mutated genes can facilitate the intracellular production of disease-causing proteins or hamper the production of critical, life-sustaining, proteins. The introduction of a new transgene can facilitate the restoration of production of normal proteins within the diseased cell, thus restoring natural biological function. Critically, the implementation of this traditional method of gene therapy cannot eliminate the expression, or the potential deleterious effects of, the underlying mutant gene (as mutant proteins may be continually expressed and aggregate or drive the aggregation of other native proteins within the diseased cell). In this regard, the dual capabilities of the proprietary silence and replace approach to silence a disease-causing gene via ddRNAi and simultaneously replace the wild type activity of a mutant gene via the delivery of an engineered transgene could facilitate the development of differentially efficacious treatments for a range of genetic disorders.

Overview of RNAi and the siRNA Approach

The mutation of a single gene can cause a chronic disease via the resulting intracellular production of a disease-causing protein (i.e., an abnormal form of the protein of interest), and many chronic and/or fatal disorders are known to result from the inappropriate expression of a single gene or multiple genes. In some cases, genetic disorders of this type can be treated exclusively by “silencing” the intracellular production of the disease- causing disease-causing protein through well-validated biological approaches like RNA interference (“RNAi”). RNAi employs small nucleic acid molecules to activate an intracellular enzyme complex, and this biological pathway temporarily reduces the production of the disease-causing protein. In the absence of the disease-causing protein, normal cellular function is restored and the chronic disease that initially resulted from the presence of the mutant protein is partially or completely resolved. RNAi is potentially applicable to over 20,000 human genes and a large number of disease- causing disease-causing microorganism-specific genes.

Figure 1

A small double stranded RNA, or dsRNA, molecule (A, Figure 1), comprising one strand known as the sense strand and another strand known as the antisense strand, which are complementary to each other, is synthesized in the laboratory. These small dsRNAs are called small interfering RNAs, or siRNAs. The sequence of the sense strand corresponds to a short region of the target gene mRNA. The siRNA is delivered to the target cell (B, Figure 1), where a group of enzymes, referred to as the RNA-Induced Silencing Complex, or RISC, process the siRNA (C, Figure 1), where one of the strands (usually the sense strand) is released (D, Figure 1). RISC uses the antisense strand to find the mRNA that has a complementary sequence (E, Figure 1) leading to the cleavage of the target mRNA (F, Figure 1). As a consequence, the output of the mRNA (protein production) does not occur (G, Figure 1). Several companies, including Alnylam Pharmaceuticals Inc. (“Alnylam”), utilize this approach in their RNAi product candidates.

Importantly, many genetic disorders are not amenable to the traditional gene silencing approach outlined in Figure 1, as the diseased cells may produce a mixture of the wild type protein of interest and the disease-causing mutant variant of the protein, and the underlying genetic mutation may be too small to allow for selective targeting of the disease-causing variant of the protein through the use of siRNA-based approaches exclusively. In these cases, it is extraordinarily difficult to selectively silence the disease-causing protein without simultaneously silencing the wild type intracellular protein of interest whose presence is vital to the conduct of normal cellular functions.

Our proprietary silence and replace technology utilizes the unique specificity and robust gene silencing capabilities of RNAi while overcoming many of the key limitations of siRNA-based approaches to disease management.

In the standard RNAi approach, double-stranded siRNA is produced synthetically and, subsequently, introduced into the target cell via chemical modification of the RNA or alternative methods of delivery. While efficacy has been demonstrated in several clinical indications through the use of this approach, siRNA-based approaches maintain a number of limitations, including:

- Clinical management requires repeat administration of the siRNA-based therapeutic agent for multiple cycles to maintain efficacy;

- Long-term patient compliance challenges due to dosing frequencies and treatment durations;

- Therapeutic concentrations of siRNA are not stably maintained because the levels of synthetic siRNA in the target cells decrease over time;

- Novel chemical modifications or novel delivery materials are typically required to introduce the siRNA into the target cells, making it complicated to develop a broad range of therapeutics agents;

- Potential adverse immune responses, resulting in serious adverse effects;

- Requirement for specialized delivery formulations for genetic disorders caused by mutations of multiple genes; and

- siRNA acts only to silence genes and cannot be used to replace defective genes with normally functioning genes.

Our Approach to the Treatment of Genetic Diseases—ddRNAi and Silence and Replace

Our proprietary silence and replace approach to the treatment of genetic diseases combines RNAi with wild type gene replacement to drive permanent silencing of disease-causing genes and concomitant restoration of functional wild type genes following a single administration of the therapeutic agent. Benitec employs ddRNAi in combination with classical gene therapy (i.e., transgene delivery via viral vectors) to overcome several of the fundamental limitations of RNAi.

The silence and replace approach to the treatment of genetic disorders employs adeno-associated viral vectors ("AAVs") to deliver genetic constructs which may, after a single administration to the target tissues:

- Chronically express RNAi molecules inside of the target, diseased, cells (to serially silence the intracellular production of mutant, disease- causing, disease-causing, protein and the wild type protein of interest);

- Simultaneously drive the expression of a wild type variant of the protein of interest (to restore native intracellular biological processes); and

- AAV vectors can accommodate the multi-functional DNA expression cassettes containing the engineered wild type transgenes and the novel genes encoding short hairpinRNA/microRNA molecules (shRNA/miRNA) that are required to support the development of therapeutic agents capable of the achievement of the goals of the silence and replace approach to therapy.

Our silence and replace technology utilizes proprietary DNA expression cassettes to foster continuous production of gene silencing shRNAs and wild type proteins (via expression of the wild type transgene). A range of viral and non-viral gene therapy vectors can be used to deliver the DNA construct into the nucleus of the target cell and, upon delivery, shRNA molecules are expressed and subsequently processed by intracellular enzymes into siRNA molecules that silence the expression of the mutant, disease-causing protein (Figure 2).

In the silence and replace approach (Figure 2):

- A DNA construct is delivered to the nucleus of the target cell by a gene therapy vector (A) such as an AAV vector;

- Once inside of the nucleus, the DNA construct drives the continuous production of shRNA molecules (B) which are processed by an enzyme called Dicer into siRNAs (C);

- The processed siRNA is incorporated into RISC and silences the target gene using the same mechanism shown in Figure 1; and

- When the DNA expression cassette is additionally comprised of a wild type transgene, upon entry of the DNA construct into the nucleus of the target cell via the use of the AAV vector, the DNA construct also drives the continuous production of wild type protein (to restore native intracellular biological processes).

Figure 2

Our strategy is to discover, develop and commercialize treatments that leverage the capabilities of ddRNAi and the silence and replace approach to disease management.

For selected product candidates, at the appropriate stage, we may collaborate with large biopharmaceutical companies to further co-develop and, if approved, commercialize our ddRNAi-based and silence and replace-based products to achieve broad clinical and commercial distribution. For specific clinical indications that we deem to be outside of our immediate areas of focus, we will continue to out-license, where appropriate, applications of our ddRNAi and silence and replace technology to facilitate the development of differentiated therapeutics, which could provide further validation of our proprietary technology and approach to disease management.

Our cash and cash equivalents will be deployed for the advancement of our product candidate BB-301 for the treatment of OPMD-derived dysphagia, including the natural history lead-in study and the Phase 1b/2a BB-301 treatment study, for the continued advancement of development activities for other existing and new product candidates, for general corporate purposes and for strategic growth opportunities.

Oculopharyngeal Muscular Dystrophy—OPMD

OPMD is an insidious, autosomal-dominant, late-onset degenerative muscle disorder that typically presents in patients at 40-to-50 years of age. The disease is characterized by progressive swallowing difficulties (dysphagia) and eyelid drooping (ptosis). OPMD is caused by a specific mutation in the poly(A)-binding protein nuclear 1, or PABPN1, gene. OPMD is a rare disease; however, patients have been diagnosed with OPMD in at least 33 countries. Patient populations suffering from OPMD are well-identified, and significant geographical clustering has been noted for patients with this disorder, which could simplify clinical development and global commercialization efforts.

BB-301 is an AAV-based gene therapy designed to silence the expression of disease-causing genes (to slow, or halt, the underlying mechanism of disease progression) and to simultaneously replace the mutant genes with normal, “wildtype” genes (to drive restoration of function in diseased cells). This fundamental therapeutic approach to disease management is called “silence and replace” and this biological mechanism offers the potential to restore the underlying physiology of the treated tissues and, in the process, improve treatment outcomes for patients suffering from the chronic and, potentially, fatal effects of Oculopharyngeal Muscular Dystrophy (OPMD). BB-301 has been granted Orphan Drug Designation in the United States and the European Union.

Our Strengths

We believe that the combination of our proprietary ddRNAi and silence and replace technology, and our deep expertise in the design and development of genetic medicines, will enable us to achieve and maintain a leading position in gene silencing and gene therapy for the treatment of human disease. Our key strengths include:

- A first mover advantage for silence and replace-based therapeutics;
- A proprietary ddRNAi-based silence and replace technology platform that may potentially enable the serial development of single-administration single-administration therapeutics capable of facilitating sustained, long-term silencing of disease-causing genes and concomitant replacement of wild type gene function;

- A proprietary AAV vector technology which improves the endosomal escape capability of virus produced in insect cells using a baculovirus system. This technology has broad application in AAV-based gene therapies;
    - A proprietary AAV vector technology which improves the endosomal escape capability of virus produced in insect cells using a baculovirus system. This technology has broad application in AAV-based gene therapies;

- The capabilities to drive the development of a pipeline of programs focused on chronic diseases with either large patient populations, or rare diseases, which may potentially support the receipt of Orphan Drug Designation, including OPMD; and

- A growing portfolio of patents protecting improvements to our ddRNAi, and silence and replace, technology and product candidates through at least 2036, with additional patent life anticipated through at least 2040.

Our Strategy

We endeavor to become the leader in discovery, development, and commercialization of silence and replace-based therapeutic agents. We apply the following general strategy to drive the Company towards these goals:

- Selectively develop proprietary and partnered programs; and

- Continue to explore and secure research and development partnerships with global biopharmaceutical companies supported by the differentiated nature of our scientific platform and intellectual property portfolio.

Our senior leadership team will continue to explore partnership opportunities with global biopharmaceutical companies, as we expect that the unique attributes of the proprietary ddRNAi and silence and replace approaches, and the breadth of potential clinical indications amenable to our proprietary methods, to support the formation of collaborations over a broad range of diseases with significant unmet medical need.

We seek to actively protect our intellectual property and proprietary technology. These efforts are central to the growth of our business and include:

- Seeking and maintaining patents claiming our ddRNAi and silence and replace technologies and other inventions relating to our specific products in development or that are otherwise commercially and/or strategically important to the development of our business;

- Protecting and enforcing our intellectual property rights; and

- Strategically licensing intellectual property from third parties to advance development of our product candidates.

Our Pipeline

The following table sets forth our current product candidate and the development status:

Table 1. Pipeline: Oculopharyngeal Muscular Dystrophy

We are developing BB-301 for the treatment of Oculopharyngeal Muscular Dystrophy (OPMD). The Investigational New Drug (IND) application for BB-301 was approved to proceed by the U.S. Food and Drug Administration in June 2023. The first study subject was safely dosed in the BB-301 Phase 1b/2a clinical trial (NCT06185673) in November 2023. 2023, and the second study subject was

safely dosed in February 2024. BB-301 is the lead investigational agent under development by Benitec, and the key attributes of BB-301 are outlined in Figure 3.

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Figure 3

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BB-301 is a first-in-class genetic medicine employing the “silence and replace” approach for the treatment of OPMD. OPMD is an insidious, autosomal-dominant, late-onset, degenerative muscle disorder that typically presents in patients at 40-to-50 years of age. The disease is characterized by progressive swallowing difficulties (dysphagia) and eyelid drooping (ptosis). OPMD is caused by a specific mutation in the poly(A)-binding protein nuclear 1 gene (PABPN1).

OPMD is a rare disease, however, patients have been diagnosed with OPMD in at least 33 countries. Patient populations suffering from OPMD are well-identified, and significant geographical clustering has been noted for patients with this disorder. Each of these attributes could facilitate efficient clinical development and global commercialization of BB-301.

PABPN1 is a ubiquitous factor that promotes the interaction between the poly(A) polymerase and CPSF (cleavage and polyadenylation specificity factor) and, thus, controls the length of mRNA poly(A) tails, mRNA export from the nucleus, and alternative poly(A) site usage. The characteristic genetic mutation underlying OPMD results in trinucleotide repeat expansion(s) within exon 1 of PABPN1 and results in an expanded poly-alanine tract at the N-terminal end of PABPN1. The mutation generates a protein with an N-terminal expanded poly-alanine tract of up to 18 contiguous alanine residues, and the mutant protein is prone to the formation of intranuclear aggregates designated as intranuclear inclusions (INIs). The INIs that sequester wildtype PABPN1 may contribute to the “loss of function” phenotype associated with OPMD.

No therapeutic agents are approved for the treatment of OPMD. Additionally, there are no surgical interventions available to OPMD patients that modify the natural history of the disease, which is principally comprised of chronic deterioration of swallowing function. BB-301 has received Orphan Drug Designation in the United States and the European Union and, upon achievement of regulatory approval for BB-301 in these respective jurisdictions, the Orphan Drug Designations would provide commercial exclusivity independent of intellectual property protection. While OPMD is a rare medical disorder, we believe the commercial opportunity for a safe and efficacious therapeutic agent in this clinical indication exceeds $1 billion $1 billion over the course of the commercial life of the product.

Investigational therapies that have been explored, unsuccessfully, in the past include:

- Intravenous administration of trehalose; and
- The use of autologous myoblast transplant.

BB-301 is our Lead, Silence and Replace-Based, OPMD Therapeutic Agent

BB-301 is composed of a modified AAV serotype 9 (AAV9) capsid that expresses a bifunctional construct under the control of a single muscle specific Spc5-12 promoter to achieve co-expression of both the codon-optimized PABPN1 mRNA and two shmiR molecules directed against wild type and mutant PABPN1. BB-301 is designed to correct the genetic defect underlying OPMD following a single localized administration.

BB-301—Design and Mechanism of Action

BB-301 is designed to target two distinct regions of the PABPN1 mRNA to accomplish gene silencing via the concomitant expression of two distinct shmiRs from a single DNA construct (Figure 4). BB-301 is also engineered to drive the simultaneous expression of a codon-optimized, siRNA-resistant, version of the wild type PABPN1 gene (Figure 4).

Figure 4

In collaboration with researchers at the Royal Holloway University of London and the Institut de Myologie in Paris, we developed a ddRNAi construct expressing three shRNAs against three distinct regions of PABPN1 mRNA and observed effective silencing of the PABPN1 gene in vitro using this ddRNAi construct. Furthermore, as part of this collaboration, we have generated a gene expression construct that produces a siRNA- resistant siRNA-resistant version of the wild type PABPN1 gene.

In subsequent studies undertaken exclusively by Benitec, a second set of target regions within PABPN1 were identified for therapeutic development and shmiRs designed against these regions. Additional shmiRs have also been designed for the original shRNA developed in collaboration with Royal Holloway University of London and the Institut de Myologie. The ‘silence and replace’ construct, designated BB-301, incorporates the two best performing shmiRs, and the gene expression construct that produces a siRNA-resistant version of the wild type PABPN1 gene, under the control of a muscle-specific promoter. The mechanism of action of BB-301 is shown in Figure 5.

Figure 5

In initial in vivo studies evaluating the use of direct intramuscular injection of AAV-based constructs with the potential to facilitate the desired silence and replace approach in the A17 transgenic mouse model of OPMD at the Royal Holloway University of London and the Institut de Myologie, we observed decreases in muscle fibrosis, increases in cross sectional area of the treated muscles, decreases in intranuclear inclusions, and normalization of muscle strength. These nonclinical results were published in Nature Communications in April 2017.

In subsequent studies, Benitec demonstrated in a key nonclinical model (the A17 mouse model) that a single intramuscular injection of BB-301 results in robust intracellular silencing of PABPN1 protein production and concomitant expression of the normal, biologically functional PABPN1 protein. In the A17 mouse model, the treatment restores muscle strength and muscle weight to wild type levels and improves other physiological hallmarks of the disease (Figure 6a, Figure 6b, Figure 6c, Figure 6d):

- Multiple A17 animal cohorts received single doses of BB-301 (over a range of doses spanning 4x108 vg/muscle-to-7.5x1011 vg/muscle) and, following BB-301 administration, each cohort was observed for 14-weeks
    - Multiple A17 animal cohorts received single doses of BB-301 (over a range of doses spanning 4x10$_{8}$vg/muscle-to-7.5x10$_{11}$ vg/muscle) and, following BB-301 administration, each cohort was observed for 14-weeks
- BB-301 was injected into the Tibialis Anterior (TA) muscle of 10 week old-to-12 week old animals and, 14-weeks post administration, each A17 cohort was anesthetized and the contractile properties of the injected TA muscles were analyzed via in-situ muscle electrophysiology

- BB-301 was injected into the Tibialis Anterior (TA) muscle of 10 week old-to-12 week old animals and, 14-weeks post administration, each A17 cohort was anesthetized and the contractile properties of the injected TA muscles were analyzed via in-situ muscle electrophysiology

- Intermediate doses of BB-301 resulted in 75% silencing of PABPN1 and 26% replacement of wild type PABPN1 activity, leading to full restoration of muscle strength, clearance of INIs, and a reduction of fibrosis
    - Intermediate doses of BB-301 resulted in 75% silencing of PABPN1 and 26% replacement of wild type PABPN1 activity, leading to full restoration of muscle strength, clearance of INIs, and a reduction of fibrosis

- An additional experiment conducted over the course of 20-weeks demonstrated that more modest doses of BB-301 (which supported only partial resolution of the disease phenotype at week-14) were, surprisingly, able to facilitate significant benefit at 20-weeks, as evidenced by restoration of parameters relating to muscle strength, weight and INI formation
    - An additional experiment conducted over the course of 20-weeks demonstrated that more modest doses of BB-301 (which supported only partial resolution of the disease phenotype at week-14) were, surprisingly, able to facilitate significant benefit at 20-weeks, as evidenced by restoration of parameters relating to muscle strength, weight and INI formation

Figure 6a. Dose-Dependent shRNA Expression

Figure 6b. Dose-Dependent PABPN1 Inhibition and Transgene Expression

Figure 6c. Dose-Dependent Decreases in Intranuclear Inclusions

Figure 6d. Dose-Dependent Increases in Muscle Force

Restoration of muscle strength was assessed by muscle contractility measurements in response to a series of induced impulses that ranged from 10 to 180 Hz

Ongoing Development Activities for BB-301

On July 8, 2020, Benitec announced the initiation of the BB-301 Pilot Dosing Study in large animal subjects.

The BB-301 Pilot Dosing Study was the first of two planned CTA-enabling and IND-enabling studies that were designed to be conducted in large animals. The BB-301 Pilot Dosing Study was carried out under the guidance of the scientific team at Benitec, with key elements of the study design and execution conducted in close collaboration with a team of leading experts in both medicine and surgery that have been deeply engaged in the treatment of OPMD patients for several decades. The BB-301 Pilot Dosing Study, along with the subsequent GLP Toxicology and Biodistribution Study, were conducted in canine subjects and were carried out to

support the validation and optimization of the newly designed method of BB-301 administration, confirm the efficiency of vector transduction and transgene expression in the key tissue compartments underlying the natural history of OPMD, confirm the optimal drug doses in advance of initiation of human clinical studies, and facilitate observation of key toxicological data-points.

The BB-301 Pilot Dosing Study was designed as an 8-week study in Beagle dogs to confirm the transduction efficiency of BB-301 upon administration via direct intramuscular injection into specific anatomical regions of the pharynx through the use of an open surgical procedure. This new route of BB-301 administration was developed in collaboration with key surgical experts in the field of Otolaryngology, and this novel method of BB-301 dosing was implemented to significantly enhance the ability of a treating physician to accurately administer the AAV-based investigational agent to the muscles that underlie the characteristic deficits associated with the progression of OPMD. It is important to note that prior nonclinical studies of BB-301 have reproducibly validated the robust biological activity achieved following direct intramuscular injection. As an example, direct injection of BB-301 into the tibialis anterior muscles of A17 mice facilitated robust transduction of the targeted skeletal muscle cells and supported complete remission of the OPMD disease phenotype in this animal model.

Benitec conducted the BB-301 Pilot Dosing Study in Beagle dog subjects to demonstrate that direct intramuscular injection of BB-301 via the use of a proprietary dosing device in an open surgical procedure could safely achieve the following goals:

- Biologically significant and dose-dependent levels of BB-301 tissue transduction (i.e., delivery of the multi-functional BB-301 genetic construct into the target pharyngeal muscle cells);
    - Biologically significant and dose-dependent levels of BB-301 tissue transduction (i.e., delivery of the multi-functional BB-301 genetic construct into the target pharyngeal muscle cells);

- Broad-based and dose-dependent expression of the three distinct genes comprising the BB-301 gene construct within the pharyngeal muscle cells; and
    - Broad-based and dose-dependent expression of the three distinct genes comprising the BB-301 gene construct within the pharyngeal muscle cells; and

- Durable and biologically significant levels of target gene knock-down (i.e., inhibition of the expression of the gene of interest) within the pharyngeal muscle cells.

The Pilot Dosing Study evaluated the safety and biological activity of two concentrations of BB-301 (1.0+E13 vg/mL and 3.0+E13 vg/mL) across three distinct doses (1.0+E13 vg/mL, 3.0+E13 vg/mL with a low injection volume, and 3.0+E13 vg/mL with a high injection volume) following direct intramuscular injection into the Hypopharyngeal (HP) muscles and the Thyropharyngeal (TP) muscles of Beagle dogs via the use of a proprietary delivery device employed in an open surgical procedure. The HP muscle in Beagle dogs corresponds to the Middle Pharyngeal Constrictor muscle in human subjects, and the TP muscle in Beagle dogs corresponds to the Inferior Pharyngeal Constrictor muscle in human subjects. Atrophy, fibrosis, and the presence of intranuclear inclusions characterize the Middle Pharyngeal Constrictor muscles and the Inferior Pharyngeal Constrictor muscles of human subjects diagnosed with OPMD. BB-301 was injected into the pharyngeal muscles of the Beagle dog subjects only on Day 1 of the Pilot Dosing Study, and the corresponding canine pharyngeal muscles were harvested for analysis after 8 weeks of observation post-dosing. BB-301 dosing was carried out independently by both a veterinary surgeon and a practicing Otolaryngologist who has extensive experience with the provision of palliative surgical care for OPMD patients.

The key results are summarized here:

Figure 7. Pharyngeal Muscle Tissue Transduction Levels for BB-301

Regarding Gene Expression Levels Observed for BB-301 Within the Pharyngeal Muscle Tissues (Figure 8, Figure 9, Figure 10):

- BB-301 encodes two distinct siRNA species (i.e., siRNA13 and siRNA17) which are each, independently, capable of inhibiting (i.e., “silencing”) the expression of the mutant form of the PABPN1 protein and the wild type (i.e., endogenous) form of the PABPN1 protein (importantly, the mutant form of the PABPN1 protein underlies the development and progression of OPMD).
    - BB-301 encodes two distinct siRNA species (i.e., siRNA13 and siRNA17) which are each, independently, capable of inhibiting (i.e., “silencing”) the expression of the mutant form of the PABPN1 protein and the wild type (i.e., endogenous) form of the PABPN1 protein (importantly, the mutant form of the PABPN1 protein underlies the development and progression of OPMD).

- BB-301 also codes for a wild type version of the PABPN1 protein whose intracellular expression is unaffected by the inhibitory activities of siRNA13 and siRNA17, and this codon optimized PABPN1 protein (i.e., coPABPN1) serves to replenish the endogenous form of the PABPN1 protein and to replace the mutant form of PABPN1 that underlies the development and progression of OPMD in diseased tissues.
    - BB-301 also codes for a wild type version of the PABPN1 protein whose intracellular expression is unaffected by the inhibitory activities of siRNA13 and siRNA17, and this codon optimized PABPN1 protein (i.e., coPABPN1) serves to replenish the endogenous form of the PABPN1 protein and to replace the mutant form of PABPN1 that underlies the development and progression of OPMD in diseased tissues.

- For comparative purposes, it should be noted that the average range of expression for wild type PABPN1 within the pharyngeal muscle cells of Beagle dogs is 4.5 copies per cell-to-7.8 copies per cell.
    - For comparative purposes, it should be noted that the average range of expression for wild type PABPN1 within the pharyngeal muscle cells of Beagle dogs is 4.5 copies per cell-to-7.8 copies per cell.

Figure 8. siRNA13 Expression Levels for BB-301 within Pharyngeal Muscle Tissues

Figure 9. siRNA17 Expression Levels for BB-301 within Pharyngeal Muscle Tissues

Figure 10. coPABPN1 Expression Levels for BB-301 within Pharyngeal Muscle Tissues

Regarding Wild Type PABPN1 Silencing (i.e. target “knock-down”) Observed for BB-301 Within the Pharyngeal Muscle Tissues (Figure 11):

- As noted above, BB-301 encodes two distinct siRNA species (i.e., siRNA13 and siRNA17) which are each, independently, capable of inhibiting (i.e., “silencing”) the expression of all forms of the PABPN1 protein (siRNA13 and siRNA17 silence the expression of both wild type PABPN1 [wtPABPN1] and mutant PABPN1).

- As noted above, BB-301 encodes two distinct siRNA species (i.e., siRNA13 and siRNA17) which are each, independently, capable of inhibiting (i.e., “silencing”) the expression of all forms of the PABPN1 protein (siRNA13 and siRNA17 silence the expression of both wild type PABPN1 [wtPABPN1] and mutant PABPN1).

- While the Beagle dog subjects treated in the BB-301 Pilot Dosing Study did not express mutant PABPN1, the level of BB-301- driven gene silencing for the PABPN1 target can be accurately assessed due to the equivalent inhibitory effects of siRNA13 and siRNA17 on both wtPABPN1 and mutant PABPN1.
    - While the Beagle dog subjects treated in the BB-301 Pilot Dosing Study did not express mutant PABPN1, the level of BB-301-driven gene silencing for the PABPN1 target can be accurately assessed due to the equivalent inhibitory effects of siRNA13 and siRNA17 on both wtPABPN1 and mutant PABPN1.

- Thus, the wtPABPN1 silencing activity observed in the BB-301 Pilot Dosing Study served as a surrogate for the activity that would be anticipated in the presence of mutant PABPN1.
    - Thus, the wtPABPN1 silencing activity observed in the BB-301 Pilot Dosing Study served as a surrogate for the activity that would be anticipated in the presence of mutant PABPN1.

- BB-301 has been evaluated in prior nonclinical studies in animals that express mutant PABPN1 and manifest the key signs and symptoms of OPMD and, in these animal models of OPMD, the achievement of PABPN1 silencing levels of 31% inhibition or higher led to resolution of OPMD disease symptoms and correction of the histological hallmarks of OPMD.
    - BB-301 has been evaluated in prior nonclinical studies in animals that express mutant PABPN1 and manifest the key signs and symptoms of OPMD and, in these animal models of OPMD, the achievement of PABPN1 silencing levels of 31% inhibition or higher led to resolution of OPMD disease symptoms and correction of the histological hallmarks of OPMD.

Figure 11. PABPN1 Silencing (i.e., “target knock-down”) within Pharyngeal Muscle Tissues

Finally, it is critical to highlight the key methodological distinctions between the recently completed BB-301 Pilot Dosing Study in Beagle dogs conducted by Benitec (i.e., the study described above) and the prior Beagle dog dosing study carried out independently by the previous BB-301 licensee of Benitec. licensee. The BB-301 dosing study conducted by the prior BB-301 licensee employed non-ideal routes and methods of BB-301 administration to the target pharyngeal muscle tissues and employed similarly limited analytical methods at the completion of the dosing phase of the study. The Benitec team worked to optimize the route and method of administration of BB-301 and to refine the core analytical methods employed following the completion of dosing.

Following the implementation of these methodological modifications, Benitec demonstrated a 248-fold improvement (+24,650%) in BB-301 transduction of the HP muscle and a 111-fold improvement (+11,027%) in BB-301 transduction of the TP muscle relative to the levels of BB-301 transduction observed by the previous BB-301 licensee (Figure 12).

Figure 12. Impact of Benitec-Initiated Methodological Improvements on the Relative Pharyngeal Muscle Tissue Transduction Levels Achieved for BB-301

Following the disclosure of the positive interim BB-301 Pilot Dosing Study results, Benitec completed pre-CTA and pre-IND meetings with regulatory agencies in France, Canada, and the United States. Summary of Regulatory Interactions:

- In June 2023 the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for BB-301 which allowed dosing of BB-301 to begin for OPMD subjects that are eligible for enrollment into the Phase 1b/2a treatment study (NCT06185673) described below.
    - In June 2023 the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for BB-301 which allowed dosing of BB-301 to begin for OPMD subjects that are eligible for enrollment into the Phase 1b/2a treatment study (NCT06185673) described below.

Operational Updates

The key milestones related to the development of BB-301 for the treatment of OPMD, along with other corporate updates, are outlined below:

BB-301 Clinical Development Program Overview:

- The BB-301 clinical development program will be conducted in the United States, and the primary elements of the program are summarized below:
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- The program will comprise approximately 76 weeks of follow-up which we anticipate will consist of:
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- The OPMD Natural History (NH) Study: 6-month pre-treatment observation periods for the evaluation of baseline disposition and natural history of OPMD-derived dysphagia (swallowing impairment) in each study participant.
    - The OPMD Natural History (NH) Study: 6-month pre-treatment observation periods for the evaluation of baseline disposition and natural history of OPMD-derived dysphagia (swallowing impairment) in each study participant.

- Dosing with BB-301: 1-day of BB-301 dosing to initiate participation in the Phase 1b/2a single-arm, open-label, sequential, dose-escalation cohort study (NCT06185673). BB-301 will be delivered directly to the pharyngeal muscles of each study subject.
    - Dosing with BB-301: 1-day of BB-301 dosing to initiate participation in the Phase 1b/2a single-arm, open-label, sequential, dose-escalation cohort study (NCT06185673). BB-301 will be delivered directly to the pharyngeal muscles of each study subject.

- Phase 1b/2a Treatment Evaluation: 52-weeks of post-dosing follow-up for conclusive evaluation of the primary and secondary endpoints of the BB-301 Phase 1b/2a treatment study (NCT06185673), with interim safety and efficacy results expected to be available at the end of each 90-day period following the administration of BB-301.
    - Phase 1b/2a Treatment Evaluation: 52-weeks of post-dosing follow-up for conclusive evaluation of the primary and secondary endpoints of the BB-301 Phase 1b/2a treatment study (NCT06185673), with interim safety and efficacy results expected to be available at the end of each 90-day period following the administration of BB-301.

- The OPMD NH Study will characterize the level of dysphagia borne by each OPMD subject at baseline and assess subsequent progression of dysphagia via the use of the following quantitative radiographic measures (i.e., videofluoroscopic swallowing studies or “VFSS”). The VFSS outlined below collectively provide objective assessments of global swallowing function and the function of the pharyngeal constrictor muscles (i.e., the muscles whose functional deterioration drives disease progression in OPMD):
    - Total Pharyngeal Residue %(C2-4)%(C2-4)2
- Pharyngeal Area at Maximum Constriction (PhAMPC)
- Dynamic Imaging Grade of Swallowing Toxicity Scale (DIGEST)
    - Vallecular Residue %(C2-4)%(C2-4)2, Pyriform Sinus Residue %(C2-4)%(C2-4)2, and Other Pharyngeal Residue %(C2-4)%(C2-4)2
    - Normalized Residue Ratio Scale (NRRSv, NRRSp)
- Pharyngeal Construction Ratio (PCR)
- The NH study will also employ clinical measures of global swallowing capacity and oropharyngeal dysphagia, along with two distinct patient-reported outcome instruments targeting the assessment of oropharyngeal dysphagia.
- Upon the achievement of 6-months of follow-up in the NH Study, participants will, potentially, be eligible for enrollment into the BB-301 Phase 1b/2a treatment study (NCT06185673).
    - Upon the achievement of 6-months of follow-up in the NH Study, participants will, potentially, be eligible for enrollment into the BB-301 Phase 1b/2a treatment study (NCT06185673).
- BB-301 Phase 1b/2a Treatment Study (NCT06185673):
    - BB-301 Phase 1b/2a Treatment Study (NCT06185673):
- This first-in-human (FIH) study will evaluate the safety and clinical activity of intramuscular doses of BB-301 administered to subjects with OPMD.
    - This first-in-human (FIH) study will evaluate the safety and clinical activity of intramuscular doses of BB-301 administered to subjects with OPMD.
- The primary endpoint of the FIH study will be safety.
- Secondary endpoints are designed to determine the impact of BB-301 on swallowing efficiency, swallowing safety, and pharyngeal constrictor muscle function in subjects diagnosed with OPMD with dysphagia via the use of serial clinical and videofluoroscopic assessments. Critically, each of the clinical and videofluoroscopic assessments employed in the FIH study will be equivalent to those employed for the NH study to facilitate comparative clinical and statistical analyses for each study subject.
    - Secondary endpoints are designed to determine the impact of BB-301 on swallowing efficiency, swallowing safety, and pharyngeal constrictor muscle function in subjects diagnosed with OPMD with dysphagia via the use of serial clinical and videofluoroscopic assessments. Critically, each of the clinical and videofluoroscopic assessments employed in the FIH study will be equivalent to those employed for the NH study to facilitate comparative clinical and statistical analyses for each study subject.

- The primary and secondary endpoints will be evaluated during each 90-day period following BB-301 intramuscular injection (Day 1).
    - The primary and secondary endpoints will be evaluated during each 90-day period following BB-301 intramuscular injection (Day 1).

- The NH of dysphagia observed for each OPMD study participant, as characterized by the VFSS and clinical swallowing assessments carried out during the NH Study, will serve as the baseline for comparative assessments of safety and efficacy of BB-301 upon rollover from the NH Study onto the BB-301 Phase 1b/2a Treatment Study (NCT06185673).
    - The NH of dysphagia observed for each OPMD NH Study participant, as characterized by the VFSS and clinical swallowing assessments carried out during the NH Study, will serve as the baseline for comparative assessments of safety and efficacy of BB-301 upon rollover from the NH Study onto the BB-301 Phase 1b/2a Treatment Study (NCT06185673).

- In December 2022, Benitec began screening OPMD subjects at the lead clinical study site in the United States.

- In January 2023, Benitec announced the enrollment of the first OPMD subject into the NH Study in the United States.

- In November 2023, Benitec announced the completion of the administration of BB-301 to the first study subject in the Phase 1b/2a clinical study (NCT06185673) in the United States.
    - In November 2023, Benitec announced the completion of the administration of BB-301 to the first study subject in the Phase 1b/2a clinical study (NCT06185673) in the United States. The second study subject was dosed with BB-301 in February 2024.

- As of January 2024, 23 subjects are had enrolled into the NH study in the United States.

    - On April 18, 2024 Benitec reported positive interim clinical trial data for the first study subject dosed with BB-301 (i.e., “Subject 1”) in the BB-301 Phase 1b/2a Treatment Study (NCT06185673)

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    - BB-301 facilitated improvements across multiple measures of swallowing function in the first Phase 1b/2a clinical study subject as compared to pretreatment assessments conducted during the observational natural history portion of the study

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    - During the OPMD Natural History Study, which represents the pre-dose observational period for each subject, Subject 1 experienced progressive worsening of dysphagia as demonstrated by the results of the videofluoroscopic swallowing studies (VFSS), the cold water timed drinking test, and the key subject-reported outcome measure (the Sydney Swallow Questionnaire).
- Videofluoroscopic swallowing studies represent the gold standard analytical method for the quantitative assessment of dysphagia (swallowing difficulty) in the clinical setting.
    - At the 90-day timepoint following the administration of BB-301, Subject 1 demonstrated improvements in key videofluoroscopic assessments which correlated with the observation of similar improvement in the key subject-reported outcome measure as compared to the average values for the respective assessments completed during the pre-dose observational period (as summarized in Figure 13).
        - Notably, the results of many assessments completed at the 90-day timepoint demonstrated improvements over the initial measurements assessed at the subject’s first visit for the natural history observational study which occurred more than 12 months prior to the 90-day assessment.

- The most significant VFSS improvements at Day 90 were observed for swallowing tasks centered on the evaluation of pharyngeal constrictor muscle function and swallowing efficiency in the context of the consumption of thin liquids, solid foods and thick, non-solid foods (e.g., yogurt or pudding) (Figure 13).

- The VFSS improvements correlated with an improvement in the key subject-reported outcome measure the Sydney Swallow Questionnaire, indicating an improvement in swallowing function as reported by Subject 1 (Figure 13).

Figure 13. Improvement in all Outcome Measures 90-Days Post-BB-301 Administration

Closing of Private Placement and Entry into Board Designation Letter.

On April 18, 2024 we closed a private investment in public equity (PIPE) financing (the “April 2024 private placement”) in which we sold 5,749,152 shares of common stock at a price per share of $4.80 and, in lieu of shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,584,239 shares of common stock at a price per pre-funded warrant of $4.7999, to certain institutional accredited investors. The pre-funded warrants were immediately exercisable until exercised in full at an exercise price of $0.0001 per share of common stock. Gross proceeds from the financing totaled $40.0 million. Net proceeds, net of commissions and other offering expenses, totaled approximately $ 37.2 million.

In connection with the April 2024 private placement, we entered into a Voting Commitment Agreement with the purchasers in the private placement (the “Voting Commitment Agreement”). Pursuant to the Voting Commitment Agreement, the Company is obligated to use its reasonable best efforts to obtain stockholder approval of the exercise of the Pre-Funded Warrants issued in the private placement and the warrants issued in the Company’s underwritten public offerings on September 15, 2022 and August 11, 2023 (the “Existing Warrants,” and together with the Pre-Funded Warrants, the “Warrants”) in accordance with the rules of the Nasdaq Stock Market which otherwise would be subject to the Beneficial Ownership Limitation (the “Stockholder Approval”) at the Company’s 2024 annual meeting of stockholders (the “Annual Meeting”), provided that the Company may elect to call a special meeting of its stockholders (the “Special Meeting”) before the Annual Meeting to obtain the Stockholder Approval. If the Stockholder Approval is not obtained at the Annual Meeting (or at a Special Meeting called prior to the Annual Meeting, at the election of the Company), the Company is obligated to use its reasonable best efforts to obtain the Stockholder Approval at its 2025 annual meeting of stockholders (the “2025 Annual Meeting”). If the Stockholder Approval is not obtained before or at the 2025 Annual Meeting, then the Company would no longer be obligated to seek to obtain the Stockholder Approval. The purchasers agreed that the Company will not be liable for any penalty, damages, or other remedy if the Company fails, after using its reasonable best efforts in accordance with the Voting Commitment Agreement, to obtain the Stockholder Approval. Pursuant to the Voting Commitment Agreement, the purchasers agreed to vote or cause to be voted any and all shares of the Company’s Common Stock over which it or its affiliates has or shares voting control on the record date for shares eligible to vote at any Company Special Meeting or Annual Meeting seeking the Stockholder Approval where such proposal is presented in favor of approving the proposal or proposals seeking the Stockholder Approval.

We also entered into a Board Designation Side Letter (the “Board Designation Agreement”) with Suvretta Capital Management, LLC (“Suvretta”) at the closing of the private placement. Pursuant to the Board Designation Agreement, the Company agreed to consider for appointment and appoint Kishen Mehta to the Company’s Board of Directors (the “Board”) upon consummation of the transactions contemplated by the Securities Purchase Agreement, and in such board class as determined by the Company prior to his appointment. Suvretta will be entitled to propose additional candidates for appointment to the Board to the extent the Board does not appoint Mr. Mehta for one or more of the reasons set forth in the Board Designation Agreement. Pursuant to the Board Designation Agreement, Suvretta agreed that (1) in connection with the closing of the Private Placement, (i) the Company and Suvretta will take such action as may be required to permit Suvretta to exercise its Warrants up to the 19.99% Beneficial Ownership

Limitation, and (ii) Suvretta will vote all of its shares of Common Stock owned on the record date for such votes in favor of (1) all of the Company's director nominees for election to the Board at the Company's annual meetings of stockholders to be held during the term of the Board Designation Agreement, and (2) the proposal seeking the Stockholder Approval pursuant to the Voting Commitment Agreement at any annual or special meeting of the Company where such proposal is presented.

Intellectual Property

Benitec seeks to actively procure rights to and protect the intellectual property and proprietary technology that it believes is important to its business. Such intellectual property rights include patents claiming our ddRNAi and silence and replace technologies, as well as know-how and trade secrets related to our product candidates and proprietary technology.

ddRNAi-based treatment for OPMD

Benitec's patent portfolio for OPMD includes five patent families relating to shRNA and shmiRs targeting PABPN1 (the causative gene for OPMD), as well as 'silence and replace' therapeutics and treatment strategies for OPMD. These five families cover the OPMD therapeutic candidate, BB-301, under development at Benitec, treatment strategies for OPMD that silence PABPN1 which is causative for OPMD and replace with functional PABPN1, and Benitec's AAV patent family which covers the delivery system for BB-301. BB-301 is a 'silence and replace' construct encoding two shmiRs targeting the endogenous PABPN1 (including variants causative of OPMD) internally designated shmiR-13 and shmiR-17, as well as a codon-optimized PABPN1 replacement construct, the transcript of which is not targeted by shmiR-13 and shmiR-17. Both shmiRs and the codon-optimized PABPN1 replacement construct are under the control of a muscle-specific promoter.

The first patent family, entitled "Reagents for treatment of oculopharyngeal muscular dystrophy (OPMD) and use thereof (OPMD family #1)", arose out of a collaboration with Royal Holloway University of London (RHUL) and relates to three shRNA target regions within PABPN1. RHUL assigned its ownership interests in this patent family to Benitec, and the PCT application and the related U.S. priority document were filed solely in the name of Benitec. This patent family is directed to RNAi agents targeting specific regions within mutant PABPN1 variants causative of OPMD, as well as use of those RNAi agents in combination with PABPN1 replacement constructs to treat OPMD. More specifically, this family includes claims covering shmiR17 of BB-301 This patent family entered the national/regional phase in October/November 2018.

The second patent family, entitled "Reagents for treatment of oculopharyngeal muscular dystrophy (OPMD) and use thereof (OPMD family #2)" relates to a second set of target gene sequences within PABPN1 as well as 'silence and replace' construct BB-301 under development at Benitec. The PCT application and the related U.S. priority document were filed solely in the name of Benitec, and this family entered the national/regional phase in June/July 2019. This patent family is directed to RNAi agents targeting specific regions within mutant PABPN1 variants causative of OPMD, as well as 'silence and replace' constructs and use of same for treatment of OPMD. More specifically, this family includes claims covering shmiR13 and shmiR17 of BB-301 separately, as well as the full BB-301 'knockdown and replacement' construct.

A third patent family, entitled "Methods for Treating Oculopharyngeal Muscular Dystrophy (OPMD) (OPMD family #3)" has been filed to pursue claims which are broadly directed to the 'silence and replace' treatment concept for OPMD, relying on RNAi agents to knockdown PABPN1 and replacement with functional PABPN1 which is not targeted by the RNAi agents. The claims in this application are not limited to BB-301. This patent family exists as a PCT application and was filed solely in the name of Benitec.

A fourth patent family, entitled "Methods for Treating Oculopharyngeal Muscular Dystrophy (OPMD) (OPMD family #4)" has been filed to specifically claim the OPMD therapeutic candidate developed by Benitec, BB-301 (described herein). This patent family exists as a PCT application and was filed solely in the name of Benitec.

AAV with modified phospholipase domain

The Benitec patent portfolio includes a single patent family, entitled “Adeno-associated virus (AAV) with modified phospholipase domain,” which relates to an AAV having a modified phospholipase (PLA2) domain in the capsid. The modified AAV will be used as the delivery system for the OPMD therapeutic.

We are aware of a third party patent directed to AAV vectors that expires in 2026. In the event we receive regulatory marketing approval before the expiration date it may be necessary for us to obtain a license to the patent in order to commercialize. We cannot guarantee the availability of the license or that it can be obtained on commercially reasonable terms.

Know-How

In addition to patent protection of ddRNAi and other technology and our product candidates, we also rely on proprietary know-how that is not patentable or that we elect not to patent, as valuable intellectual property for our business. This know-how is related to the areas of, among others, identifying nucleic acid targets for ddRNAi technology and designing ddRNAi constructs for targeting preferred genes. We have implemented a number of security measures designed to safeguard our know-how including limiting access to our research facilities, databases and networks. We also seek to protect our know-how by way of confidentiality agreements when engaging with external providers for progressing our pipeline of therapeutic candidates.

Laws and Regulations Regarding Patent Terms

The term of individual patents depends upon the legal terms of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee. A patent’s term may be lengthened by a patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. The patent term of a European patent is 20 years from its filing date, which, unlike in the United States, is not subject to patent term adjustments.

The term of a patent that covers an FDA-approved biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the biologic is under clinical testing regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved biologic may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved biologic although the eligibility requirements for any duration of such extension vary. In the future, if and when our products receive FDA approval, or approval from an equivalent regulatory body in another jurisdiction in which patent protection is sought or obtained, we expect to apply for patent term extensions on patents covering those products.

Trademarks

Our trademarks include registrations for company branding and product names for our pipeline in development. The trademarks that we use in connection with our business include the following:

Country or Territory	Trademark (program)	Application or Registration number	Status
USA	BENITEC BIOPHARMA	86190065	Registered

USA	SILENCING GENES FOR LIFE	86488147	Registered
Australia	SILENCING GENES FOR LIFE	1448041	Registered
Australia	BENITEC BIOPHARMA	1448046	Registered
Australia	BENITEC—logo	1448052	Registered
Australia	Nervarna	1526478	Registered
Australia	TRIBETARNA	1526479	Registered
Australia	HEPBARNA	1526483	Registered
International Bureau (WIPO) – designating EU; UK and US	GIVING DISEASE THE SILENT TREATMENT	1389399	Registered
USA	BENITEC	86795296	Registered
USA	GIVING DISEASE THE SILENT TREATMENT	79226988	Registered
European Union	BENITEC	14680003	Registered
Australia	BENITEC	1728797	Registered
Australia	BENITEC	1103049	Registered
Australia	BENITEC	1103300	Registered
Australia	GIVING DISEASE THE SILENT TREATMENT	1851660	Registered
United Kingdom	BENITEC	3238275	Registered

Manufacturing

The manufacture of the biological products required for gene therapy is complex and difficult. We do not currently own or operate manufacturing facilities for the production of preclinical, clinical or commercial quantities of any of our product candidates. We are exploring long-term manufacturing alliances with a number of potential partners to investigate manufacturing processes in order to produce materials at reasonable scale and cost of goods to support future commercialization efforts. We do not have a long-term agreement with any third-party manufacturer, but we plan to establish such a relationship with an appropriate manufacturer to serve our long-term needs.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our contract manufacturing organizations manufacture our product candidates under cGMP conditions. cGMP is a regulatory standard for the production of pharmaceuticals that will be used in humans.

Sales and Marketing

We have not yet established sales, marketing or product distribution operations because our product candidates are in preclinical or clinical development. If we receive marketing and commercialization approval for any of our product candidates, we intend to market the product through strategic alliances and distribution agreements with third parties. In certain cases, we may market an approved product directly worldwide or in selected geographical segments. The ultimate implementation of our strategy for realizing the financial value of our product candidates is dependent on the results of clinical trials for our product candidates, the availability of funds and the ability to negotiate acceptable commercial terms with third parties.

Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies.

Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary technology and scientific expertise in gene silencing using ddRNAi provide us with competitive advantages, we face potential competition from many different sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions and governmental agencies and public and private research institutions that may develop potentially competitive products or technologies. We are aware of several companies focused on developing gene therapy or gene silencing product candidates.

We are not aware of any companies developing a gene therapy or gene silencing approach for OPMD. Our product candidates, if approved, would also compete with treatments that have already been approved and accepted by the medical community, patients and third-party payers.

Many of our competitors and potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and the commercialization of those treatments. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of competition and the availability of reimbursement from government and other third party-payers.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our therapeutic products, if approved, will be priced at a significant premium over competitive products and our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of competitive products including biosimilar or generic products.

This increasingly competitive landscape may compromise the development of our product candidates.

Government Regulation

As a pharmaceutical and biological product company that wishes to conduct clinical trials and ultimately obtain marketing approval in the United States, we are subject to extensive regulation by the FDA, and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, the Public Health Service Act, or PHS Act, and their implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB, of a suspension on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product

recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

Although the discussion below focuses on regulation in the United States, we anticipate seeking approval for the testing and marketing of our products in other countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way through the EMA, but country-specific regulation remains essential in many respects.

Government regulation may delay or prevent testing or marketing of our products and impose costly procedures upon our activities. The testing and marketing approval process, and the subsequent compliance with appropriate statutes and regulations, requires substantial time, effort, and financial resources, and we cannot be certain that the FDA or any other regulatory agency will grant marketing approvals for our products or any future products on a timely basis, if at all. The FDA's or any other regulatory agency's policies may change and additional governmental regulations may be enacted that could prevent or delay regulatory approval of our products or any future products or approval of new indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative, judicial, or administrative action, either in the United States or abroad.

Recent Developments in Regulation of Gene Therapy

Government Regulation in the United States

The FDA has provided guidance for the development of gene therapy products. For example, the FDA has established the Office of Tissues and Advanced Therapies (formerly Office of Cellular, Tissue and Gene Therapies) within the Center for Biologics Evaluation and Research (CBER), to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. In addition, the FDA has issued a growing body of clinical guidelines, chemical, manufacturing and control, or CMC, guidelines, regenerative medicine guidelines and other guidelines, all of which are intended to facilitate industry's development of gene therapy products.

In 2016, Section 3033 of the 21st Century Cures Act created a new product category called "regenerative medicine advanced therapy", or the RMAT designation. The RMAT designation gives the sponsor of a new investigational biologic access to increased meeting opportunities with the FDA, in a manner comparable to those offered to sponsors of therapies designated as "breakthrough therapies" by the FDA. Because the designated products meet the criteria for unmet medical need in the treatment of a serious condition, they may be eligible for priority review, in which the initial assessment of the BLA is reduced from 12 months to eight months, and accelerated approval, which bases approval on an effect on a predictive surrogate endpoint or an intermediate clinical endpoint. RMATs qualifying for such accelerated approval may be able to satisfy licensing requirements through commitment to post-approval clinical studies as well as real-world data such as patient registries and health record analysis. The eligibility of the RMAT-designated product for these expedited

programs can be discussed with the FDA at specific development meetings, but we do not know whether any of our current or future product candidates will be eligible for RMAT designation. We believe the increased access to the FDA during early development is a benefit for sponsors, because the typical Type B development meetings are normally restricted to one each at the stages of pre-IND, end of Phase II/pre-Phase III and pre-BLA submission. In addition, the option to qualify for a fast-track program, also based on the potential to serve an unmet medical need in the treatment of a serious condition, allows for a so-called "rolling review" of parts of the BLA, which can be submitted for assessment following agreement of a review timetable with CBER.

The FDA plans to include certain gene therapy products that permanently alter tissue and produce a sustained therapeutic benefit as part of the products that will meet the definition of being eligible to come under the pathway enabled by RMAT designation. RMAT

designation enables gene therapy products to access the FDA's existing expedited programs to help foster the development and approval of gene therapy products. Our product candidates may not be eligible for RMAT designation now or in the future.

In May 2016, the EMA approved a second gene therapy product called Strimvelis, the first approved ex vivo stem cell gene therapy, to treat patients with a very rare disease called ADA-SCID (Severe Combined Immunodeficiency due to Adenosine Deaminase deficiency).

In August 2017, the FDA approved the first gene therapy product in the United States. The FDA approved Kymriah (tisagenlecleucel) for the treatment of certain pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL). Kymriah is a genetically-modified autologous T-cell immunotherapy. Because of the risk of cytokine release syndrome and neurological events, Kymriah is being approved with a REMS. In December 2017, the FDA approved Luxturna (voretigene neparvovec-rzyl), a gene therapy to treat children and adult patients with an inherited form of vision loss that may result in blindness. Luxturna is the first directly administered gene therapy approved in the United States that targets a disease caused by mutations in a specific gene.

Marketing Approval

In the United States, for premarket approval purposes, the FDA regulates gene therapy products as biologics under the FDC Act, the PHS Act and related regulations.

The steps required before a new biologic may be marketed in the United States generally include:

- nonclinical pharmacology and toxicology laboratory and animal tests according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission of an IND application which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials according to GCPs and any additional requirements for the protection of human research subjects and their health information to establish the safety and efficacy of the investigational product for each targeted indication;
- submission of a biologics license application, or BLA, to the FDA;
- FDA's pre-approval inspection of manufacturing facilities to assess compliance with cGMPs and, if applicable, the FDA's good tissue practices, or GTPs, for the use of human cellular and tissue products to prevent the introduction, transmission, or spread of communicable diseases;
    - FDA's pre-approval inspection of manufacturing facilities to assess compliance with cGMPs and, if applicable, the FDA's good tissue practices, or GTPs, for the use of human cellular and tissue products to prevent the introduction, transmission, or spread of communicable diseases;
- FDA's audit of clinical trial sites that generated data in support of the BLA; and
- FDA approval of a BLA, which must occur before a product can be marketed or sold.

Product Development Process

Before testing any biologic in humans, the product enters the nonclinical, or preclinical, testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and activity of the product. The conduct of nonclinical tests must comply with federal regulations and requirements including GLPs.

Where a gene therapy trial is conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the trial is registered with the NIH Office of Science Policy, or OSP.

The product sponsor then submits the results of the nonclinical testing, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA in an IND, which is a request for authorization from the FDA to administer an investigational product to humans. Some nonclinical testing may continue even after the IND application is submitted. IND authorization is required before interstate shipping and administration of any new product to humans that is not the subject of an approved BLA. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the clinical trial on a clinical hold. In such case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. Further, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. If the site has an IBC, it may also have to review and approve the proposed clinical trial. Clinical trials involve the administration of the investigational product to patients under the supervision of qualified investigators following GCPs, requirements meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors. Clinical trials are conducted under protocols that detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The informed written consent of each participating subject is required and the form and content of the informed consent must be approved by each IRB.

The clinical investigation of an investigational product is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined in some cases. The three phases of an investigation are as follows:

- Phase I includes the initial introduction of an investigational product into humans. Phase I clinical trials may be conducted in patients with the target disease or condition or on healthy volunteers. These studies are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase II clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.

- Phase II includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the product. Phase II clinical trials are typically well- controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants. Phase IIa trials provide information on the impact of dose ranging on safety, biomarkers and proof of concept, while Phase IIb trials are patient dose-ranging efficacy trials.

- Phase III clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide an adequate basis for product approval. Phase III clinical trials usually involve several

hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase III clinical trials to demonstrate the efficacy of the product. FDA may accept a single Phase III trial with other confirmatory evidence in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA typically recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by 10 years of annual queries, either in person or by questionnaire, of trial subjects.

The decision to terminate a clinical trial of an investigational biologic may be made by the FDA or other regulatory authority, an IRB, an IBC, or institutional ethics committee, or by a company for various reasons. The FDA may place a clinical hold and order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. If the FDA imposes a clinical hold, trials may not recommence without FDA and IRB authorization and then only under terms authorized by the FDA and IRB. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board or DSMB. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of a clinical trial can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of drugs and biologics on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product information is submitted to the FDA in the form of a BLA for a biologic to request marketing approval for the product in specified indications.

Human gene therapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. The NIH and the FDA have a publicly accessible database, the Genetic Modification

Clinical Research Information System, which includes information on gene transfer trials and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these trials. Over the last several years the FDA has issued helpful guidance on development of gene therapy products and shown a willingness to work closely with developers, especially with those working in orphan disease areas.

Biologics License Application Approval Process

In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data from nonclinical studies and clinical trials and manufacturing information establishing to the FDA's satisfaction the safety, purity, and

potency or efficacy of the investigational product for the proposed indication. The BLA must be accompanied by a substantial user fee payment unless a waiver or exemption applies.

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The FDA will initially review the BLA for completeness before it accepts it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product's identity, safety, strength, quality, potency and purity, and in accordance with biological product standards. The FDA will inspect the facilities at which the product is manufactured to ensure the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. For a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP.

If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information, or corrective action for a manufacturing facility. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. The FDA also may determine a REMS is necessary to assure the safe use of the biologic, in which case the BLA sponsor must submit a proposed REMS. The REMS may include, but is not limited to, a Medication Guide, a communications plan, and other elements to assure safe use, such as restrictions on distribution, prescribing, and dispensing.

After the FDA completes its initial review of a BLA, it will either license, or approve, the product, or issue a complete response letter to communicate that it will not approve the BLA in its current form and to inform the sponsor of changes that the sponsor must make or additional clinical, nonclinical or manufacturing data that must be received before the FDA can approve the application, with no implication regarding the ultimate approvability of the application. If a complete response letter is issued, the sponsor may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

The testing and approval process for both a drug and biologic requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical trials is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

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Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product candidate. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication than the one for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of

the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life- threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic or drug may request the FDA to designate the biologic or drug as a fast track product at any time during the clinical development of the product. Unique to a fast track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it would, if approved, be a significant improvement in the safety, effectiveness, treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological or drug product designated for priority review in an effort to reduce the review period from 12 to eight months. Additionally, a product may be eligible for accelerated approval. Biological or drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint. As a condition of approval, the FDA may require that a sponsor of a biological or drug product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA

currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Lastly, under the provisions of the new Food and Drug Administration Safety and Innovation Act, enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug or biological that is intended, alone or in combination with one or more other drugs or biological, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs and biologicals designated as breakthrough therapies receive the same benefits as drugs and biologicals with Fast Track designation. In addition, the FDA must take certain additional actions, such as intensive guidance on an efficient drug development program (beginning as early as Phase 1), and organizational commitment involving senior managers, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Fast Track designation and breakthrough therapy designation may expedite the product development and approval process, and priority review may expedite the approval process. However, these three paths do not change the standards for approval. Accelerated approval designation changes the standards for product approval and thus may expedite the development and/or approval process.

FDA Additional Requirements

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied for continuing drug and biologic approval. The results of Phase 4 clinical trials can confirm the efficacy of a product candidate and can provide important safety information. In addition, the FDA has expressed statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of an onerous REMS, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Medical Device Requirements

Our contemplated diagnostics, for use with certain of our therapeutic products, are regulated by FDA as in vitro diagnostic, or IVD, medical devices. Such IVD devices must comply with applicable FDA IVD-specific regulations as well as FDA regulations applicable more broadly to medical devices. These FDA regulations include requirements for registering establishments with FDA; listing IVD devices with FDA; reporting certain adverse events related to IVD devices to FDA; complying with the Quality System Regulation (current good manufacturing practices for devices); labeling IVD devices; and obtaining premarket approval or clearance prior to marketing IVD devices (unless exempt). There are also regulations covering the requirements for investigational devices and the conduct of clinical investigations of devices. Like drugs and biologics, failure to comply with applicable device/IVD requirements can result in legal or administrative enforcement actions against an IVD device firm, its officers or employees, and/or its products.

FDA Post-Approval Requirements

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences with the biologic or drug, and submitting biological product deviation reports to notify the FDA of unanticipated changes in distributed products. Manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic announced or unannounced inspections

by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain quality processes, manufacturing controls and documentation requirements upon us and our third- party manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality, purity and potency characteristics that it purports to have. In November 2013, the Drug Quality and Security Act, or DQSA, became law and establishes requirements to facilitate the tracing of prescription drug and biological products through the supply distribution chain. This law includes a number of new requirements that are being implemented over time and require us to devote additional resources to satisfy these requirements, including serializing the product and using new technology and data storage to electronically trace the product from manufacturer to dispenser. If our products are not covered by the serialization and tracing requirements of the DQSA, they may be subject to state pedigree and traceability requirements. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, refuse to approve any BLA, force us to recall a product from distribution, shut down manufacturing operations or withdraw approval of the applicable BLA. Noncompliance with cGMP or other requirements can result in issuance of warning or untitled letters, civil and criminal penalties, seizures, and injunctive action.

The FDA and other federal and state agencies closely regulate the labeling, marketing and promotion of drugs and biologics. Government regulators, including the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities, recently have increased their scrutiny of the promotion and marketing of drugs and biologics. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a product that are consistent with FDA approval, and the company is allowed to market a product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must, among other things, be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning or untitled letters, corrective advertising, injunctions, potential civil and criminal penalties, criminal prosecution, and agreements with governmental agencies that materially restrict the manner in which a company promotes or distributes products.

Pediatric Research Equity Act

Under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Manufacturers must submit a pediatric study plan to the IND not later than 60 days after the end-of-phase 2 meeting with the FDA; if there is no such meeting, before the initiation of any phase 3 studies or a combined phase 2 and phase 3 study; or if no such study will be conducted, no later than 210 days before a marketing application or supplement is submitted. The intent of PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. The FDA may grant deferrals for submission of data or full or partial waivers. By its terms, PREA does not apply to any product for an indication for which orphan designation has been granted, unless the FDA issues regulations stating otherwise. Because the FDA has not issued any such regulations, submission of a pediatric assessment is not required for an application to market a product for an orphan-designated indication. In a July 2018 guidance, the FDA announced that it does not expect to grant any additional orphan drug designations to drugs for pediatric subpopulations of common diseases (i.e., diseases or conditions with an overall prevalence of 200,000 or greater). Pediatric subpopulation orphan designations that have already been granted will not be affected by this change.

Patent Term Restoration and Marketing Exclusivity

Depending on the timing, duration and specifics of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a

patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the biological product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The Biologics Price Competition and Innovation Act of 2009, which was included within the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product, and grants a reference biologic twelve years of exclusivity from the time of first licensure. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to be attached to any existing marketing exclusivity, e.g., twelve year exclusivity, or patent protection for a drug. This six month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Government regulation outside the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a request for a clinical trial authorization, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product approval or licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a biological product under European Union regulatory systems, we must submit a marketing authorization application. The application required in the European Union is similar to a BLA in the United States, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, a new biological generally receives eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a biosimilar application. During the additional two-year period of market exclusivity, a biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no

biosimilar product can be marketed until the expiration of the market exclusivity. The innovator may obtain an additional one year of market exclusivity if the innovator obtains an additional authorization during the initial eight year period for one or more new indications that demonstrate significant clinical benefit over existing therapies. This data and market exclusivity regime in the European Union of a total of 10 or 11 years protects against generic competition, but does not protect against the launch of a competing product if the competitor, rather than referencing the clinical data of the originator, has conducted its own clinical trials to support its marketing authorization application.

Orphan drugs in the European Union are eligible for 10-year market exclusivity. This 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payers, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations. These third-party payers are increasingly reducing reimbursements for medical products, biologicals, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of interchangeable products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

The containment of healthcare costs has become a priority of federal, state and foreign governments. Third-party payers are increasingly challenging the prices charged for drug products and medical services, examining the medical necessity and reviewing the cost effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the ACA, was enacted. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee

on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, in August, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which includes, in part, provisions to lower certain products' costs for Medicare beneficiaries. Beginning in 2023, if a manufacturer of any of our products increases the prices for the products faster than inflation for such products used by Medicare beneficiaries, then the manufacturer would be required to pay rebates to Medicare. If we establish any relationships with manufacturers for our products, and if our products are used by Medicare beneficiaries, manufacturers would be required to pay rebates to Medicare or else face a penalty fine representing the difference between the actual and the inflated price. Depending on the financial aspects of our relationships with manufacturers for such products, we may incur additional compliance costs which could impact our financial results.

Other Healthcare Laws

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and other countries in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine and open payment laws and regulations, many of which may become more applicable to us if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Employees

As of January 31, 2024 April 12, 2024, we had 16 full-time employees, 6 of whom have a Ph.D., 4 have Masters Degrees, and 2 have Biotechnology Certificates, and one has an M.D., for a total of 12 13 with post-graduate degrees. Of these full-time employees, 12 14 are engaged in research and development activities and 4 2 are engaged in finance, legal, human resources, facilities, and general management. None of our employees are represented by any labor union. As of January 31, 2024 April 12, 2024, 15 employees were located in the United States of America, and 1 employee was located in Australia.

Corporate Information

We were incorporated as a Delaware corporation on November 22, 2019 and completed the Re-domiciliation April 15, 2020. Our predecessor, Benitec Limited, was incorporated under the laws of Australia in 1995. Our principal executive offices are located at 3940 Trust Way, Hayward, California 94545.

Re-domiciliation

On April 15, 2020, or the Implementation Date, the re-domiciliation, or the Re-domiciliation, of Benitec Biopharma Limited, a public company incorporated under the laws of the State of Western Australia, or Benitec Limited, was completed in accordance with the Scheme Implementation Agreement, as amended and restated as of January 30, 2020, between Benitec Limited and us. As a result

of the Re-domiciliation, our jurisdiction of incorporation was changed from Australia to Delaware, and Benitec Limited became our wholly owned subsidiary.

The Re-domiciliation was effected pursuant to a statutory scheme of arrangement under Australian law, or the Scheme, whereby on the Implementation Date, all of the issued and outstanding ordinary shares of Benitec Limited were exchanged for newly issued shares of our common stock, on the basis of one share of our common stock, par value $0.0001 per share, for every 300 ordinary shares of Benitec Limited issued and outstanding. Holders of Benitec Limited's American Depository Shares, or ADSs (each of which represented 200 ordinary shares), received two shares of our common stock for every three ADSs held.

Our common stock began trading on The Nasdaq Capital Market, or Nasdaq, at the start of trading on the Implementation Date under the symbol "BNTC."

COVID-19

COVID-19 has been declared a pandemic by the World Health Organization and has spread to nearly every country, including Australia and the United States. The impact of this pandemic has been and may continue to be extensive in many aspects of society, which has resulted in and may continue to result in significant disruptions to businesses and capital markets around the world. The extent to which the coronavirus continues to impact us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and its variants, and the actions to contain the coronavirus or treat its impact, including the effectiveness and adoption of vaccines for the virus, among others.

Certain of our research and development efforts are conducted globally, including the ongoing development of our silence and replace therapeutic for the treatment of Oculopharyngeal Muscular Dystrophy (OPMD), and will be dependent upon our ability to continue our preclinical and clinical studies and related work despite the COVID-19 pandemic and any similar events.

Reverse Stock Split

On July 26, 2023, the Company effected a 1-for-17 reverse stock split (the "Reverse Stock Split") of its common stock. In accordance with the Reverse Stock Split, 17 pre-split shares of the Company's common stock were automatically converted into one issued and outstanding post-split share. Proportional adjustments were also made to all outstanding stock options, pre-funded warrants, and common warrants in accordance with their respective terms. The Reverse Stock Split did not change the par value of the Company's common stock or the authorized number of shares. No fractional shares were issued in connection with the Reverse Stock Split. All fractional shares were rounded up to the nearest whole share with respect to outstanding shares of common stock. All share and earnings per share amounts presented in this Form 10-Q reflect the impact of this reverse split.

Available Information

Our telephone number is (510) 780-0819, and our Internet website is www.benitec.com. The information on, or that can be accessed through, our website is not part of this Quarterly Report on Form 10-Q and is not incorporated by reference herein.

Royalties, milestone payments and other license fees

We are required to pay royalties, milestone payments and other license fees in connection with our licensing of intellectual property from third parties, including as discussed below.

Foreign Currency Translation and Other Comprehensive Income (Loss)

The Company's functional currency and reporting currency is the United States dollar. BBL's functional currency is the Australian dollar (AUD). Assets and liabilities are translated at the exchange rate in effect at the balance sheet date. Revenues and expenses are translated at the average rate of exchange prevailing during the reporting period. Equity transactions are translated at each historical transaction date spot rate. Translation adjustments arising from the use of different exchange rates from period to period are included as a

component of stockholders' equity as "Accumulated other comprehensive loss." Gains and losses resulting from foreign currency translation are included in the consolidated statements of operations and comprehensive loss as other comprehensive income (loss).

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April 2021 Capital Raise

On April 30, 2021, the Company announced the closing of an underwritten public offering of common stock and common stock equivalents. The Company received gross proceeds of approximately $14.3 million $14.3 million and net proceeds of approximately $12.7 million $12.7 million from the offering.

September 2022 Capital Raise

On September 15, 2022, the Company announced the closing of an underwritten public offering of common stock and common stock equivalents. The Company received gross proceeds of approximately $17.9 million $17.9 million and net proceeds of approximately $16.0 million $16.0 million from the offering.

August 2023 Capital Raise

On August 11, 2023 we closed an underwritten public offering in which we sold 875,949 shares of common stock, 15,126,226 pre-funded warrants to purchase 15,126,226 shares of common stock, and 16,002,175 common warrants to purchase up to 16,002,175 shares of common stock. The pre-funded warrants were immediately exercisable until exercised in full at an exercise price of $0.0001 per share of common stock. The common warrants were immediately exercisable at a price per share of common stock of $3.86 and expire on the fifth anniversary of such initial exercisable date. The combined purchase price for each share of common stock and accompanying common warrant was $1.93, which was allocated as $1.9299 per share of common stock and $0.0001 per common warrant. Each pre-funded warrant was sold together with one common warrant at a combined price of $1.9299, which was allocated as $1.9298 per pre-funded warrant and $0.0001 per common warrant. In addition, the Company granted the underwriter a 30-day option to purchase up to 2,331,606 additional shares of common stock and/or up to 2,331,606 additional common warrants. As of December 31, 2023 the The underwriter had partially exercised this option and purchased 458,134 additional shares of common stock and 458,134 additional common warrants. Net proceeds from the offering, including the impact of the underwriter's partial exercise of its option and net of underwriting discounts, commissions, and other offering expenses, totaled $27.9 million. $27.9 million.

The Company has outstanding Series 2 warrants (the "Series 2 Warrants") which are currently exercisable into 1,733,503 shares of common stock after giving effect to the Reverse Stock Split and exercises during the three months ended December 31, 2023 as of March 31, 2024. The Series 2 Warrants contain an exercise price adjustment mechanism providing that certain issuances of common stock (or common stock equivalents) if made at a price lower than the existing exercise price of $11.22 of such Series 2 Warrants, would reset the exercise price to such lower price. As a result of the August 11, 2023 public offering, the exercise price of the Series 2 Warrants has been automatically reset as of the closing time of such public offering to $1.9299.

April 2024 Capital Raise

On April 18, 2024 we closed a private investment in public equity (PIPE) financing in which we sold 5,749,152 shares of common stock at a price per share of $4.80 and, in lieu of shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,584,239 shares of common stock at a price per pre-funded warrant of $4.7999, to certain accredited institutional investors. The pre-funded warrants were immediately exercisable until exercised in full at an exercise price of $0.0001 per share of common stock. Gross proceeds from the financing totaled $40.0 million. Net proceeds, net of commissions and other offering expenses, totaled approximately $ 37.2 million.

Results of Operations

Revenues

The Company has not generated any revenues from the sales of products. Revenues from licensing fees are included in the revenue from customers line item on our consolidated statements of operations and comprehensive loss. Our licensing fees have been generated through the licensing of our ddRNAi technology to biopharmaceutical companies. The Company did not recognize any revenue during the six nine months ended December 31, 2023 March 31, 2024, and recognized $14 $68 thousand during the six nine months ended December 31, 2022 March 31, 2023.

Royalties and License Fees

Royalties and license fees consist primarily of payments we are required to remit for royalties and other payments related to in-licensed intellectual property. Under our in-license agreements, we may pay up-front fees and milestone payments and be subject to future royalties. We cannot precisely predict the amount, if any, of royalties we will owe in the future, and if our calculations of royalty payments are incorrect, we may owe additional royalties, which could negatively affect our results of operations. As our product sales increase, we may, from time to time, disagree with our third-party collaborators as to the appropriate royalties owed, and the resolution of such disputes may be costly, may consume management's time, and may damage our relationship with our collaborators. Furthermore, we may enter into additional license agreements in the future, which may also include royalty, milestone, and other payments.

Research and Development Expenses

Research and development expenses relate primarily to the cost of conducting clinical and preclinical trials. Preclinical and clinical development costs are a significant component of research and development expenses. The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in trade and other payables on the consolidated balance sheets and within research and development expenses on the consolidated statements of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel, and equity-based compensation expense. General and administrative expenses also include facility expenses, professional fees for legal, consulting, accounting and audit services and other related costs.

We anticipate that our general and administrative expenses may increase as the Company focuses on the continued development of the clinical OPMD program. The Company also anticipates an increase in expenses relating to accounting, legal and regulatory-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and other similar costs.

On September 13, 2023, the Compensation Committee (the "Compensation Committee") of the Company's Board of Directors approved increases of the base salaries of Dr. Jerel Banks, the Company's Executive Chairman and Chief Executive Officer, and Megan Boston, the Company's Executive Director, to $655,200 and $350,784 (Ms. Boston's salary as noted has been converted from AUD $1.00 to USD $0.64, which was the conversion rate as of September 13, 2023) respectively, each adjustment being effective as of October 1, 2023.

Operating Expenses

The following tables sets forth a summary of our expenses for each of the periods:

	Three Months Ended December 31,		Six Months Ended December 31,		Three Months Ended March 31,		Nine Months Ended March 31,	
	2023	2022	2023	2022	2024	2023	2024	2023
Operating Expenses:	(US$'000)				(US$'000)			
Royalties and License Fees	$ 1	$ —	$ (105)	$ —	$ (3)	$ —	$ (108)	$ —
Research and development	5,102	3,761	9,531	6,421	2,566	3,167	12,097	9,588
General and administrative	1,824	1,863	3,375	3,783	1,578	1,228	4,953	5,011
Total operating expenses	$ 6,927	$ 5,624	$ 12,801	$ 10,204	$ 4,141	$ 4,395	$ 16,942	$ 14,599

During the three months ended December 31, 2023 March 31, 2024 and December 31, 2022 March 31, 2023, we incurred royalties and license fees expenses of $1 $(3) thousand and ($105) thousand, zero, respectively. The credit credits to expense during the six three and nine months ended December 31, 2023 reflects March 31, 2024 relate to the reversal of an accrual accruals for license fees no longer due.

During the three and six nine months ended December 31, 2023 March 31, 2024, respectively, we incurred $5.1 million $2.6 million and $9.5 million $12.1 million in research and development expenses, respectively, as compared to $3.8 million $3.2 million and $6.4 million $9.6 million for the comparable periods ended December 31, 2022 March 31, 2023. Research and development expenses relate primarily The year-over-year increase for the nine-month period ended March 31, 2024 relates to the ongoing clinical development of BB-301 for the treatment of OPMD. The year-over-year decrease for the three-month period ended March 31, 2024 reflects a slow-down in contract manufacturing activity and the timing of payments for the OPMD Natural History and Dosing study.

General and administrative expenses totaled $1.8 million $1.6 million and $3.4 million $5.0 million for the three and six nine months ended December 31, 2023 March 31, 2024, compared to $1.9 million $1.2 million and $3.8 million $5.0 million for the comparable periods ended December 31, 2022 March 31, 2023. The year-over-year decrease for the six-month nine-month periods ended December 31 March 31, 2024 relates primarily to lower stock-based compensation ($70 thousand) and legal fees ($396 304 thousand); partially offset by higher travel expense audit/tax fees ($109 111 thousand) and filing fees ($67 thousand). The higher audit/tax fees relate to the completion of an Internal Revenue Code Section 382 analysis. Increased legal fees relate to the filing of the S-3 Registration Statement in February 2024, and higher filing fees reflect increased franchise taxes. The increase for three months ended March 31, 2024 relates primarily to higher filing, legal, and audit/tax fees ($122 thousand, $92 thousand, and $61 thousand, respectively). Specifically, the higher audit/tax fees relate to the completion of the IRC Section 382 analysis. Increased legal fees relate to the filing of the S-3 Registration Statement on February 23, 2024, and higher filing fees reflect the franchise tax increase for Benitec Inc.

Other Income (Expense)

The following tables sets forth a summary of our other income (loss) for each of the periods:

Other Income (Loss):	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Six Months Ended December 31, 2023	Six Months Ended December 31, 2022	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Nine Months Ended March 31, 2024	Nine Months Ended March 31, 2023
	(US$'000)				(US$'000)			
Foreign currency transaction gain (loss)	$ 152	$ 161	$ 96	$ (346)				
Foreign currency transaction loss	$ (118)	$ (45)	$ (22)	$ (391)				
Interest expense, net	(6)	(9)	(12)	(18)	(4)	(7)	(16)	(25)
Other income (expense), net	(16)	50	(34)	50	(16)	—	(50)	50
Unrealized loss on investment	(1)	(3)	(1)	—	—	(4)	(1)	(4)
Total other income (loss), net	$ 129	$ 199	$ 49	$ (314)	$ (138)	$ (56)	$ (89)	$ (370)

Other income (loss), net during the three and six nine months ended December 31, 2023 March 31, 2024, which consists of foreign currency transaction gain (loss), interest expense, other income (expense), and unrealized loss on investment, totaled $129 $(138) thousand and $49 $(89) thousand, respectively. During the three and six nine months ended December 31, 2022 March 31, 2023, respectively, other income (loss) totaled $199 $(56) thousand and $(314) $(370) thousand. Foreign currency transaction gains and losses reflect changes in foreign exchange rates. Other income recognized during the nine months ended March 31, 2023 relates to recognition of a tax penalty refund receivable. Other expense for the nine months ended March 31, 2024 relates to state franchise taxes. Unrealized loss on investment decreased for both the three months ended December 31, 2023, and increased slightly for the six nine months ended December 31, 2023 March 31, 2024.

Liquidity and Capital Resources

The Company has incurred cumulative losses and negative cash flows from operations since our predecessor's inception in 1995. The Company had accumulated losses of $180 million $185 million as of December 31, 2023 March 31, 2024. We expect that our research and development expenses may will increase due to the continued development of the OPMD program. It is also likely that there will be an increase in the general and administrative expenses due to the obligations of being a domestic public company in the United States.

We had no borrowings as of December 31, 2023 March 31, 2024 and do not currently have a credit facility.

As of December 31, 2023 March 31, 2024, we had cash and cash equivalents of approximately $20.4 million. $14.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash and cash equivalents are held in bank accounts.

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below:

Net cash provided by (used in):	Six Months Ended December 31, 2023	Six Months Ended December 31, 2022	Nine Months Ended March 31, 2024	Nine Months Ended March 31, 2023
	(US$'000)		(US$'000)	
Operating activities	$ (9,942)	$ (9,888)	$ (16,110)	$ (13,917)
Investing activities	—	—	(179)	—

Financing activities	27,958	16,015	27,958	16,015
Effects of exchange rate changes on cash and cash equivalents	(118)	348	(3)	391
Net increase in cash, cash equivalents, and restricted cash	$ 17,898	$ 6,475	$ 11,666	$ 2,489

Operating activities

Net cash used in operating activities for both the six months nine-month periods ended December 31, 2023 March 31, 2024 and 2022 2023 was $9.9 million. $16.1 million and $13.9 million, respectively. Net cash used in operating activities was primarily the result of our net loss, partially offset by non-cash expenses and changes in working capital, including increases in payables and prepaid expenses. capital.

Investing activities

Net cash used in investing activities for the nine-month periods ended March 31, 2024 and 2023 was $179 thousand and zero, respectively. Net cash used in investing activities relates to purchases of laboratory equipment.

Financing activities

Net cash provided by financing activities was $28.0 million $28.0 million and $16.0 for the six nine months ended December 31, 2023 March 31, 2024 and 2022, 2023, respectively. Cash from financing activities in 2023 for the nine months ended March 31, 2024 relates to the issuance and exercise of common stock, pre-funded warrants, and common warrants, with gross proceeds of $30.9 $30.9 million, partially offset by $2.9 million $3.0 million in share issuance costs. Cash from financing activities in 2022 for the nine months ended March 31, 2023 was related to the issuance of common stock, pre-funded warrants, and Series 2 warrants, including $17.9 million $17.9 million in gross proceeds from the September 2022 Capital Raise, partially offset by $1.9 million $1.9 million in share issuance costs.

The future of the Company as an operating business will depend on its ability to manage operating costs and budgeted amounts and obtain adequate financing. While we continue to progress discussions and advance opportunities to engage with pharmaceutical companies and continue to seek licensing partners for ddRNAi in disease areas that are not our focus, there can be no assurance as to whether we will enter into such arrangements or what the terms of any such arrangement could be.

While we have established some licensing arrangements, we do not have any products approved for sale and have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates.

Unless and until we establish significant revenues from licensing programs, strategic alliances or collaboration arrangements with pharmaceutical companies, or from product sales, we anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of product candidates and begin to prepare to commercialize any product that receives regulatory approval. We are subject to the risks inherent in the development of new gene therapy products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. We estimate that our cash and cash equivalents will be sufficient to fund the Company's operations for at least the next twelve months from the date of this report.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research,

development, and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing and costs of our clinical trials for our ddRNAi and silence and replace product candidates;
- the timing and costs of our preclinical studies for our ddRNAi and silence and replace product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing, and costs of seeking regulatory approvals;
- revenue received from commercial sales of any of our product candidates that may receive regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting, or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we need to in-license or acquire other products and technologies.
    - the extent to which we need to in-license or acquire other products and technologies.

Contractual Obligations and Commercial Commitments

On October 1, 2016, the Company entered into an operating lease for office space in Hayward, California that originally expired in April 2018. The Company has entered into lease amendments that extended the lease through June 2025. See Note 8 of the Notes to Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

The Company enters into contracts in the normal course of business with third-party contract research organizations, contract development and manufacturing organizations and other service providers and vendors. These contracts generally provide for termination on notice and, therefore, are cancellable contracts and not considered contractual obligations and commitments.

Critical Accounting Policies and Significant Accounting Estimates

The preparation of consolidated financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make judgments, assumptions and estimates that affect the amounts reported. Note 2 of the Notes to Consolidated Financial Statements included in this Quarterly Report on Form 10-Q describes the significant accounting policies used in the preparation of the consolidated financial statements. Certain of these significant accounting policies are considered to be critical accounting policies.

A critical accounting policy is defined as one that is both material to the presentation of the Company's consolidated financial statements and requires management to make difficult, subjective, or complex judgments that could have a material effect on the Company's financial condition or results of operations. Specifically, these policies have the following attributes: (1) the Company is required to make

assumptions about matters that are highly uncertain at the time of the estimate; and (2) different estimates the Company could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on the Company's financial condition or results of operations.

Estimates and assumptions about future events and their effects cannot be determined with certainty. The Company bases its estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as the Company's operating environment changes. These changes have historically been minor and have been included in the consolidated financial statements as soon as they became known. In addition, management is periodically faced with uncertainties, the outcomes of which are not within its control and will not be known for prolonged periods of time. These uncertainties are discussed in the section above entitled "Risk Factors." Based on a critical assessment of its accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that the Company's consolidated financial statements are fairly stated in accordance with accounting principles generally accepted in the United States of America and provide a meaningful presentation of the Company's financial condition and results of operations.

Management believes that the following are critical accounting policies:

Research and Development Expense

Research and development expenses relate primarily to the cost of conducting clinical and preclinical trials. Preclinical and clinical development costs are a significant component of research and development expenses. The Company records accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in trade and other payables on the consolidated balance sheets and within research and development expenses on the consolidated statements of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred.

Share-based Compensation Expense

The Company records share-based compensation in accordance with ASC 718, *Stock Compensation*. ASC 718 requires the fair value of all share-based employee compensation awarded to employees and non-employees to be recorded as an expense over the shorter of the service period or the vesting period. The Company determines employee and non-employee share-based compensation based on grant-date fair value using the Black-Scholes Option Pricing Model.

Recent Accounting Pronouncements

Accounting Standards recently adopted

ASU 2016-13 – In June 2016, the FASB issued ASU No. 2016-13: "*Financial Instruments-Credit Losses (Topic 326*)". This ASU represents a significant change in the accounting for credit losses model by requiring immediate recognition of management's estimates of current expected credit losses (CECL). Under the prior model, losses were recognized only as they were incurred. The Company adopted this ASU effective July 1, 2023 and determined that its impact on the accompanying consolidated financial statements is immaterial.

Recently Issued Accounting Standards not yet adopted

In December 2023, the FASB issued ASU No. 2023-09, "*Income Taxes (Topic 740*) – Improvements to Income Tax Disclosures", which enhances the transparency, effectiveness and comparability of income tax disclosures by requiring consistent categories and greater disaggregation of information related to income tax rate reconciliations and the jurisdictions in which income taxes are paid. This guidance is effective for annual periods beginning after December 15, 2024 with early adoption permitted. The Company is currently evaluating the impact of the ASU on its income tax disclosures within the consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures", which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. This ASU also expands disclosure requirements to enable users of financial statements to better understand the entity's measurement and assessment of segment performance and resource allocation. This guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of the ASU on its disclosures within the consolidated financial statements.

53 3. Liquidity

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. For the nine months ended March 31, 2024, and 2023, the Company incurred net losses of $17.0 million and $14.9 million, respectively, and used cash in operations of $16.1 million and $13.9 million, respectively. The Company expects to continue to incur additional operating losses in the foreseeable future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information pursuant to this Item.

Item 4. Controls and Procedures

We have established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). As of the end of the period covered by this Report we carried out an evaluation under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 of the Securities and Exchange Act of 1934, as amended. Based upon that evaluation, our principal executive officer and principal financial and accounting officer concluded that our disclosure controls and procedures are effective.

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We do not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings

We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in Item 1A of the Company's Annual Report onForm 10-Kfor the fiscal year ended

June 30, 2023.
June 30, 2023, other than the following:

The exercise of Warrants to purchase our Common Stock would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. Such dilution will increase if more of our shares are redeemed.

As of May 6th, 2024, we had outstanding(i) Pre-FundedWarrants to purchase an aggregate of 17,703,340 shares of our Common Stock and (ii) Ordinary Warrants to purchase an aggregate of 17,630,135 shares of our Common Stock. The likelihood that those Warrants will be exercised increases if the trading price of shares of our stock exceeds the exercise price of the Warrants (or the purchase price of the Warrants). To the extent the Warrants are exercised, additional shares of Common Stock will be issued, which will result in dilution to the holders of our stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of shares of Common Stock issued upon the exercise of Warrants in the public market or the potential that such Warrants may be exercised could also adversely affect the market price of our Common Stock.

A number of our stockholders hold significant amounts of our Common Stock and unexercised Warrants to acquire Common Stock, and therefore could exert significant influence over us.

While our stockholder base and relative holdings may change over time, a number of institutional investors and similar stockholders currently hold significant ownership positions in our outstanding Common Stock and outstanding Warrants to acquire Common Stock. In addition, in connection with the April 2024 private placement, we entered into the Board Designation Agreement with Suvretta Capital pursuant to which the Company agreed to consider for appointment and appoint Kishen Mehta or an alternative candidate proposed by Suvretta Capital to the Board. If such a candidate is appointed to the Board, Suvretta Capital will be able to exert influence not only as a significant stockholder but also through such appointee.

The interests of these significant shareholders might not always coincide with the interests of other stockholders, and any influence exerted over our business and affairs by these significant stockholders directly or through an appointee to the Board might not always coincide with the wishes of other stockholders. In addition, the control and influence held by these significant stockholders might have the effect of delaying, deferring, or preventing a transaction or change in control of us, which might involve a premium price for shares of our Common Stock, or which otherwise could have been in your best interests as a stockholder.

Sales of a substantial amount of the Common Stock in the public markets may cause the market price of the Common Stock to decline.

In connection with a private investment in public equity (PIPE) financing which closed on April 18, 2024 (the "April 2024 private placement"), we agreed to register forre-sale5,749,152 shares of common stock andpre-fundedwarrants to purchase up to an aggregate of 2,584,239 shares of common stock issued in the private placement together with any shares of Common Stock held by each purchaser as of the filing date that could not otherwise be sold without being subject to the volume limitations contained in Rule 144(e), including any shares of Common Stock then issued or issuable upon exercise of any warrants to purchase Common Stock (without regard to any exercise limitations therein). Such number of shares of Common Stock to be registered is significantly higher than the amount of shares outstanding prior to, and following, the April 2024 private placement. Sales of those shares, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock. The sale or possibility of sale of these shares could have the effect of increasing the volatility in the price of our Common Stock or the market price of our Common Stock could decline if the holders of currently restricted shares of Common Stock sell them or are perceived by the market as intending to sell them. Moreover, the sale of shares issued in the April 2024 private placement, any announcement or other public disclosure regarding such sales should they occur, the perceived risk of such sales, the dilution that would result from such sales should they occur and the resulting downward pressure on our share price as a result of the foregoing could encourage investors to engage in short sales of our Common Stock. By increasing the number of shares of Common Stock offered for sale as a result of the resale registration statement we are filing and expect to file, material amounts of short selling could further contribute to progressive price declines in our Common Stock.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

During the quarter ended December 31, 2023 March 31, 2024, none of our directors or officers adopted, modified, or terminated a "Rule10b5-1trading arrangement" or a "non-Rule "non-Rule10b5-1trading arrangement" as such terms are defined under Item 408 of RegulationS-K.

Item 6. Exhibits.

Number	Description of Document
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed on April 19, 2024 (File. No. 001-39267))
10.1	Second Amendment to Securities Purchase Agreement, dated April 17, 2024, by and among Benitec Biopharma Inc. 2020 Equity and Incentive Compensation Plan, dated as of December 6, 2023 each purchaser identified on the signature pages thereto (incorporated by reference to Annex A Exhibit 10.1 to the Company's Definitive Proxy Statement on Schedule 14A Form 8-K filed on October 20, 2023). April 19, 2024 (File. No. 001-39267))
10.2	Registration Rights Agreement, dated April 22, 2024, by and between Benitec Biopharma Inc. and each of the purchasers signatory thereto*
10.3	Form of Voting Commitment Agreement (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on April 19, 2024 (File. No. 001-39267))
10.4	Board Designation Agreement, dated April 22, 2024, by and between Benitec Biopharma Inc. and Suvretta Capital Management, LLC*
31.1	Statement of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Statement of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Statement of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Statement of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document*
104	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.

** Furnished, not filed.

SIGNATURES

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

Benitec Biopharma Inc.

Dated: February 13, 2024 May 13, 2024

/s/ Jerel Banks

Jerel Banks
Executive Chairman and Chief Executive Officer
(principal executive officer)

/s/ Megan Boston

Megan Boston
Executive Director (principal financial and accounting officer)

Exhibit 10.2

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this " Agreement") is made and entered into as of April 22, 2024, between Benitec Biopharma Inc., a Delaware corporation (the "Company"), and each of the several purchasers signatory hereto (each such purchaser, a "Purchaser" and, collectively, the "Purchasers").

This Agreement is made pursuant to the Securities Purchase Agreement, dated as of the date hereof, between the Company and each Purchaser (the "PurchaseAgreement").

The Company and each Purchaser hereby agrees as follows:

1. Definitions.

Capitalized terms used and not otherwise defined herein that are defined in the Purchase Agreement shall have the meanings given to such terms in the Purchase Agreement. As used in this Agreement, the following terms shall have the following meanings:

"Advice" shall have the meaning set forth in Section 6(b).

"Effectiveness Date" means, with respect to the Initial Registration Statement required to be filed hereunder, the 60th calendar day following the closing date of the transactions contemplated by the Purchase Agreement (the "Closing Date") (or, in the event of a "full review" by the Commission, the 90th calendar day following the Closing Date) and with respect to any additional Registration Statements which may be required pursuant to Section 2(c) or Section 3(c), the 30th calendar day following the date on which an additional Registration Statement is required to be filed hereunder (or, in the event of a "full review" by the Commission, the 60th calendar day following the date such additional Registration Statement is required to be filed hereunder); provided, however, that in the event the Company is notified by the Commission that one or more of the

above Registration Statements will not be reviewed or is no longer subject to further review and comments, the Effectiveness Date as to such Registration Statement shall be the fifth Trading Day following the date on which the Company is so notified if such date precedes the dates otherwise required above (unless the Company is informed by the Commission that it will not take the Registration Statement effective on such date), provided, further, if such Effectiveness Date falls on a day that is not a Trading Day, then the Effectiveness Date shall be the next succeeding Trading Day.

"Effectiveness Period" shall have the meaning set forth in Section 2(a).

"Event" shall have the meaning set forth in Section 2(d).

"Event Date" shall have the meaning set forth in Section 2(d).

"Filing Date" means, with respect to the Initial Registration Statement required hereunder, the 30th calendar day following the Closing Date and, with respect to any additional Registration Statements which may be required pursuant to Section 2(c) or Section 3(c), the earliest practical date on which the Company is permitted by SEC Guidance to file such additional Registration Statement related to the Registrable Securities.

"Holder" or "Holders" means the holder or holders, as the case may be, from time to time of Registrable Securities.

"Indemnified Party" shall have the meaning set forth in Section 5(c).

"Indemnifying Party" shall have the meaning set forth in Section 5(c).

"Initial Registration Statement" means the initial Registration Statement filed pursuant to this Agreement.

"Losses" shall have the meaning set forth in Section 5(a).

"Plan of Distribution" shall have the meaning set forth in Section 2(a).

"Prospectus" means the prospectus included in a Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430A promulgated by the Commission pursuant to the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by a Registration Statement, and all other amendments and supplements to the Prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

"Registrable Securities" means, as of any date of determination, (a) all Shares, (b) all Warrant Shares then issued and issuable upon exercise of the Warrants (assuming on such date the Warrants are exercised in full without regard to any exercise limitations therein), (c) any additional shares of Common Stock issued and issuable in connection with any applicable anti-dilution or adjustment provisions in the Warrants (without giving effect to any limitations on exercise set forth in the Warrants), (d) any shares of Common Stock held by a Holder as of the Filing Date that could not otherwise be sold without being subject to the volume limitations contained in Rule 144(e), including any shares of Common Stock then issued or issuable upon exercise of any warrants to purchase Common Stock (other than the Warrants) held by a Holder as of the Filing Date (assuming on such date any such warrants are exercised in full without regard to any exercise

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limitations therein) and (e) any securities issued or then issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing; provided,however, that any such Registrable Securities shall cease to be Registrable Securities (and the Company shall not be required to maintain the effectiveness of any, or file another, Registration Statement hereunder with respect thereto) for so long as (i) a Registration Statement with respect to the sale of such Registrable Securities is declared effective by the Commission under the Securities Act and such Registrable Securities have been disposed of by the Holder in accordance with such effective Registration Statement, (ii) such Registrable Securities have been previously sold in accordance with Rule 144, or (iii) such securities become eligible for

resale without volume or manner-of-sale restrictions and without current public information pursuant to Rule 144 as set forth in a written opinion letter to such effect, addressed, delivered and acceptable to the Transfer Agent and the affected Holders (assuming that such securities and any securities issuable upon exercise, conversion or exchange of which, or as a dividend upon which, such securities were issued or are issuable, were at no time held by any Affiliate of the Company), as reasonably determined by the Company, upon the advice of counsel to the Company.

"Registration Statement" means any registration statement required to be filed hereunder pursuant to Section 2(a) and any additional registration statements contemplated by Section 2(c) or Section 3(c), including (in each case) the Prospectus, amendments and supplements to any such registration statement or Prospectus, including pre- and post-effective amendments, all exhibits thereto, and all material incorporated by reference or deemed to be incorporated by reference in any such registration statement.

"Rule 415" means Rule 415 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Selling Stockholder Questionnaire" shall have the meaning set forth in Section 3(a).

"SEC Guidance" means (i) any publicly-available written or oral guidance of the Commission staff, or any comments, requirements or requests of the Commission staff and (ii) the Securities Act.

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2. Shelf Registration.

(a) On or prior to each Filing Date, the Company shall prepare and file with the Commission a Registration Statement covering the resale of all of the Registrable Securities that are not then registered on an effective Registration Statement for an offering to be made on a continuous basis pursuant to Rule 415. Each Registration Statement filed hereunder shall be on Form S-1 (or, at the election of the Company and if available, Form S-3, or such other form available to register for resale the Registrable Securities as a secondary offering), and shall contain (unless otherwise directed by at least two-thirds in interest of the Holders) substantially the "Plan of Distribution" attached hereto as Annex A and substantially the "Selling Stockholder" section attached hereto as Annex B; provided, however, that no Holder shall be required to be named as an "underwriter" without such Holder's express prior written consent, and a non- consenting Holder will be removed from the Registration Statement as a Selling Stockholder if the Commission will not take the Registration Statement effective without such Holder being named as an "underwriter" and such removal will not be a breach by the Company. Subject to the terms of this Agreement, the Company shall use its best efforts to cause a Registration Statement filed under this Agreement (including, without limitation, under Section 3(c)) to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event no later than the applicable Effectiveness Date, and shall use its best efforts to keep such Registration Statement continuously effective under the Securities Act until the date that all Registrable Securities covered by such Registration Statement (i) have been sold, thereunder or pursuant to Rule 144, or (ii) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144, as determined by the counsel to the Company pursuant to a written opinion letter to such effect, addressed and acceptable to the Transfer Agent and the affected Holders (the "Effectiveness Period"). The Company shall telephonically request effectiveness of a Registration Statement as of 5:00 p.m. (New York City time) on a Trading Day. The Company shall immediately notify the Holders via e-mail of the effectiveness of a Registration Statement on the same Trading Day that the Company telephonically confirms effectiveness with the Commission, which shall be the date requested for effectiveness of such Registration Statement. The Company shall, by 9:30

a.m. (New York City time) on the second Trading Day after the effective date of such Registration Statement, file a final Prospectus with the Commission as required by Rule 424. Failure to so notify the Holder within one (1) Trading Day of such notification of effectiveness or failure to file a final Prospectus as foresaid shall be deemed an Event under Section 2(d).

(b) Notwithstanding the registration obligations set forth in Section 2(a), if the Commission informs the Company that all of the Registrable Securities cannot, as a result of the application of Rule 415, be registered for resale as a secondary offering on a single registration statement, the Company agrees to promptly inform each of the Holders thereof and use its commercially

reasonable efforts to file amendments to the Initial Registration Statement as required by the Commission, covering the maximum number of Registrable Securities permitted to be registered by the Commission, on Form S-1 (or, at the election of the Company and if available, Form S-3, or such other form available to register for resale the Registrable Securities as a secondary offering); with respect to filing on Form S-1 or other appropriate form; provided, however, that prior to filing such amendment, the Company shall be obligated to use reasonable efforts to advocate with the Commission for the registration of all of the Registrable Securities in accordance with the SEC Guidance, including without limitation, Compliance and Disclosure Interpretation 612.09.

(c) Notwithstanding any other provision of this Agreement, if the Company elects to use Form S-3, and the Commission or any SEC Guidance sets forth a limitation on the number of Registrable Securities permitted to be registered on a particular Registration Statement as a secondary offering (and notwithstanding that the Company used reasonable efforts to advocate with the Commission for the registration of all or a greater portion of Registrable Securities), unless otherwise directed in writing by a Holder as to its Registrable Securities, the number of Registrable Securities to be registered on such Registration Statement will be reduced as follows:

a. First, the Company shall reduce or eliminate any securities to be included other than Registrable Securities;

b. Second, the Company shall reduce Registrable Securities represented by Warrant Shares (applied, in the case that some Warrant Shares may be registered, to the Holders on a pro rata basis based on the total number of unregistered Warrant Shares held by such Holders); and

c. Third, the Company shall reduce Registrable Securities represented by Shares (applied, in the case that some Shares may be registered, to the Holders on a pro rata basis based on the total number of unregistered Shares held by such Holders).

In the event of a cutback hereunder, the Company shall give the Holder at least three (3) Trading Days prior written notice along with the calculations as to such Holder's allotment. In the event the Company amends the Initial Registration Statement in accordance with the foregoing, the Company will use its best efforts to file with the Commission, as promptly as allowed by Commission or SEC Guidance provided to the Company or to registrants of securities in general, one or more registration statements on Form S-3 or such other form available to register for resale those Registrable Securities that were not registered for resale on the Initial Registration Statement, as amended.

(d) If: (i) the Initial Registration Statement is not filed on or prior to its Filing Date (if the Company files the Initial Registration Statement without affording the Holders the opportunity to review and comment on the same as required by Section 3(a) herein or the Company subsequent withdraws the filing of the Registration Statement, the Company shall be deemed to have not satisfied this clause as of the Filing Date (i)), or (ii) the Company fails to file with the Commission a request for acceleration of a Registration Statement in accordance with Rule 461 promulgated by the Commission pursuant to the Securities Act, within five Trading Days of the date that the Company is notified (orally or in writing, whichever is earlier) by the Commission that such Registration Statement will not be "reviewed" or will not be subject to further review, or (iii) prior to the effective date of a Registration Statement, the Company fails to file a pre-effective amendment and otherwise respond

in writing to comments made by the Commission in respect of such Registration Statement within ten (10) business days after the receipt of comments by or notice from the Commission that such amendment is required in order for such Registration Statement to be declared effective, or (iv) a Registration Statement registering for resale all of the Registrable Securities is not declared effective by the Commission by the Effectiveness Date of the Initial Registration Statement (provided if the Registration Statement does not allow for the resale of Registrable Securities at prevailing market prices (i.e., only allows for fixed price sales), the Company shall have been deemed to have not satisfied this clause) or (v) after the effective date of a Registration Statement, such Registration Statement ceases for any reason to remain continuously effective as to all Registrable Securities included in such Registration Statement, or the Holders are otherwise not permitted to utilize the Prospectus therein to resell such Registrable Securities, for more than sixty (60) consecutive calendar days or more than an aggregate of ninety (90) calendar days (which need not be consecutive calendar days) during any 12-month period (any such failure or breach in clauses (i) – (iv) above relating to the Initial Registration Statement being referred to as an "Event", and for purposes of clauses (i) and (iv), the date on which such Event occurs, and for purpose of clause (ii) the date on which such five (5) Trading Day period is exceeded, and for purpose of clause (iii) the date which such ten (10) business day period is exceeded, as applicable, is exceeded being referred to as "Event Date"), then, in addition to any other rights the Holders may have hereunder or under applicable law, on each such Event Date and on each monthly anniversary of each such Event Date (if the applicable Event shall not have been cured by such date) until the applicable Event is cured, the Company shall pay to each Holder an amount in cash, as liquidated damages and not as a penalty, equal to the product of 2.0% multiplied by the aggregate Subscription Amount paid by such Holder pursuant to the Purchase Agreement with respect to that portion of the Registered Securities of such Holder that are not then registered. If the Company fails to pay any liquidated damages pursuant to this Section in full within seven days after the date payable, the Company will pay interest thereon at a rate of 18% per annum (or such lesser maximum amount that is permitted to be paid by applicable law) to the Holder, accruing daily from the date such liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The liquidated damages pursuant to the terms hereof shall apply on a daily pro rata basis for any portion of a month prior to the cure of an Event.

(e) Notwithstanding anything to the contrary contained herein, in no event shall the Company be permitted to name any Holder or affiliate of a Holder as any Underwriter without the prior written consent of such Holder, except as required by law.

3. Registration Procedures.

In connection with the Company's registration obligations hereunder, the Company shall:

(a) Not less than five (5) Trading Days prior to the filing of each Registration Statement and not less than one (1) Trading Day prior to the filing of any related Prospectus or any amendment or supplement thereto (including any document that would be incorporated or deemed to be incorporated therein by reference, but not including any quarterly report on Form 10-Q, annual report on Form 10-K, proxy statement on Schedule 14A, or other filings with the Commission that do not include information about the Holders), the Company shall (i) furnish to each Holder copies of all such documents proposed to be filed, which documents (other than those incorporated or deemed to be incorporated by reference) will be subject to the review of such Holders, and (ii) cause its officers and directors, counsel and independent registered public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel to each Holder, to conduct a reasonable investigation within the meaning of the Securities Act. The Company shall not file a Registration Statement or any such Prospectus or any amendments or supplements thereto to which the Holders of a majority of the Registrable Securities shall reasonably object in good faith, provided that, the Company is notified of such objection in writing no later than five (5) Trading Days after the Holders have been so furnished copies of a Registration Statement or one (1) Trading Day after the Holders have been so furnished copies of any related Prospectus or amendments or supplements thereto. Each Holder agrees to furnish to the Company a completed questionnaire in the form attached to this Agreement as Annex B (a "Selling

StockholderQuestionnaire") on a date that is not less than two (2) Trading Days prior to the Filing Date or by the end of the fourth (4th) Trading Day following the date on which such Holder receives draft materials in accordance with this Section.

(b) (i) Prepare and file with the Commission such amendments, including post-effective amendments, to a Registration Statement and the Prospectus used in connection therewith as may be necessary to keep a Registration Statement continuously effective as to the applicable Registrable Securities for the Effectiveness Period and prepare and file with the Commission such additional Registration Statements in order to register for resale under the Securities Act all of the Registrable Securities, (ii) cause the related Prospectus to

be amended or supplemented by any required Prospectus supplement (subject to the terms of this Agreement), and, as so supplemented or amended, to be filed pursuant to Rule 424, (iii) respond as promptly as reasonably possible to any comments received from the Commission with respect to a Registration Statement or any amendment thereto and provide as promptly as reasonably possible to the Holders true and complete copies of all correspondence from and to the Commission relating to a Registration Statement (provided that, the Company shall excise any information contained therein which would constitute material non-public information regarding the Company or any of its Subsidiaries), and (iv) comply in all material respects with the applicable provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by a Registration Statement during the applicable period in accordance (subject to the terms of this Agreement) with the intended methods of disposition by the Holders thereof set forth in such Registration Statement as so amended or in such Prospectus as so supplemented.

(c) If during the Effectiveness Period, the number of Registrable Securities at any time exceeds 100% of the number of shares of Common Stock constituting Registerable Securities then registered in a Registration Statement, then the Company shall file as soon as reasonably practicable, but in any case prior to the applicable Filing Date, an additional Registration Statement covering the resale by the Holders of not less than the number of such Registrable Securities.

(d) Notify the Holders of Registrable Securities to be sold (which notice shall, pursuant to clauses (iii) through (vi) hereof, be accompanied by an instruction to suspend the use of the Prospectus until the requisite changes have been made) as promptly as reasonably possible (and, in the case of (i)(A) below, not less than one (1) Trading Day prior to such filing) and (if requested by any such Person) confirm such notice in writing no later than one (1) Trading Day following the day (i)(A) when a Prospectus or any Prospectus supplement or post-effective amendment to a Registration Statement is proposed to be filed, (B) when the Commission notifies the Company whether there will be a "review" of such Registration Statement and whenever the Commission comments in writing on such Registration Statement, and (C) with respect to a Registration Statement or any post-effective amendment, when the same has become effective, (ii) of any request by the Commission or any other federal or state governmental authority for amendments or supplements to a Registration Statement or Prospectus or for additional information, (iii) of the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Registrable Securities or the initiation of any Proceedings for that purpose, (iv) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Registrable Securities for sale in any jurisdiction, or the initiation or threatening of any Proceeding for such purpose, (v) of the occurrence of any event or passage of time that makes the

financial statements included in a Registration Statement ineligible for inclusion therein or any statement made in a Registration Statement or Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to a Registration Statement, Prospectus or other documents so that, in the case of a Registration Statement or the Prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in

light of the circumstances under which they were made, not misleading, and (vi) of the occurrence or existence of any pending corporate development with respect to the Company that the Company believes may be material and that, in the determination of the Company, makes it not in the best interest of the Company to allow continued availability of a Registration Statement or Prospectus; provided, however, that in no event shall any such notice contain any information which would constitute material, non-public information regarding the Company or any of its Subsidiaries, and the Company agrees that the Holders shall not, solely as a result of the receipt of such notice, have any duty of confidentiality to the Company or any of its Subsidiaries and shall not, solely as a result of the receipt of such notice, have any duty to the Company or any of its Subsidiaries not to trade on the basis of such information.

(e) Use its best efforts to avoid the issuance of, or, if issued, obtain the withdrawal of (i) any order stopping or suspending the effectiveness of a Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, at the earliest practicable moment.

(f) Furnish to each Holder, without charge, at least one conformed copy of each such Registration Statement and each amendment thereto, including financial statements and schedules, all documents incorporated or deemed to be incorporated therein by reference to the extent requested by such Person, and all exhibits to the extent requested by such Person (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission, provided that any such item which is available on the EDGAR system (or successor thereto) need not be furnished in physical form.

(g) Subject to the terms of this Agreement, the Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by each of the selling Holders in connection with the offering and sale of the Registrable Securities covered by such Prospectus and any amendment or supplement thereto, except after the giving of any notice pursuant to Section 3(d).

(h) Prior to any resale of Registrable Securities by a Holder, use its commercially reasonable efforts to register or qualify or cooperate with the selling Holders in connection with the registration or qualification (or exemption from

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the Registration or qualification) of such Registrable Securities for the resale by the Holder under the securities or Blue Sky laws of such jurisdictions within the United States as any Holder reasonably requests in writing, to keep each registration or qualification (or exemption therefrom) effective during the Effectiveness Period and to do any and all other acts or things reasonably necessary to enable the disposition in such jurisdictions of the Registrable Securities covered by each Registration Statement, provided that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified, subject the Company to any material tax in any such jurisdiction where it is not then so subject or file a general consent to service of process in any such jurisdiction.

(i) If requested by a Holder, cooperate with such Holder to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be delivered to a transferee pursuant to a Registration Statement, which certificates shall be free, to the extent permitted by the Purchase Agreement, of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as any such Holder may request.

(j) Upon the occurrence of any event contemplated by Section 3(d), as promptly as reasonably possible under the circumstances taking into account the Company's good faith assessment of any adverse consequences to the Company and its stockholders of the premature disclosure of such event, prepare a supplement or amendment, including a post-effective amendment, to a Registration Statement or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, neither a Registration Statement nor such Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Company notifies the Holders in accordance with clauses (iii) through (vi) of Section 3(d) above

to suspend the use of any Prospectus until the requisite changes to such Prospectus have been made, then the Holders shall suspend use of such Prospectus. The Company will use its best efforts to ensure that the use of the Prospectus may be resumed as promptly as is practicable. The Company shall be entitled to exercise its right under this Section 3(j) to suspend the availability of a Registration Statement and Prospectus, subject to the payment of liquidated damages otherwise required pursuant to Section 2(d), for a period not to exceed 60 consecutive calendar days or ninety (90) calendar days (which need not be consecutive calendar days) in any 12-month period.

(k) Otherwise use commercially reasonable efforts to comply with all applicable rules and regulations of the Commission under the Securities Act and the Exchange Act, including, without limitation, Rule 172 under the Securities Act, file any final Prospectus, including any supplement or amendment thereof,

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with the Commission pursuant to Rule 424 under the Securities Act, promptly inform the Holders in writing if, at any time during the Effectiveness Period, the Company does not satisfy the conditions specified in Rule 172 and, as a result thereof, the Holders are required to deliver a Prospectus in connection with any disposition of Registrable Securities and take such other actions as may be reasonably necessary to facilitate the registration of the Registrable Securities hereunder.

(l) The Company may require each selling Holder to furnish to the Company a certified statement as to the number of shares of Common Stock beneficially owned by such Holder and, if required by the Commission, the natural persons thereof that have voting and dispositive control over the shares. During any periods that the Company is unable to meet its obligations hereunder with respect to the registration of the Registrable Securities solely because any Holder fails to furnish such information within three Trading Days of the Company's request, any liquidated damages that are accruing at such time as to such Holder only shall be tolled and any Event that may otherwise occur solely because of such delay shall be suspended as to such Holder only, until such information is delivered to the Company.

4. Registration Expenses. All fees and expenses incident to the performance of or compliance with this Agreement by the Company shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement. The fees and expenses referred to in the foregoing sentence shall include, without limitation, (i) all registration and filing fees (including, without limitation, fees and expenses of the Company's counsel and independent registered public accountants) (A) with respect to filings made with the Commission, (B) with respect to filings required to be made with any Trading Market on which the Common Stock is then listed for trading, and (C) in compliance with applicable state securities or Blue Sky laws reasonably agreed to by the Company in writing (including, without limitation, fees and disbursements of counsel for the Company in connection with Blue Sky qualifications or exemptions of the Registrable Securities), (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities), (iii) messenger, telephone and delivery expenses, (iv) fees and disbursements of counsel for the Company, (v) Securities Act liability insurance, if the Company so desires such insurance, and (vi) fees and expenses of all other Persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement. In addition, the Company shall be responsible for all of its internal expenses incurred in connection with the consummation of the transactions contemplated by this Agreement (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange as required hereunder. In no event shall the Company be responsible for any broker, selling, underwriting or similar commissions of any Holder, any stock transfer expenses, or, except to the extent provided for in the Transaction Documents, any legal fees or other costs of the Holders.

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5. Indemnification.

(a) Indemnification by the Company. To the extent permitted by applicable law, the Company shall, notwithstanding any termination of this Agreement, indemnify and hold harmless each Holder, the officers, directors, members, partners, agents, brokers (including brokers who offer and sell Registrable Securities as principal as a result of a pledge or any failure to perform under a margin call of Common Stock), investment advisors and employees (and any other Persons with a functionally equivalent role of a Person holding such titles, notwithstanding a lack of such title or any other title) of each of them, each Person who controls any such Holder (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, members, stockholders, partners, agents and employees (and any other Persons with a functionally equivalent role of a Person holding such titles, notwithstanding a lack of such title or any other title) of each such controlling Person, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable attorneys' fees) and expenses (collectively, "Losses"), as incurred, arising out of or relating to (1) any untrue or alleged untrue statement of a material fact contained in a Registration Statement, any Prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading or (2) any violation or alleged violation by the Company of the Securities Act, the Exchange Act or any state securities law, or any rule or regulation thereunder, in connection with the performance of its obligations under this Agreement, except to the extent, but only to the extent, that (i) such untrue statements or omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by such Holder expressly for use in a Registration Statement, such Prospectus or in any amendment or supplement thereto (it being understood that the Holder has approved Annex A hereto for this purpose) or (ii) in the case of an occurrence of an event of the type specified in Section 3(d)(iii)-(vi), the use by such Holder of an outdated, defective or otherwise unavailable Prospectus after the Company has notified such Holder in writing that the Prospectus is outdated, defective or otherwise unavailable for use by such Holder and prior to the receipt by such Holder of the Advice contemplated in Section 6(c), or (iii) in the case of a sale directly by a Holder of Registrable Securities, such untrue statement or alleged untrue statement or omission or alleged omission was corrected in a final or amended prospectus, and such Holder failed to deliver

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a copy of the final or amended prospectus at or prior to the confirmation of the sale of the Registrable Securities to the Person asserting any such loss, claim, damage or liability in any case in which such delivery is required by the Securities Act. The indemnity agreement contained in this section shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the prior written consent of the Company (which consent shall not be unreasonably withheld or delayed). The Company shall notify the Holders promptly of the institution, threat or assertion of any Proceeding arising from or in connection with the transactions contemplated by this Agreement of which the Company is aware. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such indemnified person and shall survive the transfer of any Registrable Securities by any of the Holders in accordance with Section 6(f).

(b) Indemnification by Holders. Each Holder shall, severally and not jointly, indemnify and hold harmless the Company, its directors, officers, agents and employees, each Person who controls the Company (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, agents or employees of such controlling Persons, to the fullest extent permitted by applicable law, from and against all Losses, as incurred, to the extent arising out of or based solely upon: any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus, or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading (i) to the extent, but only to the extent, that such untrue statement or omission is contained in any information so furnished in writing by such Holder to the Company expressly for inclusion in such Registration Statement or

such Prospectus or (ii) to the extent, but only to the extent, that such information relates to such Holder's information provided in the Selling Stockholder Questionnaire or the proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by such Holder expressly for use in a Registration Statement (it being understood that the Holder has approved Annex A hereto for this purpose), such Prospectus or in any amendment or supplement thereto. In no event shall the liability of a selling Holder be greater in amount than the dollar amount of the proceeds (net of all expenses paid by such Holder in connection with any claim relating to this Section 5 and the amount of any damages such Holder has otherwise been required to pay by reason of such untrue statement or omission) received by such Holder upon the sale of the Registrable Securities included in the Registration Statement giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "Indemnified Party"), such Indemnified Party shall promptly notify the Person

from whom indemnity is sought (the "Indemnifying Party") in writing, and the Indemnifying Party shall have the right to assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all fees and expenses incurred in connection with defense thereof, provided that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have materially and adversely prejudiced the Indemnifying Party.

An Indemnified Party shall have the right to employ separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Parties unless: (1) the Indemnifying Party has agreed in writing to pay such fees and expenses, (2) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding, or (3) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and counsel to the Indemnified Party shall reasonably believe that a material conflict of interest is likely to exist if the same counsel were to represent such Indemnified Party and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and the reasonable fees and expenses of no more than one separate counsel shall be at the expense of the Indemnifying Party). The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld or delayed. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

Subject to the terms of this Agreement, all reasonable fees and expenses of the Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section) shall be paid to the Indemnified Party, as incurred, within ten Trading Days of written notice thereof to the Indemnifying Party, provided that the Indemnified Party shall promptly reimburse the Indemnifying Party for that portion of such fees and expenses applicable to such actions for which such Indemnified Party is finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) not to be entitled to indemnification hereunder.

(d) Contribution. If the indemnification under Section 5(a) or 5(b) is unavailable to an Indemnified Party or insufficient to hold an Indemnified Party harmless for any Losses, then each Indemnifying Party shall contribute to the amount paid or payable by such Indemnified Party, in such proportion as is appropriate to reflect the relative fault of the Indemnifying

Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in this Agreement, any reasonable attorneys' or other fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 5(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. In no event shall the contribution obligation of a Holder of Registrable Securities be greater in amount than the dollar amount of the proceeds (net of all expenses paid by such Holder in connection with any claim relating to this Section 5 and the amount of any damages such Holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission) received by it upon the sale of the Registrable Securities giving rise to such contribution obligation.

The indemnity and contribution agreements contained in this Section are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties.

6. Miscellaneous.

(a) Remedies. In the event of a breach by the Company or by a Holder of any of their respective obligations under this Agreement, each Holder or the Company, as the case may be, in addition to being entitled to exercise all rights granted by law and under this Agreement, including recovery of damages, shall be entitled to specific performance of its rights under this Agreement. Each of the Company and each Holder agrees that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agrees that, in the event of any action for specific performance in respect of such breach, it shall not assert or shall waive the defense that a remedy at law would be adequate.

(b) Discontinued Disposition. By its acquisition of Registrable Securities, each Holder agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Section 3(d)(iii) through (vi), such Holder will forthwith discontinue disposition of such Registrable Securities under a Registration Statement until it is advised in writing (the "Advice") by the Company that the use of the applicable Prospectus (as it may have been supplemented or amended) may be resumed. The Company will use its best efforts to ensure that the use of the Prospectus may be resumed as promptly as is practicable. The Company agrees and acknowledges that any periods during which the Holder is required to discontinue the disposition of the Registrable Securities hereunder shall be subject to the provisions of Section 2(d).

(c) Amendments and Waivers. The provisions of this Agreement, including the provisions of this sentence, may not be amended, modified or supplemented, and waivers or consents to departures from the provisions hereof may not be given, unless the same shall be in writing and signed by the Company and the Holders of 50.1% or more of the then outstanding Registrable Securities (for purposes of clarification, this includes any Registrable Securities issuable upon exercise or conversion of any Warrant), provided that, if any amendment, modification or waiver disproportionately and adversely impacts a Holder (or group of Holders), the consent of such disproportionately impacted Holder (or group of Holders) shall be required. If a Registration Statement does not register all of the Registrable Securities pursuant to a waiver or amendment done in compliance with the previous sentence, then the number of Registrable Securities to be registered for each Holder shall be reduced pro rata among all Holders and each Holder shall have the right to designate which of its Registrable Securities shall be omitted from such Registration Statement. Notwithstanding the foregoing, a waiver or consent

to depart from the provisions hereof with respect to a matter that relates exclusively to the rights of a Holder or some Holders and that does not directly or indirectly affect the rights of other Holders may be given only by such Holder or Holders of all of the Registrable Securities to which such waiver or consent relates; provided, however, that the provisions of this sentence may not be amended, modified, or supplemented except in accordance with the provisions of the first sentence of this Section 6(c). No consideration shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of this Agreement unless the same consideration also is offered to all of the parties to this Agreement.

(d) Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be delivered as set forth in the Purchase Agreement.

(e) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties and shall inure to the benefit of each Holder. The Company may not assign (except by merger) its rights or obligations hereunder without the prior written consent of all of the Holders of the then outstanding Registrable Securities. Each Holder may assign their respective rights hereunder in the manner and to the Persons as permitted under Section 5.7 of the Purchase Agreement.

(f) No Inconsistent Agreements. Neither the Company nor any of its Subsidiaries has entered, as of the date hereof, nor shall the Company or any of its Subsidiaries, on or after the date of this Agreement, enter into any agreement with respect to its securities, that would have the effect of impairing the rights granted to the Holders in this Agreement or otherwise conflicts with the provisions hereof. Except as set forth on Schedule 6(f), neither the Company nor any of its Subsidiaries has previously entered into any agreement granting any registration rights with respect to any of its securities to any Person that have not been satisfied in full.

(g) Execution and Counterparts. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., www.docusign.com), such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page were an original thereof.

(h) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be determined in accordance with the provisions of the Purchase Agreement.

(i) Cumulative Remedies. The remedies provided herein are cumulative and not exclusive of any other remedies provided by law.

(j) Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

(k) Headings. The headings in this Agreement are for convenience only, do not constitute a part of the Agreement and shall not be deemed to limit or affect any of the provisions hereof.

(l) Independent Nature of Holders' Obligations and Rights. The obligations of each Holder hereunder are several and not joint with the obligations of any other Holder hereunder, and no Holder shall be responsible in any way for the performance of the obligations of any other Holder hereunder. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Holder pursuant hereto or thereto, shall be deemed to constitute the Holders as a partnership, an association, a joint venture or any other kind of group or entity, or create a presumption that the Holders are in any way acting in concert or as a group or entity with respect to such obligations or the transactions contemplated by this Agreement or any other matters, and the Company acknowledges that the Holders are not acting in concert or as a group, and the Company shall not assert any such claim, with respect to such obligations or transactions. Each Holder shall be entitled to protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Holder to be joined as an additional party in any proceeding for such purpose. The use of a single agreement with respect to the obligations of the Company contained was solely in the control of the Company, not the action or decision of any Holder, and was done solely for the convenience of the Company and not because it was required or requested to do so by any Holder. It is expressly understood and agreed that each provision contained in this Agreement is between the Company and a Holder, solely, and not between the Company and the Holders collectively and not between and among Holders.

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(Signature Pages Follow)

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

BENITEC BIOPHARMA INC.

By: /s/ Dr. Jerel Banks

Name: Dr. Jerel Banks

Title: Chief Executive Officer

[Signature Page to Registration Rights Agreement]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Nemean Asset Management, LLC

Signature of Authorized Signatory of Holder: /s/ Steven Oliveira

Name of Authorized Signatory: Steven Oliveira

Title of Authorized Signatory: Manager

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: HBM Healthcare Investments (Cayman) Ltd.

Signature of Authorized Signatory of Holder: /s/ Jean-Marc Lesieur

Name of Authorized Signatory: Jean-Marc Lesieur

Title of Authorized Signatory: Managing Director

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Blackwell Partners LLC - Series A

Signature of Authorized Signatory of Holder: /s/ Wilmot Harkey

Name of Authorized Signatory: Wilmot Harkey

Title of Authorized Signatory: Manager

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Corbin Sustainability & Engagement Fund, L.P.

Signature of Authorized Signatory of Holder: /s/ Wilmot Harkey

Name of Authorized Signatory: Wilmot Harkey

Title of Authorized Signatory: Manager

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Nantahala Capital Partners Limited Partnership

Signature of Authorized Signatory of Holder: /s/ Wilmot Harkey

Name of Authorized Signatory: Wilmot Harkey

Title of Authorized Signatory: Manager

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: NCP RFM LP

Signature of Authorized Signatory of Holder: /s/ Wilmot Harkey

Name of Authorized Signatory: Wilmot Harkey

Title of Authorized Signatory: Manager

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Pinehurt Partners, L.P.

Signature of Authorized Signatory of Holder: /s/ Wil Harkey

Name of Authorized Signatory: Wil Harkey

Title of Authorized Signatory: Managing Member

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Adage Capital Partners, L.P.

Signature of Authorized Signatory of Holder: /s/ Dan Lehan

Name of Authorized Signatory: Dan Lehan

Title of Authorized Signatory: Chief Operating Officer

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

FRANKLIN STRATEGIC SERIES –
FRANKLIN BIOTECHNOLOGY
DISCOVERY FUND

BY: FRANKLIN ADVISERS, INC., AS
INVESTMENT MANAGER

By: /s/ Evan McCulloch

Name of Authorized Signatory: Evan McCulloch
Title of Authorized Signatory: VP

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: PhiFund, LP

Signature of Authorized Signatory of Holder: /s/ Orrin Devinsky

Name of Authorized Signatory: Orrin Devinsky

Title of Authorized Signatory: Managing Partner

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Averill Master Fund, Ltd.

Signature of Authorized Signatory of Holder: /s/ Andrew Nathanson

Name of Authorized Signatory: Andrew Nathanson

Title of Authorized Signatory: Authorized Signatory

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Alyeska Master Fund, L.P.

Signature of Authorized Signatory of Holder: /s/ Jason Bragg

Name of Authorized Signatory: Jason Bragg, CFO Alyeska Investment Group, LP

Title of Authorized Signatory:

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Averill Madison Master Fund, Ltd.

Signature of Authorized Signatory of Holder: /s/ Andrew Nathanson

Name of Authorized Signatory: Andrew Nathanson

Title of Authorized Signatory: Authorized Signatory

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Special Situations Fund III QP, L.P.

Signature of Authorized Signatory of Holder: /s/ David Greenhouse

Name of Authorized Signatory: David Greenhouse

Title of Authorized Signatory: Managing Partner

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Special Situations Life Sciences Fund, L.P.

Signature of Authorized Signatory of Holder: /s/ David Greenhouse

Name of Authorized Signatory: David Greenhouse

Title of Authorized Signatory: Managing Partner

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Special Situations Cayman Fund, L.P.

Signature of Authorized Signatory of Holder: /s/ David Greenhouse

Name of Authorized Signatory: David Greenhouse

Title of Authorized Signatory: Managing Partner

[SIGNATURE PAGES CONTINUE]

[SIGNATURE PAGE OF HOLDERS TO BNTC RRA]

Name of Holder: Schonfeld Global Master Fund L.P.

Signature of Authorized Signatory of Holder: /s/ Andrew Fishman

Name of Authorized Signatory: Andrew Fishman

Title of Authorized Signatory: Authorized Signatory

Exhibit 10.4

April 22, 2024

Suvretta Capital Management, LLC 540
Madison Ave., 7th Floor
New York, NY 10022

Ladies and Gentlemen:

This letter agreement is entered into by and among Suvretta Capital Management, LLC ("***Suvretta***") and Benitec Biopharma Inc. ("***Benitec***" or the "***Company***" and, together with Suvretta, the "***Parties***"). Concurrently with the execution of this letter agreement, the Parties are entering into that certain Stock Purchase Agreement, dated as of April 17, 2024 by and among Suvretta, Benitec, and the other parties thereto (the "***Purchase Agreement***"), and that certain Voting Commitment Agreement, dated as of April 22, 2024, by and among Benitec, Suvretta, and the other parties thereto (the "***Voting Commitment Agreement*,**" and together with the Purchase Agreement, the "***Agreements***"). Prior to entering the Purchase Agreement, Suvretta and its affiliates are the beneficial owners of (i) 15,181,359 common warrants of the Company, exercisable for 5,769,583 shares of the Company's common stock, par value $0.001 per share (the "***Common Stock***") in the amounts and at the exercise prices set forth in Schedule A attached hereto (the "***Common Warrants***"), and (ii) 5,769,582 pre-funded warrants exercisable for 5,769,582 shares of the Company's common stock in the amounts and at the exercise prices set forth in Schedule A attached hereto (the "***Pre-Funded Warrants***," and together with the Common Warrants, the "***Warrants,***" and the agreements governing the terms of the Warrants, the "***Warrant Agreements***").

The Parties hereby agree that, promptly following execution of this letter agreement, Benitec shall consider in good faith Kishan Mehta for appointment to the Board of Directors of Benitec (the "***Board***") upon consummation of the transactions contemplated by the Purchase Agreement (the "***Closing***"), which consideration may include a vetting process no more onerous, burdensome or time consuming than the process for vetting any other candidate for membership on the Board. Following completion of such consideration, Benitec shall promptly inform Suvretta of its determination, and take all necessary actions (to the extent such actions are not prohibited by applicable law and are within such party's control) to appoint Kishan Mehta to the Board as promptly as practicable, in such class as

determined by Benitec after taking into account the composition of the Board to be effective at Closing, upon the occurrence of the Closing, unless (i) Kishan Mehta has participated in activities involving moral turpitude, dishonesty or fraud which would reasonably be expected to cause harm to Benitec's business or reputation, or to Kishan Mehta's ability to perform their duties on the Board or (ii) Benitec, after unbiased consideration, determines in its reasonable discretion that Kishan Mehta is not an appropriate fit for the Board. In the event that Benitec reasonably determines to reject Kishan Mehta or any Alternate Candidate (as defined below) for the foregoing reason(s), Benitec shall promptly notify Suvretta of such determination (along with an explanation for such rejection), and Suvretta shall be entitled to continue to propose additional candidates (each, an "***Alternate Candidate***") for appointment to the Board, and Benitec shall promptly consider such Alternate Candidates in good faith for appointment to the Board upon the same terms as set forth above. Following completion of such consideration with respect to an Alternate Candidate, Benitec shall promptly inform Suvretta of its determination, and take all necessary actions (to the extent such actions are not prohibited by applicable law and are within such party's control) to appoint such Alternate Candidate to the Board, in such class as determined by Benitec after taking into account the composition of the Board to be effective at Closing, upon the occurrence of (or if applicable, following) the Closing (subject to Benitec's right to reject such Alternate Candidate for the reasons set forth above).

The Parties further agree that, (1) in connection with the Closing, the Parties will take such action as may be required to permit Suvretta to exercise its Warrants up to an Alternate Beneficial Ownership Limitation (as defined in the Warrant Agreements) to be equal to 19.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of the applicable Warrants, via an amendment (where necessary) to any previously issued Warrants or Warrant Agreements and (2) Suvretta will vote all of its shares of Common Stock owned on the record date for such votes in favor of (i) all of the Company's director nominees for election to the Board at the Company's annual meetings of stockholders to be held during the term of this letter agreement, and (ii) the proposal seeking the Stockholder Approval pursuant to the Voting Commitment Agreement at any annual or special meeting of Benitec where such proposal is presented, subject to the limits imposed by applicable law or rules, including the rules of The Nasdaq Capital Market.

In the event and for so long as Kishan Mehta or an Alternate Candidate are serving on the Board, the Board shall take such actions as are reasonably requested by Suvretta to approve any acquisition of any direct or indirect pecuniary interest of Common Stock (or any securities exercisable or exchangeable for Common Stock) in connection with any purchase from the Company by Suvretta (or its affiliates) to the extent deemed a director for purposes of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as a so-called "director by deputization", for the purpose of exempting, to the extent available under applicable law, any such acquisitions from Section 16(b) of the Exchange Act as permitted by Rule 16b-3(d)(1) promulgated under the Exchange Act.

This letter agreement shall terminate upon the date on which Kishan Mehta or an Alternate Candidate ceases to serve on the Company's Board.

The Parties acknowledge that due to the unique and substantial obligations set forth herein there would be no adequate remedy at law for any actual or threatened violation of this letter agreement and actual or threatened violation would result in irreparable harm to the Parties. In the event of an actual or threatened violation of this letter agreement, each Party expressly consents to the enforcement of this letter agreement by injunctive relief or specific performance in addition to any other remedy to which such Party is entitled at law or in equity. This letter agreement shall be governed in all respects by the laws of the state of Delaware. The state or federal courts located in Wilmington, Delaware shall each have non-exclusive jurisdiction over all disputes relating to this letter agreement. This letter agreement contains the entire understanding of the parties with respect to the subject matter hereof and thereof and may be amended only by an agreement in writing executed by the parties hereto. If at any time subsequent to the date hereof, any provision of this letter agreement shall be held by any court of competent jurisdiction to be illegal, void or unenforceable, such provision shall be of no force and effect, but the illegality or unenforceability of such provision shall have no effect upon the legality or enforceability of any other provision of this letter agreement. This letter agreement may be executed in two or more counterparts either manually or by electronic or digital signature (including by facsimile or electronic mail transmission), each of which shall be deemed to be an original and all of which together shall

constitute a single agreement. Any press release or public statement to be made by a Party reciting the contents of this letter agreement shall be reasonably acceptable to the other Parties.

[Signature Pages Follow]

Please confirm your agreement with the foregoing by signing and returning one copy of this letter agreement to the undersigned, whereupon this letter agreement shall become a binding agreement among the Parties.

Very truly yours,

Benitec Biopharma Inc.

By: /s/ Dr. Jerel Banks
Name: Dr. Jerel Banks
Title: Chief Executive Officer

Accepted and agreed as of April 22, 2024
Suvretta Capital Management, LLC

By:
Name:
Title:

[Signature Page to Board Designation Letter]

Please confirm your agreement with the foregoing by signing and returning one copy of this letter agreement to the undersigned, whereupon this letter agreement shall become a binding agreement among the Parties.

Very truly yours,

Benitec Biopharma Inc.

By:
Name: Dr. Jerel Banks
Title: Chief Executive Officer

Accepted and agreed as of April 22, 2024
Suvretta Capital Management, LLC

By: /s/ Andrew Nathanson
Name: Andrew Nathansin
Title: Authorized Signatory

EXHIBIT 31.1

Statement Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by
Principal Executive Officer
Regarding Facts and Circumstances Relating to Exchange Act Filings

I, Jerel Banks, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Benitec Biopharma 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: February 13, 2024 May 13, 2024

/s/ Jerel Banks

Jerel Banks

Executive Chairman and Chief Executive Officer

EXHIBIT 31.2

Statement Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by
Principal Financial Officer
Regarding Facts and Circumstances Relating to Exchange Act Filings

I, Megan Boston, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Benitec Biopharma 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: February 13, 2024 May 13, 2024

/s/ Megan Boston
Megan Boston
Executive Director (principal financial and accounting officer)

EXHIBIT 32.1

Statement Pursuant to Section 906 the Sarbanes-Oxley Act of 2002
By
Principal Executive Officer
Regarding Facts and Circumstances Relating to Exchange Act Filings

Dated: February 13, 2024 May 13, 2024

I, Jerel Banks, Chief Executive Officer of Benitec Biopharma Inc., hereby certify, to my knowledge, that:

1. the accompanying Quarterly Report on Form 10-Q of Benitec Biopharma Inc. for the three month period ended December 31, 2023 March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities and 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 Benitec Biopharma Inc.

IN WITNESS WHEREOF, the undersigned has executed this Statement as of the date first written above.

/s/ Jerel Banks
Jerel Banks
Executive Chairman and Chief Executive Officer

EXHIBIT 32.2

Statement Pursuant to Section 906 the Sarbanes-Oxley Act of 2002
By
Principal Financial Officer
Regarding Facts and Circumstances Relating to Exchange Act Filings

Dated: February 13, 2024 May 13, 2024

I, Megan Boston, Executive Director (principal accounting officer) of Benitec Biopharma Inc., hereby certify, to my knowledge, that:

1. the accompanying Quarterly Report on Form 10-Q of Benitec Biopharma Inc. for the three month period ended December 31, 2023 March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities and 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 Benitec Biopharma Inc.

IN WITNESS WHEREOF, the undersigned has executed this Statement as of the date first written above.

/s/ Megan Boston

Megan Boston

Executive Director (principal financial and accounting officer)

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